**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 全体 | | 77 ( 40.5) | 36 ( 19.0) | 17 ( 9.3) | 15 ( 8.4) | 9 ( 5.1) | 9 ( 5.1) | 5 ( 2.9) | 3 ( 1.7) | 6 ( 3.6) | 2 ( 1.2) | 3 ( 1.8) | 1 ( 0.6) | 1 ( 0.6) |
| 血液およびリンパ系障害 | | | 1 ( 0.5) | 1 ( 0.5) | | | | 2 ( 1.2) | 1 ( 0.6) | 1 ( 0.6) | | | 1 ( 0.6) | |
| | 貧血 | | 1 ( 0.5) | | | | | | | | | | | |
| | 鉄欠乏性貧血 | | | | | | | | | | | | 1 ( 0.6) | |
| | リンパ節症 | | | | | | | | | 1 ( 0.6) | | | | |
| | 腎性貧血 | | | 1 ( 0.5) | | | | 2 ( 1.2) | 1 ( 0.6) | | | | | |
| 心臓障害 | | | | 2 ( 1.1) | 1 ( 0.6) | | | | 1 ( 0.6) | 2 ( 1.2) | | | | 2 ( 1.2) |
| | 心房細動 | | | 1 ( 0.5) | | | | | | | | | | |
| | うっ血性心不全 | | | | 1 ( 0.6) | | | | 1 ( 0.6) | | | | | |
| | 心筋梗塞 | | | | | | | | | 1 ( 0.6) | | | | |
| | 動悸 | | | | | | | | | | | | | 1 ( 0.6) |
| | 上室性期外収縮 | | | | | | | | | 1 ( 0.6) | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

出典［総括報告書 5.3.5.2-1（ONO-5163-[redacted] 試験）表 14.3.1-12］

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 1）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | 有害事象 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ONO-5163 | | | | | | | | | | | |
| | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 心室性期外収縮 | | | 1 ( 0.5) | | | | | | | | | | |
| 頻脈性不整脈 | | | | | | | | | | | | | 1 ( 0.6) |
| 耳および迷路障害 | | 3 ( 1.6) | 2 ( 1.1) | 2 ( 1.1) | | 1 ( 0.6) | 1 ( 0.6) | | 1 ( 0.6) | 2 ( 1.2) | 1 ( 0.6) | | |
| 耳鳴 | | | | | | 1 ( 0.6) | | | | | | | |
| 回転性めまい | | 3 ( 1.6) | 1 ( 0.5) | 2 ( 1.1) | | | 1 ( 0.6) | | 1 ( 0.6) | 2 ( 1.2) | | | |
| 頭位性回転性めまい | | | 1 ( 0.5) | | | | | | | | 1 ( 0.6) | | |
| 眼障害 | 2 ( 1.1) | 2 ( 1.1) | 5 ( 2.7) | | | 1 ( 0.6) | 3 ( 1.7) | 2 ( 1.2) | | 2 ( 1.2) | 1 ( 0.6) | 3 ( 1.8) | |
| 眼瞼炎 | 1 ( 0.5) | | 1 ( 0.5) | | | | | | | | | | |
| 白内障 | | 1 ( 0.5) | 1 ( 0.5) | | | | 1 ( 0.6) | | | | | 1 ( 0.6) | |
| 結膜出血 | | 1 ( 0.5) | | | | 1 ( 0.6) | 1 ( 0.6) | 1 ( 0.6) | | 1 ( 0.6) | | | |
| アレルギー性結膜炎 | 1 ( 0.5) | | 1 ( 0.5) | | 1 ( 0.6) | | | | | | | | |
| 角膜沈着物 | | | | | | | | | | 1 ( 0.6) | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 2）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 眼乾燥 | | | | 1 ( 0.5) | | | | | | | | | | |
| 眼瞼湿疹 | | | 1 ( 0.5) | | | | | | | | | | | |
| 眼脂 | | | | 1 ( 0.5) | | | | | | | | | | |
| 眼瞼下垂 | | | | | | | | 1 ( 0.6) | | | | | | |
| 網膜剥離 | | | | 1 ( 0.5) | | | | | | | | | | |
| 網膜出血 | | | | | | | | | | | | | 1 ( 0.6) | |
| 高血圧性網膜症 | | | | | | | | | | | | | 1 ( 0.6) | |
| 硝子体浮遊物 | | | | | | | | | 1 ( 0.6) | | | | | |
| 強膜出血 | | 1 ( 0.5) | | | | | | | | | | | | |
| 結膜充血 | | | | | | | | | | | | 1 ( 0.6) | | |
| 眼そう痒症 | | | | | | | | | | | | | 1 ( 0.6) | |
| 胃腸障害 | | 13 ( 6.8) | 15 ( 7.9) | 6 ( 3.3) | 9 ( 5.1) | 8 ( 4.6) | 7 ( 4.0) | 5 ( 2.9) | 9 ( 5.2) | 3 ( 1.8) | 6 ( 3.6) | 4 ( 2.4) | 4 ( 2.5) | 2 ( 1.2) |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 3）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 腹部不快感 | | 1 ( 0.5) | | | 2 ( 1.1) | | | | | 1 ( 0.6) | | | | 1 ( 0.6) |
| 腹部膨満 | | | | | | 1 ( 0.6) | | | | | | | | |
| 腹痛 | | | | | | | | | | | | | 1 ( 0.6) | |
| 下腹部痛 | | | 1 ( 0.5) | | | | | 1 ( 0.6) | | | | | | |
| 上腹部痛 | | | | | 2 ( 1.1) | 1 ( 0.6) | | | 1 ( 0.6) | | | | | |
| 口唇炎 | | | | | | | | | | | 1 ( 0.6) | | | |
| 慢性胃炎 | | | | | | | | | | | | 1 ( 0.6) | | |
| 便秘 | | | 4 ( 2.1) | | 1 ( 0.6) | 1 ( 0.6) | 2 ( 1.1) | | | | 2 ( 1.2) | 1 ( 0.6) | 1 ( 0.6) | |
| 齲歯 | | 1 ( 0.5) | 1 ( 0.5) | | 1 ( 0.6) | | 1 ( 0.6) | 1 ( 0.6) | | | 1 ( 0.6) | | | 1 ( 0.6) |
| 下痢 | | 4 ( 2.1) | 4 ( 2.1) | 2 ( 1.1) | 2 ( 1.1) | 2 ( 1.1) | 6 ( 3.4) | | 4 ( 2.3) | 3 ( 1.8) | 3 ( 1.8) | | 1 ( 0.6) | 3 ( 1.8) |
| 腸憩室 | | | | | | | | 1 ( 0.6) | | | | | | |
| 出血性腸憩室 | | | | | | | | | | | | | 1 ( 0.6) | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 4）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ONO-5163 | | | | | | | | | | | | |
| | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 十二指腸炎 | | | | | | | 1 ( 0.6) | | | | | | |
| 消化不良 | 1 ( 0.5) | | | | | | | | | | | | |
| 小腸炎 | | | | | | 1 ( 0.6) | | | | | | | |
| 腸炎 | | | 1 ( 0.5) | | | | | | | | | | |
| 胃アトニー | 1 ( 0.5) | | | | | | | | | | | | |
| 胃ポリープ | 1 ( 0.5) | | | | 2 ( 1.1) | | | 1 ( 0.6) | | 2 ( 1.2) | | 1 ( 0.6) | |
| 胃炎 | | | | | | | | 1 ( 0.6) | | 2 ( 1.2) | 1 ( 0.6) | 1 ( 0.6) | |
| 胃食道逆流性疾患 | | | 1 ( 0.5) | | 1 ( 0.6) | | | 2 ( 1.2) | | | | | |
| 歯肉痛 | 1 ( 0.5) | | | | | | | | | | | | |
| 舌炎 | | | | | | | | 1 ( 0.6) | | | | | |
| 痔核 | | | | 1 ( 0.6) | | | 1 ( 0.6) | 2 ( 1.2) | | 1 ( 0.6) | | 2 ( 1.2) | 1 ( 0.6) |
| 裂孔ヘルニア | | | | | | | | | | 1 ( 0.6) | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 5）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 大腸穿孔 | | | 1 ( 0.5) | | | | | | | | | | | |
| 口唇潰瘍 | | | | | 1 ( 0.6) | | | | | | | | | |
| 悪心 | | 1 ( 0.5) | 3 ( 1.6) | | 1 ( 0.6) | | | 2 ( 1.2) | | | | 1 ( 0.6) | 1 ( 0.6) | |
| 急性膵炎 | | | 1 ( 0.5) | | | | | | | | | | | |
| 口内炎 | | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.5) | | | | | | | | | | 1 ( 0.6) |
| 歯痛 | | | | | | | | | 1 ( 0.6) | | | | | |
| 嘔吐 | | | 1 ( 0.5) | 3 ( 1.6) | 1 ( 0.6) | 2 ( 1.1) | 2 ( 1.1) | 1 ( 0.6) | 4 ( 2.3) | | | 1 ( 0.6) | 1 ( 0.6) | 2 ( 1.2) |
| 口唇のひび割れ | | | | | | | | | | | | | 1 ( 0.6) | |
| 大腸ポリープ | | | | | | | | | 1 ( 0.6) | 2 ( 1.2) | | 1 ( 0.6) | | |
| 心窩部不快感 | | | | | 1 ( 0.6) | | | | | | | | | |
| 痔出血 | | | | | | | 1 ( 0.6) | | | | | | | |
| ブルンネル腺過形成 | | | | | | | | | | | | | 1 ( 0.6) | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 6）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 ONO-5163 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 口の感覚鈍麻 | | | | 1 ( 0.5) | | | | | | | | | | |
| 腹膜穿孔 | | | | | | | | | | 1 ( 0.6) | | | | |
| 肛門ぴらん | | | | | | 1 ( 0.6) | | | | | | | | |
| 口腔粘膜血腫 | | 1 ( 0.5) | | | | | | | | | | | | |
| 軟便 | | 2 ( 1.1) | | | | | | | | | | | | |
| 一般・全身障害および投与部位の状態 | | 2 ( 1.1) | 1 ( 0.5) | 3 ( 1.6) | 2 ( 1.1) | | 2 ( 1.1) | 2 ( 1.2) | 1 ( 0.6) | | 1 ( 0.6) | | 1 ( 0.6) | 2 ( 1.2) |
| 胸痛 | | | | 1 ( 0.5) | | | | 1 ( 0.6) | 1 ( 0.6) | | | | 1 ( 0.6) | 1 ( 0.6) |
| 異常感 | | | | | 1 ( 0.6) | | | | | | | | | |
| 倦怠感 | | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.5) | | | | | | | | | | |
| 発熱 | | | | 1 ( 0.5) | | | 1 ( 0.6) | | | | | | | |
| 突然死 | | | | | | | | | | | | | | 1 ( 0.6) |
| 虚血性潰瘍 | | | | | | | | 1 ( 0.6) | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 7）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 穿刺部位疼痛 | | 1 ( 0.5) | | | | | | | | | | | | |
| 血管穿刺部位そう痒感 | | | | | | | | | | | 1 ( 0.6) | | | |
| 穿刺部位腫脹 | | | | | 1 ( 0.6) | | 1 ( 0.6) | | | | | | | |
| 肝胆道系障害 | | | | | 1 ( 0.6) | | | | | | | 1 ( 0.6) | | |
| 胆管結石 | | | | | 1 ( 0.6) | | | | | | | | | |
| 胆嚢ポリープ | | | | | | | | | | | | 1 ( 0.6) | | |
| 免疫系障害 | | | | | | 1 ( 0.6) | | | | 1 ( 0.6) | | | | |
| 季節性アレルギー | | | | | | 1 ( 0.6) | | | | | | | | |
| 造影剤アレルギー | | | | | | | | | | 1 ( 0.6) | | | | |
| 感染症および寄生虫症 | | 32 ( 16.8) | 24 ( 12.7) | 15 ( 8.2) | 17 ( 9.6) | 13 ( 7.4) | 5 ( 2.9) | 1 ( 0.6) | 6 ( 3.5) | 6 ( 3.6) | 4 ( 2.4) | 7 ( 4.2) | 4 ( 2.5) | 3 ( 1.8) |
| 細菌性膣症 | | | | | 1 ( 0.6) | | | | | | | | | |
| 気管支炎 | | 3 ( 1.6) | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.6) | 1 ( 0.6) | | 1 ( 0.6) | | | 1 ( 0.6) | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 8）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 気管支肺炎 | | | | | | 1 ( 0.6) | | | | | | | | |
| 慢性副鼻腔炎 | | | | | | | | | | | | 1 ( 0.6) | | |
| 結膜炎 | | | | | 1 ( 0.6) | | | | | | | | 1 ( 0.6) | |
| 膀胱炎 | | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.5) | | 3 ( 1.7) | | 1 ( 0.6) | 1 ( 0.6) | | | | | |
| 感染性皮膚炎 | | | | | | 1 ( 0.6) | | | 1 ( 0.6) | | | | | |
| 毛包炎 | | | | | | | | | 1 ( 0.6) | | | 2 ( 1.2) | | 1 ( 0.6) |
| せつ | | | | | | | | | | | 1 ( 0.6) | | | |
| 胃腸炎 | | 1 ( 0.5) | | 3 ( 1.6) | 2 ( 1.1) | | | | | | | | 1 ( 0.6) | 3 ( 1.8) |
| 歯肉炎 | | 2 ( 1.1) | | | | | 1 ( 0.6) | | | 1 ( 0.6) | | | | |
| 単純ヘルペス | | | | | | | | | | | 1 ( 0.6) | | | |
| 麦粒腫 | | 1 ( 0.5) | | | | 2 ( 1.1) | | | | | | | | 1 ( 0.6) |
| インフルエンザ | | 1 ( 0.5) | 3 ( 1.6) | | 1 ( 0.6) | | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 9）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 大葉性肺炎 | | | | | | | | | | | | 1 ( 0.6) | | |
| リステリア菌性髄膜炎 | | | | | | | 1 ( 0.6) | | | | | | | |
| 鼻咽頭炎 | | 24 ( 12.6) | 17 ( 9.0) | 12 ( 6.6) | 14 ( 7.9) | 7 ( 4.0) | 3 ( 1.7) | 2 ( 1.2) | 6 ( 3.5) | 7 ( 4.2) | 3 ( 1.8) | 7 ( 4.2) | 6 ( 3.7) | 1 ( 0.6) |
| 爪真菌症 | | | | | | 1 ( 0.6) | | | 1 ( 0.6) | | 1 ( 0.6) | | | |
| 精巣炎 | | | | | | | | | | | | | | 1 ( 0.6) |
| 中耳炎 | | | | | | | 1 ( 0.6) | | | | | | | |
| 歯冠周囲炎 | | 1 ( 0.5) | | | | | | | | | | | | |
| 歯周炎 | | | 1 ( 0.5) | | 1 ( 0.6) | | | | | 1 ( 0.6) | | | | |
| 咽頭炎 | | 1 ( 0.5) | | | | | | 1 ( 0.6) | | 2 ( 1.2) | | | | 1 ( 0.6) |
| 偽膜性大腸炎 | | | | | | 1 ( 0.6) | | | | | | | | |
| 歯髄炎 | | | | | | | 1 ( 0.6) | | | | | | | |
| 膿皮症 | | | | | | | | 1 ( 0.6) | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 10）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 皮下組織膿瘍 | | | | | | | | 1 ( 0.6) | | | | | | |
| 足部白癬 | | | | | 1 ( 0.6) | 1 ( 0.6) | | 1 ( 0.6) | | | 1 ( 0.6) | | | 1 ( 0.6) |
| 尿路感染 | | | | | | | | 1 ( 0.6) | | | | | | |
| 単径部感染 | | | | | 1 ( 0.6) | | | | | | | | | |
| 細菌性咽頭炎 | | | | | | | | | | | | | 1 ( 0.6) | |
| シャント感染 | | | 1 ( 0.5) | | 1 ( 0.6) | 1 ( 0.6) | | | 1 ( 0.6) | 1 ( 0.6) | | | | |
| 腎嚢胞感染 | | | | | | | | | | | | 1 ( 0.6) | | |
| 細菌性結膜炎 | | | | | | | | | | | | 1 ( 0.6) | | |
| ウイルス性腸炎 | | | | | | | | | | | | | | 1 ( 0.6) |
| 化膿 | | | | 1 ( 0.5) | | | | | | | | | | |
| 細菌性腸炎 | | | | | | | | | | | | 1 ( 0.6) | | |
| 口腔ヘルペス | | | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.6) | | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 11）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ONO-5163 | | | | | | | | | | | | |
| | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 感染性皮膚嚢腫 | | | 1 ( 0.5) | | 1 ( 0.6) | | | 2 ( 1.2) | | | | | 1 ( 0.6) |
| 傷害、中毒および処置合併症 | 8 ( 4.2) | 12 ( 6.3) | 7 ( 3.8) | 9 ( 5.1) | 3 ( 1.7) | 6 ( 3.4) | 6 ( 3.5) | 5 ( 2.9) | 4 ( 2.4) | 8 ( 4.8) | 6 ( 3.6) | 4 ( 2.5) | 5 ( 3.1) |
| 足関節部骨折 | | | 1 ( 0.5) | | | | | | | | | | |
| 節足動物刺傷 | | | | | | 1 ( 0.6) | | 1 ( 0.6) | | | | | |
| 上顎炎 | | | | | | | | | | | 1 ( 0.6) | | |
| 足骨折 | | | | | | | | | 1 ( 0.6) | | | | 1 ( 0.6) |
| 上腕骨骨折 | | | | | | | | | | 1 ( 0.6) | | | |
| 裂傷 | | | | 1 ( 0.6) | | | | 1 ( 0.6) | | | | | |
| 靭帯捻挫 | | 1 ( 0.5) | | | | | | | | | | | 1 ( 0.6) |
| 爪裂離 | | | | | | | | | | | | 1 ( 0.6) | |
| 引っかき傷 | | | | | | | | | 1 ( 0.6) | | | | |
| シャント閉塞 | | 2 ( 1.1) | | 1 ( 0.6) | | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 12）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 皮下血腫 | | | | | | | | | 1 ( 0.6) | | | | 1 ( 0.6) | |
| 外傷性血腫 | | | | | 1 ( 0.6) | | | | | | | | | |
| 擦過傷 | | | 3 ( 1.6) | 1 ( 0.5) | 1 ( 0.6) | 1 ( 0.6) | | 1 ( 0.6) | 1 ( 0.6) | | 3 ( 1.8) | | | 1 ( 0.6) |
| 挫傷 | | 4 ( 2.1) | 2 ( 1.1) | | 2 ( 1.1) | 3 ( 1.7) | 6 ( 3.4) | 3 ( 1.7) | 2 ( 1.2) | 1 ( 0.6) | 1 ( 0.6) | 2 ( 1.2) | 2 ( 1.2) | 2 ( 1.2) |
| 創傷 | | 1 ( 0.5) | | 1 ( 0.5) | | 2 ( 1.1) | | 1 ( 0.6) | 1 ( 0.6) | | 3 ( 1.8) | 3 ( 1.8) | 1 ( 0.6) | 3 ( 1.8) |
| 熱傷 | | | 1 ( 0.5) | 1 ( 0.5) | | | 1 ( 0.6) | 1 ( 0.6) | | 1 ( 0.6) | 1 ( 0.6) | 1 ( 0.6) | | |
| 外耳道損傷 | | | | | | | | 1 ( 0.6) | | | | | | |
| シャント狭窄 | | 2 ( 1.1) | | 1 ( 0.5) | | | | | | 2 ( 1.2) | | | 2 ( 1.2) | |
| 舌損傷 | | | | | | | | | 1 ( 0.6) | | | | | |
| シャント機能不全 | | 1 ( 0.5) | | | | | | 1 ( 0.6) | 1 ( 0.6) | | 1 ( 0.6) | | | |
| 処置による低血圧 | | | 2 ( 1.1) | 2 ( 1.1) | 4 ( 2.2) | | 1 ( 0.6) | | | 1 ( 0.6) | 1 ( 0.6) | 2 ( 1.2) | | 1 ( 0.6) |
| 歯牙破折 | | | | | | | | | | | 1 ( 0.6) | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 13）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 処置後炎症 | | | | | 1 ( 0.6) | | | | | | | | | |
| シャント血流過剰 | | | 1 ( 0.5) | | | | | | | | | | | |
| 熱中症 | | | | | | | | 1 ( 0.6) | | | | | | |
| 爪損傷 | | | | 1 ( 0.5) | | | | | | | | | | |
| 血液透析合併症 | | | | | | | | | | | | | 1 ( 0.6) | |
| 眼挫傷 | | | | | | | | 1 ( 0.6) | | | | | | |
| 臨床検査 | | 16 ( 8.4) | 13 ( 6.9) | 3 ( 1.6) | 2 ( 1.1) | 2 ( 1.1) | | | | | 1 ( 0.6) | 1 ( 0.6) | 2 ( 1.2) | 1 ( 0.6) |
| 血中カルシウム減少 | | 6 ( 3.2) | 7 ( 3.7) | 2 ( 1.1) | | | | | | | | | 1 ( 0.6) | |
| 血中カルシウム増加 | | | | | | 1 ( 0.6) | | | | | | | | |
| 血中クレアチンホスホキナーゼ増加 | | | | | | 1 ( 0.6) | | | | | 2 ( 1.2) | | 1 ( 0.6) | |
| 血中カリウム増加 | | | | | | | | | | | | 1 ( 0.6) | | |
| 血圧低下 | | | | | 1 ( 0.6) | | | | | | | | 1 ( 0.6) | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 14）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ONO-5163 | | | | | | | | | | | | |
| | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 心電図ＳＴ部分下降 | 1 ( 0.5) | | | | | | | | | | | | |
| 尿量減少 | 2 ( 1.1) | | | | | | | | | | | | |
| 補正カルシウム減少 | 7 ( 3.7) | 6 ( 3.2) | 1 ( 0.5) | 2 ( 1.1) | 1 ( 0.6) | | | | | | 1 ( 0.6) | | 1 ( 0.6) |
| 代謝および栄養障害 | 4 ( 2.1) | | | 2 ( 1.1) | 1 ( 0.6) | | | 1 ( 0.6) | 2 ( 1.2) | 1 ( 0.6) | 1 ( 0.6) | | |
| 脱水 | | | | | | | | | 1 ( 0.6) | | | | |
| 糖尿病 | | | | | | | | | | | 1 ( 0.6) | | |
| 高カルシウム血症 | 1 ( 0.5) | | | | | | | | | | | | |
| 高リン酸塩血症 | | | | | 1 ( 0.6) | | | 1 ( 0.6) | 1 ( 0.6) | 1 ( 0.6) | | | |
| 低カルシウム血症 | 1 ( 0.5) | | 1 ( 0.5) | | | | | | | | | | |
| 低血糖症 | 1 ( 0.5) | | | | | | | | | | | | |
| 栄養障害 | | | | 1 ( 0.6) | | | | | | | | | |
| 食欲減退 | 1 ( 0.5) | | | 1 ( 0.6) | | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 15）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 筋骨格系および結合組織障害 | | 5 ( 2.6) | 5 ( 2.6) | 2 ( 1.1) | 2 ( 1.1) | 7 ( 4.0) | 2 ( 1.1) | 8 ( 4.6) | 5 ( 2.9) | 5 ( 3.0) | 8 ( 4.8) | 5 ( 3.0) | 3 ( 1.8) | 2 ( 1.2) |
| | 関節痛 | | 1 ( 0.5) | 1 ( 0.5) | | 1 ( 0.6) | | | 2 ( 1.2) | | | 1 ( 0.6) | | 1 ( 0.6) |
| | 関節炎 | | 1 ( 0.5) | | | | | | | | 1 ( 0.6) | | 1 ( 0.6) | |
| | 背部痛 | | | 1 ( 0.5) | 1 ( 0.6) | 1 ( 0.6) | | 4 ( 2.3) | 1 ( 0.6) | 2 ( 1.2) | 4 ( 2.4) | 1 ( 0.6) | 1 ( 0.6) | |
| | 滑液包炎 | | | | | | | | | | 1 ( 0.6) | | | |
| | 肋軟骨炎 | | | | | | | | | 1 ( 0.6) | | | | |
| | 筋膜炎 | | | | | | | 1 ( 0.6) | | | | | | 1 ( 0.6) |
| | 側腹部痛 | | | | | | | | | | | 1 ( 0.6) | | |
| | 腰部脊柱管狭窄症 | | | | | | | | | | 1 ( 0.6) | | 1 ( 0.6) | |
| | 筋痙縮 | | 1 ( 0.5) | | | | | 2 ( 1.2) | | | 1 ( 0.6) | | | |
| | 筋力低下 | 1 ( 0.5) | | | | | | | | | | | | |
| | 筋骨格痛 | 1 ( 0.5) | | | | 1 ( 0.6) | 1 ( 0.6) | 1 ( 0.6) | | | | 1 ( 0.6) | | 1 ( 0.6) |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 16）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 筋肉痛 | | 1 ( 0.5) | | | 1 ( 0.6) | | | | | 1 ( 0.6) | | | | |
| 頚部痛 | | | | | | 1 ( 0.6) | | 1 ( 0.6) | | | | 2 ( 1.2) | | 2 ( 1.2) |
| 変形性関節症 | | | | | | | | | | | | 2 ( 1.2) | | 1 ( 0.6) |
| 四肢痛 | | 2 ( 1.1) | | | | 2 ( 1.1) | | | 2 ( 1.2) | 1 ( 0.6) | 1 ( 0.6) | 1 ( 0.6) | | 1 ( 0.6) |
| 関節周囲炎 | | | | | | | | | 1 ( 0.6) | | | 1 ( 0.6) | 1 ( 0.6) | |
| 側弯症 | | | | | | | | | | | | | | 1 ( 0.6) |
| 変形性脊椎症 | | | 1 ( 0.5) | | | 1 ( 0.6) | | | | 1 ( 0.6) | | | | |
| 腱鞘炎 | | | | 1 ( 0.5) | | | 1 ( 0.6) | | | | | | | |
| 下肢腫瘤 | | | | | | 1 ( 0.6) | | | | | | | | |
| 筋骨格硬直 | | | | | | | | | | | 1 ( 0.6) | | | |
| 狭窄性腱鞘炎 | | | | | | | | 1 ( 0.6) | | | | | | |
| 脊椎すべり症 | | | 1 ( 0.5) | | | | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 17）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | 有害事象 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ONO-5163 | | | | | | | | | | | |
| | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） | 1 ( 0.5) | | 1 ( 0.5) | | | 1 ( 0.6) | 2 ( 1.2) | 1 ( 0.6) | 1 ( 0.6) | | 1 ( 0.6) | | |
| カルチノイド腫瘍 | | | | | | | | | 1 ( 0.6) | | | | |
| ケラトアカントーマ | | | | | | | 1 ( 0.6) | | | | | | |
| 肺腺癌 | | | 1 ( 0.5) | | | | | | | | | | |
| 脂漏性角化症 | | | | | | 1 ( 0.6) | | | | | | | |
| 骨の良性新生物 | 1 ( 0.5) | | | | | | | | | | | | |
| 胃新生物 | | | | | | | | 1 ( 0.6) | | | | | |
| 肝細胞癌 | | | | | | | 1 ( 0.6) | | | | 1 ( 0.6) | | |
| 神経系障害 | 3 ( 1.6) | 3 ( 1.6) | 1 ( 0.5) | 4 ( 2.2) | 1 ( 0.6) | 6 ( 3.4) | 3 ( 1.7) | 3 ( 1.7) | 3 ( 1.8) | 1 ( 0.6) | 3 ( 1.8) | 3 ( 1.8) | 1 ( 0.6) |
| 脳幹出血 | | | | | | | | 1 ( 0.6) | | | | | |
| 手根管症候群 | | 1 ( 0.5) | 1 ( 0.5) | | | | | | | | | 1 ( 0.6) | 1 ( 0.6) |
| アルツハイマー型認知症 | | | | | | | | | | | 1 ( 0.6) | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 18）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 浮動性めまい | | | | | | | 1 ( 0.6) | | | | 1 ( 0.6) | | | |
| 味覚異常 | | 1 ( 0.5) | 1 ( 0.5) | | 1 ( 0.6) | | | | | | | | | |
| ジスキネジア | | | 1 ( 0.5) | | | | | 1 ( 0.6) | | | | | | |
| 頭痛 | | 1 ( 0.5) | | | 1 ( 0.6) | | 2 ( 1.1) | | | | | | 1 ( 0.6) | |
| 感覚鈍麻 | | | | | | 1 ( 0.6) | 1 ( 0.6) | | | 1 ( 0.6) | | 1 ( 0.6) | 1 ( 0.6) | |
| 意識消失 | | | | | | | | | 1 ( 0.6) | 1 ( 0.6) | | | | 1 ( 0.6) |
| 末梢性ニューロパチー | | | | | | | | | 1 ( 0.6) | 1 ( 0.6) | | | | |
| 視神経炎 | | | | | | | | | | | | 1 ( 0.6) | | |
| 傾眠 | | | | | 2 ( 1.1) | | | | | | | | | |
| 失神 | | | | | | | 1 ( 0.6) | | | | | | | |
| 緊張性頭痛 | | 1 ( 0.5) | | | | | | 1 ( 0.6) | | | | | | |
| ラクナ梗塞 | | | | | | | | | | | 1 ( 0.6) | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 19）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | 有害事象 ONO-5163 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 下肢静止不能症候群 | | | | | | 1 ( 0.6) | | | | | | 1 ( 0.6) | |
| 橋本脳症 | | | | | | | 1 ( 0.6) | | | | | | |
| 精神障害 | 1 ( 0.5) | | 1 ( 0.5) | 1 ( 0.6) | | | | | | 2 ( 1.2) | | 1 ( 0.6) | |
| うつ病 | | | 1 ( 0.5) | | | | | | | | | | |
| 不眠症 | | | 1 ( 0.5) | 1 ( 0.6) | | | | | | 1 ( 0.6) | | 1 ( 0.6) | |
| 神経症 | 1 ( 0.5) | | | | | | | | | | | | |
| 夢遊症 | | | | | | | | | | 1 ( 0.6) | | | |
| 腎および尿路障害 | | | | | | | 1 ( 0.6) | | | | | 1 ( 0.6) | |
| 尿路結石 | | | | | | | | | | | | 1 ( 0.6) | |
| 水腎症 | | | | | | | 1 ( 0.6) | | | | | | |
| 生殖系および乳房障害 | | | | | | | 1 ( 0.6) | | | | | | |
| 卵巣嚢胞 | | | | | | | 1 ( 0.6) | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 20）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | 有害事象 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | ONO-5163 | | | | | | | | | | | |
| | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 呼吸器、胸郭および縦隔障害 | 3 ( 1.6) | 2 ( 1.1) | 2 ( 1.1) | 1 ( 0.6) | | 2 ( 1.1) | | 2 ( 1.2) | 1 ( 0.6) | 3 ( 1.8) | | 4 ( 2.5) | 3 ( 1.8) |
| 慢性気管支炎 | | | | | | | | | | | | 1 ( 0.6) | |
| 咳嗽 | 1 ( 0.5) | | | | | 1 ( 0.6) | | | | | | | |
| 呼吸困難 | | | | | | | | | | | | | 1 ( 0.6) |
| 鼻出血 | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.5) | | | 1 ( 0.6) | | | | | | | |
| 気胸 | | | | | | | | | | 1 ( 0.6) | | | |
| 湿性咳嗽 | | | | | | | | | | 1 ( 0.6) | | | |
| 肺うっ血 | | | | | | | | | | | | 1 ( 0.6) | |
| 鼻漏 | | | | | | | | | | | | | 2 ( 1.2) |
| 上気道の炎症 | 1 ( 0.5) | | 1 ( 0.5) | | | | | 2 ( 1.2) | | 1 ( 0.6) | | 1 ( 0.6) | |
| 縦隔出血 | | | | | | | | | 1 ( 0.6) | | | | |
| 口腔咽頭不快感 | | | | | | | | | | | | 1 ( 0.6) | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 21）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | | | | | | | | |
| | | 1日目～28日目 | | 29日目～56日目 | | 57日目～84日目 | | 85日目～112日目 | | 113日目～140日目 | | 141日目～168日目 | | 169日目～196日目 | | 197日目～224日目 | | 225日目～252日目 | | 253日目～280日目 | | 281日目～308日目 | | 309日目～336日目 | | 337日目～ | |
| PT | | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) |
| | N[a)] | 190 | | 189 | | 183 | | 178 | | 175 | | 175 | | 173 | | 173 | | 168 | | 167 | | 165 | | 163 | | 163 | |
| 口腔咽頭痛 | | | | 1 | ( 0.5) | | | 1 | ( 0.6) | | | | | | | | | | | | | | | | | | |
| 皮膚および皮下組織障害 | | 6 | ( 3.2) | 6 | ( 3.2) | 1 | ( 0.5) | 3 | ( 1.7) | 6 | ( 3.4) | 4 | ( 2.3) | 7 | ( 4.0) | 2 | ( 1.2) | 6 | ( 3.6) | 3 | ( 1.8) | 4 | ( 2.4) | 3 | ( 1.8) | 1 | ( 0.6) |
| 水疱 | | | | | | 1 | ( 0.5) | | | | | | | | | | | | | | | | | | | | |
| 皮膚嚢腫 | | | | | | | | | | | | | | 1 | ( 0.6) | | | | | | | | | | | | |
| アレルギー性皮膚炎 | | | | | | | | | | | | 1 | ( 0.6) | | | | | | | | | | | | | | |
| 接触性皮膚炎 | | 1 | ( 0.5) | 2 | ( 1.1) | | | 1 | ( 0.6) | 2 | ( 1.1) | | | 2 | ( 1.2) | | | 1 | ( 0.6) | 1 | ( 0.6) | 1 | ( 0.6) | | | 1 | ( 0.6) |
| 皮膚乾燥 | | 1 | ( 0.5) | | | | | | | | | | | 1 | ( 0.6) | | | | | 1 | ( 0.6) | | | | | | |
| 湿疹 | | | | | | 1 | ( 0.5) | | | 2 | ( 1.1) | 1 | ( 0.6) | 4 | ( 2.3) | | | 1 | ( 0.6) | | | | | 2 | ( 1.2) | | |
| 貨幣状湿疹 | | | | | | | | | | | | | | | | | | 1 | ( 0.6) | | | | | | | | |
| 紅斑 | | | | 1 | ( 0.5) | | | | | | | | | | | | | | | | | | | | | 1 | ( 0.6) |
| 皮下出血 | | | | | | | | | | | | | | | | | | 1 | ( 0.6) | | | | | 1 | ( 0.6) | | |
| 嵌入爪 | | 1 | ( 0.5) | | | | | | | | | | | | | | | | | | | 1 | ( 0.6) | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted]試験）（続き 22）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 ONO-5163 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| ケロイド瘢痕 | | | | | | | | | 1 ( 0.6) | | | | | |
| そう痒症 | | 1 ( 0.5) | | | 1 ( 0.6) | | 2 ( 1.1) | | 1 ( 0.6) | | | 1 ( 0.6) | 2 ( 1.2) | |
| 発疹 | | 1 ( 0.5) | 1 ( 0.5) | | 1 ( 0.6) | | | | | | | 1 ( 0.6) | | 1 ( 0.6) |
| 脂漏性皮膚炎 | | | | | | 1 ( 0.6) | | | | | | | | |
| 皮膚剥脱 | | 1 ( 0.5) | 2 ( 1.1) | | | | | 1 ( 0.6) | 1 ( 0.6) | 2 ( 1.2) | 1 ( 0.6) | 1 ( 0.6) | | |
| 皮膚潰瘍 | | | | | 1 ( 0.6) | | | | | | | | | |
| 蕁麻疹 | | | | | | 1 ( 0.6) | | | | | | | | |
| 乾皮症 | | | | | | | | | | | | | 1 ( 0.6) | |
| 皮脂欠乏症 | | | | | | | | | | | 1 ( 0.6) | | | |
| 血管障害 | | 1 ( 0.5) | 3 ( 1.6) | 1 ( 0.5) | 4 ( 2.2) | 1 ( 0.6) | | | 2 ( 1.2) | | 1 ( 0.6) | 2 ( 1.2) | 2 ( 1.2) | 2 ( 1.2) |
| 大動脈解離 | | | | | | | | | | | | 1 ( 0.6) | | |
| 血腫 | | | | | | 1 ( 0.6) | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-13　有害事象の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 23）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 高血圧 | | | 2 ( 1.1) | 1 ( 0.5) | 2 ( 1.1) | | | | 1 ( 0.6) | | | 1 ( 0.6) | | |
| 起立性低血圧 | | | | | | | | | 1 ( 0.6) | | 1 ( 0.6) | | | |
| 末梢冷感 | | | | | | | | | | | | | | 1 ( 0.6) |
| 血管痛 | | 1 ( 0.5) | | | 1 ( 0.6) | | | | | | | | | |
| 動脈瘤破裂 | | | | | | | | | | | | | 1 ( 0.6) | |
| 内出血 | | | 1 ( 0.5) | | 1 ( 0.6) | | | | | | | | 1 ( 0.6) | 1 ( 0.6) |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
a）各時期において有害事象の観察が行われた被験者とした．

出典［総括報告書 5.3.5.2-1（ONO-5163-[redacted] 試験）表 14.3.1-12］

**表 2.7.4.7-14　副作用の時期別発現頻度（ONO-5163-[redacted] 試験）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | | 副作用 ONO-5163 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 全体 | | 21 ( 11.1) | 14 ( 7.4) | 6 ( 3.3) | 2 ( 1.1) | 1 ( 0.6) | 1 ( 0.6) | | | 2 ( 1.2) | 1 ( 0.6) | 2 ( 1.2) | 1 ( 0.6) | 2 ( 1.2) |
| 心臓障害 | | | | | | | | | | 2 ( 1.2) | | | | 1 ( 0.6) |
| | 心筋梗塞 | | | | | | | | | 1 ( 0.6) | | | | |
| | 上室性期外収縮 | | | | | | | | | 1 ( 0.6) | | | | |
| | 頻脈性不整脈 | | | | | | | | | | | | | 1 ( 0.6) |
| 眼障害 | | 1 ( 0.5) | | | | | | | | | | | | |
| | 眼瞼炎 | 1 ( 0.5) | | | | | | | | | | | | |
| 胃腸障害 | | 3 ( 1.6) | 2 ( 1.1) | 2 ( 1.1) | 2 ( 1.1) | | 1 ( 0.6) | | | | | | | |
| | 腹部不快感 | 1 ( 0.5) | | | | | | | | | | | | |
| | 便秘 | | | | | | 1 ( 0.6) | | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．
a）各時期において有害事象の観察が行われた被験者とした．

出典［総括報告書 5.3.5.2-1（ONO-5163-[redacted] 試験）表 14.3.1-13］

**表 2.7.4.7-14　副作用の時期別発現頻度（ONO-5163-[redacted]試験）（続き 1）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC | | 副作用 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | | | | | | | |
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 下痢 | | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.5) | | | | | | | | | | |
| 胃食道逆流性疾患 | | | | 1 ( 0.5) | | | | | | | | | | |
| 悪心 | | | 1 ( 0.5) | | | | | | | | | | | |
| 口内炎 | | | | | | | 1 ( 0.6) | | | | | | | |
| 嘔吐 | | | | 1 ( 0.5) | 1 ( 0.6) | | | | | | | | | |
| 心窩部不快感 | | | | | 1 ( 0.6) | | | | | | | | | |
| 痔出血 | | | | | | | 1 ( 0.6) | | | | | | | |
| 口の感覚鈍麻 | | | | 1 ( 0.5) | | | | | | | | | | |
| 軟便 | | 1 ( 0.5) | | | | | | | | | | | | |
| 一般・全身障害および投与部位の状態 | | | | 1 ( 0.5) | | | | | | | | | | 1 ( 0.6) |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-14　副作用の時期別発現頻度（ONO-5163-[redacted] 試験）（続き 2）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC | 副作用 ONO-5163 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 倦怠感 | | | 1 ( 0.5) | | | | | | | | | | |
| 突然死 | | | | | | | | | | | | | 1 ( 0.6) |
| 感染症および寄生虫症 | | | | | | | | | | 1 ( 0.6) | | | |
| 単純ヘルペス | | | | | | | | | | 1 ( 0.6) | | | |
| 臨床検査 | 16 ( 8.4) | 12 ( 6.3) | 3 ( 1.6) | 1 ( 0.6) | 1 ( 0.6) | | | | | | 1 ( 0.6) | 1 ( 0.6) | 1 ( 0.6) |
| 血中カルシウム減少 | 6 ( 3.2) | 7 ( 3.7) | 2 ( 1.1) | | | | | | | | | 1 ( 0.6) | |
| 心電図ＳＴ部分下降 | 1 ( 0.5) | | | | | | | | | | | | |
| 尿量減少 | 2 ( 1.1) | | | | | | | | | | | | |
| 補正カルシウム減少 | 7 ( 3.7) | 5 ( 2.6) | 1 ( 0.5) | 2 ( 1.1) | 1 ( 0.6) | | | | | | 1 ( 0.6) | | 1 ( 0.6) |
| 代謝および栄養障害 | 1 ( 0.5) | | 1 ( 0.5) | | | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-14　副作用の時期別発現頻度（ONO-5163-[redacted]試験）（続き 3）**
**（治験薬投与開始 365 日目の評価時）**
**析対象集団：SAF**

| SOC | 副作用 ONO-5163 | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1日目～28日目 | | 29日目～56日目 | | 57日目～84日目 | | 85日目～112日目 | | 113日目～140日目 | | 141日目～168日目 | | 169日目～196日目 | | 197日目～224日目 | | 225日目～252日目 | | 253日目～280日目 | | 281日目～308日目 | | 309日目～336日目 | | 337日目～ | |
| PT | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) | n | (%) |
| N[a)] | 190 | | 189 | | 183 | | 178 | | 175 | | 175 | | 173 | | 173 | | 168 | | 167 | | 165 | | 163 | | 163 | |
| 低カルシウム血症 | 1 | ( 0.5) | | | 1 | ( 0.5) | | | | | | | | | | | | | | | | | | | | |
| 筋骨格系および結合組織障害 | | | 2 | ( 1.1) | | | | | | | | | | | | | | | | | | | | | | |
| 筋痙縮 | | | 1 | ( 0.5) | | | | | | | | | | | | | | | | | | | | | | |
| 脊椎すべり症 | | | 1 | ( 0.5) | | | | | | | | | | | | | | | | | | | | | | |
| 神経系障害 | 1 | ( 0.5) | 2 | ( 1.1) | | | | | | | | | | | | | | | | | 1 | ( 0.6) | 1 | ( 0.6) | | |
| 手根管症候群 | | | | | | | | | | | | | | | | | | | | | | | 1 | ( 0.6) | | |
| 味覚異常 | 1 | ( 0.5) | 1 | ( 0.5) | | | | | | | | | | | | | | | | | | | | | | |
| ジスキネジア | | | 1 | ( 0.5) | | | | | | | | | | | | | | | | | | | | | | |
| 視神経炎 | | | | | | | | | | | | | | | | | | | | | 1 | ( 0.6) | | | | |
| 呼吸器、胸郭および縦隔障害 | | | | | 1 | ( 0.5) | | | | | | | | | | | | | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．
a）各時期において有害事象の観察が行われた被験者とした．

**表 2.7.4.7-14　副作用の時期別発現頻度（ONO-5163-[redacted]試験）（続き 4）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC | | 副作用 ONO-5163 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1日目～28日目 | 29日目～56日目 | 57日目～84日目 | 85日目～112日目 | 113日目～140日目 | 141日目～168日目 | 169日目～196日目 | 197日目～224日目 | 225日目～252日目 | 253日目～280日目 | 281日目～308日目 | 309日目～336日目 | 337日目～ |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N[a)] | 190 | 189 | 183 | 178 | 175 | 175 | 173 | 173 | 168 | 167 | 165 | 163 | 163 |
| 鼻出血 | | | | 1 ( 0.5) | | | | | | | | | | |
| 皮膚および皮下組織障害 | | | 1 ( 0.5) | | | | | | | | | | | |
| 発疹 | | | 1 ( 0.5) | | | | | | | | | | | |
| 血管障害 | | | | | | | | | | | | 1 ( 0.6) | | |
| 大動脈解離 | | | | | | | | | | | | 1 ( 0.6) | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者にて，同じ有害事象が複数回発現している場合は，最も発現時期が早い事象を集計対象とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．
a）各時期において有害事象の観察が行われた被験者とした．

出典［総括報告書 5.3.5.2-1（ONO-5163-[redacted]試験）表 14.3.1-13］

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 全体 | | 70 ( 56.0) | 85 ( 85.9) | 119 ( 62.6) | 9 ( 34.6) | 48 ( 64.9) | 5 ( 71.4) | 23 ( 76.7) |
| 血液およびリンパ系障害 | | 1 ( 0.8) | 3 ( 3.0) | 3 ( 1.6) | | | | |
| 貧血 | | | | 1 ( 0.5) | | | | |
| 鉄欠乏性貧血 | | | 1 ( 1.0) | | | | | |
| リンパ節症 | | | 1 ( 1.0) | | | | | |
| 腎性貧血 | | 1 ( 0.8) | 1 ( 1.0) | 2 ( 1.1) | | | | |
| 心臓障害 | | | 4 ( 4.0) | 2 ( 1.1) | | 2 ( 2.7) | | 1 ( 3.3) |
| 心房細動 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |
| うっ血性心不全 | | | | | | 2 ( 2.7) | | |
| 心筋梗塞 | | | | | | | | 1 ( 3.3) |
| 動悸 | | | 1 ( 1.0) | | | | | |
| 上室性期外収縮 | | | | 1 ( 0.5) | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

出典［総括報告書 5.3.5.2-1（ONO-5163-[redacted] 試験）表 14.3.1-14］

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 1）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 心室性期外収縮 | | | 1 ( 1.0) | | | | | |
| 頻脈性不整脈 | | | 1 ( 1.0) | | | | | |
| 耳および迷路障害 | | 5 ( 4.0) | 2 ( 2.0) | 4 ( 2.1) | 2 ( 7.7) | 2 ( 2.7) | | |
| 耳鳴 | | 1 ( 0.8) | | | | | | |
| 回転性めまい | | 3 ( 2.4) | 2 ( 2.0) | 4 ( 2.1) | 2 ( 7.7) | 1 ( 1.4) | | |
| 頭位性回転性めまい | | 1 ( 0.8) | | | | 1 ( 1.4) | | |
| 眼障害 | | 5 ( 4.0) | 3 ( 3.0) | 9 ( 4.7) | | 5 ( 6.8) | 1 ( 14.3) | 1 ( 3.3) |
| 眼瞼炎 | | | | 1 ( 0.5) | | 1 ( 1.4) | | |
| 白内障 | | | 1 ( 1.0) | 2 ( 1.1) | | | | 1 ( 3.3) |
| 結膜出血 | | 2 ( 1.6) | 2 ( 2.0) | | | 2 ( 2.7) | | |
| アレルギー性結膜炎 | | 1 ( 0.8) | | 2 ( 1.1) | | | | |
| 角膜沈着物 | | | | | | | 1 ( 14.3) | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 2）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 眼乾燥 | | | | 1 ( 0.5) | | | | |
| 眼瞼湿疹 | | | | | | 1 ( 1.4) | | |
| 眼脂 | | | | | | 1 ( 1.4) | | |
| 眼瞼下垂 | | | | 1 ( 0.5) | | | | |
| 網膜剥離 | | 1 ( 0.8) | | | | | | |
| 網膜出血 | | 1 ( 0.8) | | | | | | |
| 高血圧性網膜症 | | | | 1 ( 0.5) | | | | |
| 硝子体浮遊物 | | | 1 ( 1.0) | | | | | |
| 強膜出血 | | | | 1 ( 0.5) | | | | |
| 結膜充血 | | | | 1 ( 0.5) | | | | |
| 眼そう痒症 | | | | 1 ( 0.5) | | | | |
| 胃腸障害 | | 20 ( 16.0) | 30 ( 30.3) | 38 ( 20.0) | 3 ( 11.5) | 16 ( 21.6) | 3 ( 42.9) | 5 ( 16.7) |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 3）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 腹部不快感 | | 2 ( 1.6) | 1 ( 1.0) | 1 ( 0.5) | 1 ( 3.8) | 1 ( 1.4) | | |
| 腹部膨満 | | 1 ( 0.8) | | | | | | |
| 腹痛 | | | 1 ( 1.0) | | | | | |
| 下腹部痛 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 上腹部痛 | | | 3 ( 3.0) | 1 ( 0.5) | | | | |
| 口唇炎 | | | 1 ( 1.0) | | | | | |
| 慢性胃炎 | | | | | | | | 1 ( 3.3) |
| 便秘 | | 4 ( 3.2) | 3 ( 3.0) | 4 ( 2.1) | 1 ( 3.8) | 1 ( 1.4) | | |
| 齲歯 | | 2 ( 1.6) | 3 ( 3.0) | 2 ( 1.1) | | | | |
| 下痢 | | 10 ( 8.0) | 8 ( 8.1) | 10 ( 5.3) | | 6 ( 8.1) | 2 ( 28.6) | 1 ( 3.3) |
| 腸憩室 | | | | 1 ( 0.5) | | | | |
| 出血性腸憩室 | | 1 ( 0.8) | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 4）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 十二指腸炎 | | | 1 ( 1.0) | | | | | |
| 消化不良 | | | | 1 ( 0.5) | | | | |
| 小腸炎 | | | | | | 1 ( 1.4) | | |
| 腸炎 | | | | | | 1 ( 1.4) | | |
| 胃アトニー | | | | 1 ( 0.5) | | | | |
| 胃ポリープ | | 1 ( 0.8) | | 4 ( 2.1) | | 2 ( 2.7) | | |
| 胃炎 | | 1 ( 0.8) | 2 ( 2.0) | 2 ( 1.1) | | | | |
| 胃食道逆流性疾患 | | | 1 ( 1.0) | 1 ( 0.5) | | 2 ( 2.7) | | |
| 歯肉痛 | | | | 1 ( 0.5) | | | | |
| 舌炎 | | 1 ( 0.8) | 1 ( 1.0) | | | | | |
| 痔核 | | 1 ( 0.8) | 1 ( 1.0) | 5 ( 2.6) | | | | 1 ( 3.3) |
| 裂孔ヘルニア | | | | | | 1 ( 1.4) | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 5）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 大腸穿孔 | | | 1 ( 1.0) | | | | | |
| 口唇潰瘍 | | | | 1 ( 0.5) | | | | |
| 悪心 | | 2 ( 1.6) | 4 ( 4.0) | 4 ( 2.1) | | 1 ( 1.4) | | |
| 急性膵炎 | | | | | | 1 ( 1.4) | | |
| 口内炎 | | | 2 ( 2.0) | 2 ( 1.1) | | | | |
| 歯痛 | | | 1 ( 1.0) | | | | | |
| 嘔吐 | | 4 ( 3.2) | 3 ( 3.0) | 5 ( 2.6) | 2 ( 7.7) | 2 ( 2.7) | 1 ( 14.3) | 2 ( 6.7) |
| 口唇のひび割れ | | | 1 ( 1.0) | | | | | |
| 大腸ポリープ | | 1 ( 0.8) | 1 ( 1.0) | 1 ( 0.5) | | 1 ( 1.4) | | |
| 心窩部不快感 | | | | 1 ( 0.5) | | | | |
| 痔出血 | | | | 1 ( 0.5) | | | | |
| ブルンネル腺過形成 | | | | 1 ( 0.5) | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 6）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 口の感覚鈍麻 | | | | | | 1 ( 1.4) | | |
| 腹膜穿孔 | | | | 1 ( 0.5) | | | | |
| 肛門びらん | | | | | | 1 ( 1.4) | | |
| 口腔粘膜血腫 | | | | 1 ( 0.5) | | | | |
| 軟便 | | | | 2 ( 1.1) | | | | |
| 一般・全身障害および投与部位の状態 | | 7 ( 5.6) | 3 ( 3.0) | 5 ( 2.6) | | 3 ( 4.1) | | |
| 胸痛 | | 3 ( 2.4) | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 異常感 | | | | 1 ( 0.5) | | | | |
| 倦怠感 | | | | 1 ( 0.5) | | 2 ( 2.7) | | |
| 発熱 | | 2 ( 1.6) | | | | | | |
| 突然死 | | 1 ( 0.8) | | | | | | |
| 虚血性潰瘍 | | | 1 ( 1.0) | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 7）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 穿刺部位疼痛 | | | | 1 ( 0.5) | | | | |
| 血管穿刺部位そう痒感 | | | | | | 1 ( 1.4) | | |
| 穿刺部位腫脹 | | 1 ( 0.8) | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 肝胆道系障害 | | 2 ( 1.6) | | | | | | |
| 胆管結石 | | 1 ( 0.8) | | | | | | |
| 胆嚢ポリープ | | 1 ( 0.8) | | | | | | |
| 免疫系障害 | | 1 ( 0.8) | 1 ( 1.0) | | | | | |
| 季節性アレルギー | | 1 ( 0.8) | | | | | | |
| 造影剤アレルギー | | | 1 ( 1.0) | | | | | |
| 感染症および寄生虫症 | | 34 ( 27.2) | 47 ( 47.5) | 65 ( 34.2) | 7 ( 26.9) | 28 ( 37.8) | 3 ( 42.9) | 13 ( 43.3) |
| 細菌性膣症 | | | 1 ( 1.0) | | | | | |
| 気管支炎 | | 2 ( 1.6) | 2 ( 2.0) | 5 ( 2.6) | 1 ( 3.8) | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 8）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 気管支肺炎 | | 1 ( 0.8) | | | | | | |
| 慢性副鼻腔炎 | | | | | | 1 ( 1.4) | | |
| 結膜炎 | | | 1 ( 1.0) | | | | | 1 ( 3.3) |
| 膀胱炎 | | 1 ( 0.8) | 3 ( 3.0) | 4 ( 2.1) | | 1 ( 1.4) | | |
| 感染性皮膚炎 | | | | 1 ( 0.5) | 1 ( 3.8) | | | |
| 毛包炎 | | | 2 ( 2.0) | 2 ( 1.1) | | | | |
| せつ | | | | | | 1 ( 1.4) | | |
| 胃腸炎 | | | 4 ( 4.0) | 4 ( 2.1) | | 1 ( 1.4) | | 1 ( 3.3) |
| 歯肉炎 | | 1 ( 0.8) | | 3 ( 1.6) | | | | |
| 単純ヘルペス | | | | | | 1 ( 1.4) | | |
| 麦粒腫 | | 2 ( 1.6) | | 1 ( 0.5) | | 1 ( 1.4) | | |
| インフルエンザ | | | | 4 ( 2.1) | | 1 ( 1.4) | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 9）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 大葉性肺炎 | | | | | 1 ( 3.8) | | | |
| リステリア菌性髄膜炎 | | 1 ( 0.8) | | | | | | |
| 鼻咽頭炎 | | 22 ( 17.6) | 35 ( 35.4) | 48 ( 25.3) | 5 ( 19.2) | 25 ( 33.8) | 2 ( 28.6) | 10 ( 33.3) |
| 爪真菌症 | | 2 ( 1.6) | | 1 ( 0.5) | | | | |
| 精巣炎 | | | 1 ( 1.0) | | | | | |
| 中耳炎 | | | | | | 1 ( 1.4) | | |
| 歯冠周囲炎 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 歯周炎 | | 1 ( 0.8) | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 咽頭炎 | | 1 ( 0.8) | 1 ( 1.0) | 2 ( 1.1) | | | | 1 ( 3.3) |
| 偽膜性大腸炎 | | 1 ( 0.8) | | | | | | |
| 歯髄炎 | | | 1 ( 1.0) | | | | | |
| 膿皮症 | | | 1 ( 1.0) | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 10）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 皮下組織膿瘍 | | | | | | | | 1 ( 3.3) |
| 足部白癬 | | | 3 ( 3.0) | | | | 1 ( 14.3) | 1 ( 3.3) |
| 尿路感染 | | 1 ( 0.8) | | | | | | |
| 肛径部感染 | | | | | | 1 ( 1.4) | | |
| 細菌性咽頭炎 | | | | | 1 ( 3.8) | | | |
| シャント感染 | | 3 ( 2.4) | 1 ( 1.0) | 1 ( 0.5) | | | | 1 ( 3.3) |
| 腎嚢胞感染 | | | | | | 1 ( 1.4) | | |
| 細菌性結膜炎 | | | 1 ( 1.0) | | | | | |
| ウイルス性腸炎 | | 1 ( 0.8) | | | | | | |
| 化膿 | | | | | | 1 ( 1.4) | | |
| 細菌性腸炎 | | | 1 ( 1.0) | | | | | |
| 口腔ヘルペス | | | 1 ( 1.0) | 1 ( 0.5) | | | | 1 ( 3.3) |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 11）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 感染性皮膚嚢腫 | | 2 ( 1.6) | 3 ( 3.0) | | | 1 ( 1.4) | | |
| 傷害、中毒および処置合併症 | | 23 ( 18.4) | 35 ( 35.4) | 22 ( 11.6) | 2 ( 7.7) | 16 ( 21.6) | | 6 ( 20.0) |
| 足関節部骨折 | | 1 ( 0.8) | | | | | | |
| 節足動物刺傷 | | 1 ( 0.8) | | | | 1 ( 1.4) | | |
| 上顆炎 | | | 1 ( 1.0) | | | | | |
| 足骨折 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 上腕骨骨折 | | 1 ( 0.8) | | | | | | |
| 裂傷 | | 1 ( 0.8) | | 1 ( 0.5) | | | | |
| 靭帯捻挫 | | | 1 ( 1.0) | | | 1 ( 1.4) | | |
| 爪裂離 | | | | | | | | 1 ( 3.3) |
| 引っかき傷 | | | | | | | | 1 ( 3.3) |
| シャント閉塞 | | 1 ( 0.8) | 1 ( 1.0) | 1 ( 0.5) | | 1 ( 1.4) | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 12）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 皮下血腫 | | | | 1 ( 0.5) | 1 ( 3.8) | | | |
| 外傷性血腫 | | | 1 ( 1.0) | | | | | |
| 擦過傷 | | 2 ( 1.6) | 6 ( 6.1) | 1 ( 0.5) | | 2 ( 2.7) | | 1 ( 3.3) |
| 挫傷 | | 5 ( 4.0) | 12 ( 12.1) | 10 ( 5.3) | | 5 ( 6.8) | | 2 ( 6.7) |
| 創傷 | | 3 ( 2.4) | 5 ( 5.1) | 5 ( 2.6) | | 2 ( 2.7) | | 1 ( 3.3) |
| 熱傷 | | 3 ( 2.4) | | 3 ( 1.6) | 1 ( 3.8) | | | |
| 外耳道損傷 | | | 1 ( 1.0) | | | | | |
| シャント狭窄 | | 1 ( 0.8) | 2 ( 2.0) | 2 ( 1.1) | | 2 ( 2.7) | | 1 ( 3.3) |
| 舌損傷 | | 1 ( 0.8) | | | | | | |
| シャント機能不全 | | | 3 ( 3.0) | 2 ( 1.1) | | | | |
| 処置による低血圧 | | 5 ( 4.0) | 3 ( 3.0) | 4 ( 2.1) | | 2 ( 2.7) | | 2 ( 6.7) |
| 歯牙破折 | | | 1 ( 1.0) | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 13）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 処置後炎症 | | | 1 ( 1.0) | | | | | |
| シャント血流過剰 | | | | | | 1 ( 1.4) | | |
| 熱中症 | | | | | | | | 1 ( 3.3) |
| 爪損傷 | | 1 ( 0.8) | | | | | | |
| 血液透析合併症 | | | | | | 1 ( 1.4) | | |
| 眼挫傷 | | | | | | 1 ( 1.4) | | |
| 臨床検査 | | 4 ( 3.2) | 11 ( 11.1) | 24 ( 12.6) | 1 ( 3.8) | 11 ( 14.9) | | 4 ( 13.3) |
| 血中カルシウム減少 | | 1 ( 0.8) | 2 ( 2.0) | 6 ( 3.2) | 1 ( 3.8) | 9 ( 12.2) | | 4 ( 13.3) |
| 血中カルシウム増加 | | 1 ( 0.8) | | | | | | |
| 血中クレアチンホスホキナーゼ増加 | | | 4 ( 4.0) | | | | | |
| 血中カリウム増加 | | | 1 ( 1.0) | | | | | |
| 血圧低下 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 14）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 心電図ＳＴ部分下降 | | | | 1 ( 0.5) | | | | |
| 尿量減少 | | | 1 ( 1.0) | 2 ( 1.1) | | | | |
| 補正カルシウム減少 | | 2 ( 1.6) | 4 ( 4.0) | 15 ( 7.9) | | 2 ( 2.7) | | |
| 代謝および栄養障害 | | 2 ( 1.6) | 3 ( 3.0) | 4 ( 2.1) | | 3 ( 4.1) | | 1 ( 3.3) |
| 脱水 | | 1 ( 0.8) | | | | | | |
| 糖尿病 | | | 1 ( 1.0) | | | | | |
| 高カルシウム血症 | | 1 ( 0.8) | | | | | | |
| 高リン酸塩血症 | | | 1 ( 1.0) | 1 ( 0.5) | | 1 ( 1.4) | | 1 ( 3.3) |
| 低カルシウム血症 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 低血糖症 | | | | 1 ( 0.5) | | | | |
| 栄養障害 | | | | | | 1 ( 1.4) | | |
| 食欲減退 | | | | 1 ( 0.5) | | 1 ( 1.4) | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 15）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 筋骨格系および結合組織障害 | | 13 ( 10.4) | 19 ( 19.2) | 22 ( 11.6) | 1 ( 3.8) | 7 ( 9.5) | 1 ( 14.3) | 6 ( 20.0) |
| 関節痛 | | 1 ( 0.8) | 1 ( 1.0) | 2 ( 1.1) | 1 ( 3.8) | 1 ( 1.4) | | 2 ( 6.7) |
| 関節炎 | | 1 ( 0.8) | | 1 ( 0.5) | | | | 1 ( 3.3) |
| 背部痛 | | 4 ( 3.2) | 2 ( 2.0) | 4 ( 2.1) | | 2 ( 2.7) | 1 ( 14.3) | 3 ( 10.0) |
| 滑液包炎 | | | 1 ( 1.0) | | | | | |
| 肋軟骨炎 | | | 1 ( 1.0) | | | | | |
| 筋膜炎 | | 1 ( 0.8) | 1 ( 1.0) | | | | | |
| 側腹部痛 | | | | | | | | 1 ( 3.3) |
| 腰部脊柱管狭窄症 | | | 2 ( 2.0) | | | | | |
| 筋痙縮 | | | 1 ( 1.0) | 2 ( 1.1) | | 1 ( 1.4) | | |
| 筋力低下 | | | | 1 ( 0.5) | | | | |
| 筋骨格痛 | | 2 ( 1.6) | 1 ( 1.0) | 2 ( 1.1) | | 1 ( 1.4) | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 16）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 筋肉痛 | | | 1 ( 1.0) | 1 ( 0.5) | | 1 ( 1.4) | | |
| 頚部痛 | | 1 ( 0.8) | 4 ( 4.0) | 1 ( 0.5) | | | | |
| 変形性関節症 | | | 1 ( 1.0) | | | 1 ( 1.4) | | 1 ( 3.3) |
| 四肢痛 | | 3 ( 2.4) | 2 ( 2.0) | 5 ( 2.6) | 1 ( 3.8) | 2 ( 2.7) | | |
| 関節周囲炎 | | | 2 ( 2.0) | 1 ( 0.5) | | | | |
| 側弯症 | | 1 ( 0.8) | | | | | | |
| 変形性脊椎症 | | 1 ( 0.8) | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 腱鞘炎 | | | | 1 ( 0.5) | 1 ( 3.8) | | | |
| 下肢腫瘤 | | | | 1 ( 0.5) | | | | |
| 筋骨格硬直 | | | 1 ( 1.0) | | | | | |
| 狭窄性腱鞘炎 | | | | 1 ( 0.5) | | | | |
| 脊椎すべり症 | | | | | | 1 ( 1.4) | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 17）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|
| N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） | 2 ( 1.6) | 2 ( 2.0) | 3 ( 1.6) | | | | 1 ( 3.3) |
| カルチノイド腫瘍 | | | | | | | 1 ( 3.3) |
| ケラトアカントーマ | | 1 ( 1.0) | | | | | |
| 肺腺癌 | 1 ( 0.8) | | | | | | |
| 脂漏性角化症 | 1 ( 0.8) | | | | | | |
| 骨の良性新生物 | | | 1 ( 0.5) | | | | |
| 胃新生物 | | | 1 ( 0.5) | | | | |
| 肝細胞癌 | | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 神経系障害 | 8 ( 6.4) | 9 ( 9.1) | 10 ( 5.3) | | 7 ( 9.5) | 1 ( 14.3) | 2 ( 6.7) |
| 脳幹出血 | 1 ( 0.8) | | | | | | |
| 手根管症候群 | 1 ( 0.8) | 1 ( 1.0) | 1 ( 0.5) | | 1 ( 1.4) | | |
| アルツハイマー型認知症 | | 1 ( 1.0) | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 18）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC / PT | | 有害事象 ONO-5163 0 mg n (%) | 2.5 mg n (%) | 5 mg n (%) | 7.5 mg n (%) | 10 mg n (%) | 12.5 mg n (%) | 15 mg n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 浮動性めまい | | | 2 ( 2.0) | | | | | |
| 味覚異常 | | | | 2 ( 1.1) | | 1 ( 1.4) | | |
| ジスキネジア | | | | | | 2 ( 2.7) | | |
| 頭痛 | | 2 ( 1.6) | | 2 ( 1.1) | | 1 ( 1.4) | | |
| 感覚鈍麻 | | | 1 ( 1.0) | 1 ( 0.5) | | 1 ( 1.4) | | 2 ( 6.7) |
| 意識消失 | | 2 ( 1.6) | 1 ( 1.0) | | | | | |
| 末梢性ニューロパチー | | 1 ( 0.8) | 1 ( 1.0) | | | | | |
| 視神経炎 | | | | 1 ( 0.5) | | | | |
| 傾眠 | | 1 ( 0.8) | | | | 1 ( 1.4) | | |
| 失神 | | | | 1 ( 0.5) | | | | |
| 緊張性頭痛 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |
| ラクナ梗塞 | | | | | | | 1 ( 14.3) | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted]試験）（続き 19）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 下肢静止不能症候群 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 橋本脳症 | | 1 ( 0.8) | | | | | | |
| 精神障害 | | 1 ( 0.8) | 2 ( 2.0) | 2 ( 1.1) | | 1 ( 1.4) | | |
| うつ病 | | | 1 ( 1.0) | | | | | |
| 不眠症 | | | 2 ( 2.0) | 1 ( 0.5) | | 1 ( 1.4) | | |
| 神経症 | | | | 1 ( 0.5) | | | | |
| 夢遊症 | | 1 ( 0.8) | | | | | | |
| 腎および尿路障害 | | 1 ( 0.8) | 1 ( 1.0) | | | | | |
| 尿路結石 | | | 1 ( 1.0) | | | | | |
| 水腎症 | | 1 ( 0.8) | | | | | | |
| 生殖系および乳房障害 | | 1 ( 0.8) | | | | | | |
| 卵巣嚢胞 | | 1 ( 0.8) | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 20）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 呼吸器、胸郭および縦隔障害 | | 4 ( 3.2) | 4 ( 4.0) | 9 ( 4.7) | | 3 ( 4.1) | 1 ( 14.3) | 2 ( 6.7) |
| 慢性気管支炎 | | | | 1 ( 0.5) | | | | |
| 咳嗽 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 呼吸困難 | | | | | | | 1 ( 14.3) | |
| 鼻出血 | | 1 ( 0.8) | | 1 ( 0.5) | | 2 ( 2.7) | | |
| 気胸 | | | | 1 ( 0.5) | | | | |
| 湿性咳嗽 | | 1 ( 0.8) | | | | | | |
| 肺うっ血 | | | 1 ( 1.0) | | | | | |
| 鼻漏 | | 1 ( 0.8) | | 1 ( 0.5) | | | | |
| 上気道の炎症 | | | 2 ( 2.0) | 2 ( 1.1) | | 1 ( 1.4) | | 1 ( 3.3) |
| 縦隔出血 | | | | | | | | 1 ( 3.3) |
| 口腔咽頭不快感 | | | | 1 ( 0.5) | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 21）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| | | 有害事象 | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | ONO-5163 | | | | | | |
| SOC | | 0 mg | 2.5 mg | 5 mg | 7.5 mg | 10 mg | 12.5 mg | 15 mg |
| PT | | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 口腔咽頭痛 | | 1 ( 0.8) | | 1 ( 0.5) | | | | |
| 皮膚および皮下組織障害 | | 14 ( 11.2) | 15 ( 15.2) | 19 ( 10.0) | | 8 ( 10.8) | | 6 ( 20.0) |
| 水疱 | | | | 1 ( 0.5) | | | | |
| 皮膚嚢腫 | | | | 1 ( 0.5) | | | | |
| アレルギー性皮膚炎 | | | | | | 1 ( 1.4) | | |
| 接触性皮膚炎 | | 5 ( 4.0) | 3 ( 3.0) | 5 ( 2.6) | | 1 ( 1.4) | | 1 ( 3.3) |
| 皮膚乾燥 | | | 1 ( 1.0) | 1 ( 0.5) | | | | 1 ( 3.3) |
| 湿疹 | | 1 ( 0.8) | 2 ( 2.0) | 3 ( 1.6) | | 2 ( 2.7) | | 3 ( 10.0) |
| 貨幣状湿疹 | | | | 1 ( 0.5) | | | | |
| 紅斑 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 皮下出血 | | | 1 ( 1.0) | | | 1 ( 1.4) | | |
| 嵌入爪 | | 1 ( 0.8) | | 1 ( 0.5) | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 22）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| ケロイド瘢痕 | | | 1 ( 1.0) | | | | | |
| そう痒症 | | 1 ( 0.8) | 2 ( 2.0) | 3 ( 1.6) | | 1 ( 1.4) | | 1 ( 3.3) |
| 発疹 | | 2 ( 1.6) | | 2 ( 1.1) | | | | 1 ( 3.3) |
| 脂漏性皮膚炎 | | 1 ( 0.8) | | | | | | |
| 皮膚剥脱 | | 3 ( 2.4) | 3 ( 3.0) | 4 ( 2.1) | | 1 ( 1.4) | | |
| 皮膚潰瘍 | | | | | | 1 ( 1.4) | | |
| 蕁麻疹 | | 1 ( 0.8) | | | | | | |
| 乾皮症 | | | 1 ( 1.0) | | | | | |
| 皮脂欠乏症 | | | 1 ( 1.0) | | | | | |
| 血管障害 | | 5 ( 4.0) | 1 ( 1.0) | 5 ( 2.6) | 1 ( 3.8) | 4 ( 5.4) | | 3 ( 10.0) |
| 大動脈解離 | | | 1 ( 1.0) | | | | | |
| 血腫 | | 1 ( 0.8) | | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

**表 2.7.4.7-15　有害事象の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 23）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 有害事象<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 高血圧 | | | | 2 ( 1.1) | 1 ( 3.8) | 2 ( 2.7) | | 2 ( 6.7) |
| 起立性低血圧 | | 1 ( 0.8) | | | | 1 ( 1.4) | | |
| 末梢冷感 | | | | 1 ( 0.5) | | | | |
| 血管痛 | | 1 ( 0.8) | | 1 ( 0.5) | | | | |
| 動脈瘤破裂 | | 1 ( 0.8) | | | | | | |
| 内出血 | | 1 ( 0.8) | | 1 ( 0.5) | | 1 ( 1.4) | | 1 ( 3.3) |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．

出典［総括報告書 5.3.5.2-1（ONO-5163-[redacted] 試験）表 14.3.1-14］

**表 2.7.4.7-16　副作用の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC<br>PT | | 副作用<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 全体 | | 4 ( 3.2) | 12 ( 12.1) | 32 ( 16.8) | 1 ( 3.8) | 16 ( 21.6) | | 5 ( 16.7) |
| 心臓障害 | | | 1 ( 1.0) | 1 ( 0.5) | | | | 1 ( 3.3) |
| 心筋梗塞 | | | | | | | | 1 ( 3.3) |
| 上室性期外収縮 | | | | 1 ( 0.5) | | | | |
| 頻脈性不整脈 | | | 1 ( 1.0) | | | | | |
| 眼障害 | | | | 1 ( 0.5) | | | | |
| 眼瞼炎 | | | | 1 ( 0.5) | | | | |
| 胃腸障害 | | | 2 ( 2.0) | 5 ( 2.6) | | 3 ( 4.1) | | 1 ( 3.3) |
| 腹部不快感 | | | | 1 ( 0.5) | | | | |
| 便秘 | | | | 1 ( 0.5) | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．
出典［総括報告書 5.3.5.2-1（ONO-5163-[redacted] 試験）表 14.3.1-15］

**表 2.7.4.7-16　副作用の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 1）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC / PT | | 副作用 ONO-5163 0 mg n (%) | 2.5 mg n (%) | 5 mg n (%) | 7.5 mg n (%) | 10 mg n (%) | 12.5 mg n (%) | 15 mg n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 下痢 | | | 1 ( 1.0) | 1 ( 0.5) | | 1 ( 1.4) | | |
| 胃食道逆流性疾患 | | | | | | 1 ( 1.4) | | |
| 悪心 | | | | 1 ( 0.5) | | | | |
| 口内炎 | | | 1 ( 1.0) | | | | | |
| 嘔吐 | | | 1 ( 1.0) | | | | | 1 ( 3.3) |
| 心窩部不快感 | | | | 1 ( 0.5) | | | | |
| 痔出血 | | | | 1 ( 0.5) | | | | |
| 口の感覚鈍麻 | | | | | | 1 ( 1.4) | | |
| 軟便 | | | | 1 ( 0.5) | | | | |
| 一般・全身障害および投与部位の状態 | | 1 ( 0.8) | | | | 1 ( 1.4) | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

**表 2.7.4.7-16　副作用の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 2）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC / PT | | 副作用 ONO-5163 0 mg n (%) | 2.5 mg n (%) | 5 mg n (%) | 7.5 mg n (%) | 10 mg n (%) | 12.5 mg n (%) | 15 mg n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 倦怠感 | | | | | | 1 ( 1.4) | | |
| 突然死 | | 1 ( 0.8) | | | | | | |
| 感染症および寄生虫症 | | | | | | 1 ( 1.4) | | |
| 単純ヘルペス | | | | | | 1 ( 1.4) | | |
| 臨床検査 | | 1 ( 0.8) | 7 ( 7.1) | 23 ( 12.1) | 1 ( 3.8) | 11 ( 14.9) | | 3 ( 10.0) |
| 血中カルシウム減少 | | | 2 ( 2.0) | 6 ( 3.2) | 1 ( 3.8) | 9 ( 12.2) | | 3 ( 10.0) |
| 心電図ＳＴ部分下降 | | | | 1 ( 0.5) | | | | |
| 尿量減少 | | | 1 ( 1.0) | 2 ( 1.1) | | | | |
| 補正カルシウム減少 | | 1 ( 0.8) | 4 ( 4.0) | 15 ( 7.9) | | 2 ( 2.7) | | |
| 代謝および栄養障害 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

**表 2.7.4.7-16　副作用の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 3）**
（治験薬投与開始 365 日目の評価時）
**解析対象集団：SAF**

| SOC<br>PT | | 副作用<br>ONO-5163<br>0 mg<br>n (%) | <br><br>2.5 mg<br>n (%) | <br><br>5 mg<br>n (%) | <br><br>7.5 mg<br>n (%) | <br><br>10 mg<br>n (%) | <br><br>12.5 mg<br>n (%) | <br><br>15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 低カルシウム血症 | | | 1 ( 1.0) | 1 ( 0.5) | | | | |
| 筋骨格系および結合組織障害 | | | | 1 ( 0.5) | | 1 ( 1.4) | | |
| 筋痙縮 | | | | 1 ( 0.5) | | | | |
| 脊椎すべり症 | | | | | | 1 ( 1.4) | | |
| 神経系障害 | | 1 ( 0.8) | | 2 ( 1.1) | | 2 ( 2.7) | | |
| 手根管症候群 | | 1 ( 0.8) | | | | | | |
| 味覚異常 | | | | 1 ( 0.5) | | 1 ( 1.4) | | |
| ジスキネジア | | | | | | 1 ( 1.4) | | |
| 視神経炎 | | | | 1 ( 0.5) | | | | |
| 呼吸器、胸郭および縦隔障害 | | | | | | 1 ( 1.4) | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

**表 2.7.4.7-16　副作用の発現時投与量別発現頻度（ONO-5163-[redacted] 試験）（続き 4）**
**（治験薬投与開始 365 日目の評価時）**
**解析対象集団：SAF**

| SOC<br>PT | | 副作用<br>ONO-5163<br>0 mg<br>n (%) | 2.5 mg<br>n (%) | 5 mg<br>n (%) | 7.5 mg<br>n (%) | 10 mg<br>n (%) | 12.5 mg<br>n (%) | 15 mg<br>n (%) |
|---|---|---|---|---|---|---|---|---|
| | N | 125 | 99 | 190 | 26 | 74 | 7 | 30 |
| 鼻出血 | | | | | | 1 ( 1.4) | | |
| 皮膚および皮下組織障害 | | 1 ( 0.8) | | | | | | |
| 発疹 | | 1 ( 0.8) | | | | | | |
| 血管障害 | | | 1 ( 1.0) | | | | | |
| 大動脈解離 | | | 1 ( 1.0) | | | | | |

医師から報告された有害事象名は，MedDRA ver 18.0Jを用いて読み替えた．
同一被験者で同じ有害事象が複数回発現し，投与量が異なる場合，投与量別に1回の発現とした．
因果関係の判断基準：因果関係は，「関連なし」，「関連ないともいえない」，「多分関連あり」，「明らかに関連あり」の4段階で評価され，「関連ないともいえない」，「多分関連あり」又は「明らかに関連あり」と判定された場合，若しくは因果関係が不明と判定された場合に，副作用として集計した．

出典［総括報告書 5.3.5.2-1（ONO-5163-[redacted] 試験）表 14.3.1-15］

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 血液およびリンパ系障害 | | | | | | | | |
| 貧血 | 15/355.2 ( 4.2) | 3.9 | 15/360.7 ( 4.2) | 3.9 | 8/105.1 ( 7.6) | 6.5 | 38/821.0 ( 4.6) | 4.3 |
| 心臓障害 | | | | | | | | |
| 心房細動 | 16/354.7 ( 4.5) | 4.2 | 8/366.9 ( 2.2) | 2.1 | 0/109.8 ( 0.0) | 0.0 | 24/831.4 ( 2.9) | 2.7 |
| うっ血性心不全 | 10/356.7 ( 2.8) | 2.6 | 9/364.4 ( 2.5) | 2.3 | 3/108.1 ( 2.8) | 2.4 | 22/829.2 ( 2.7) | 2.5 |
| 胃腸障害 | | | | | | | | |
| 腹痛 | 24/349.7 ( 6.9) | 6.3 | 14/360.3 ( 3.9) | 3.6 | 4/107.8 ( 3.7) | 3.3 | 42/817.8 ( 5.1) | 4.7 |
| 便秘 | 15/354.4 ( 4.2) | 3.9 | 12/363.4 ( 3.3) | 3.1 | 4/108.4 ( 3.7) | 3.3 | 31/826.1 ( 3.8) | 3.5 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
n＝有害事象発現例数.
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

出典［総括報告書 5.3.5.2-4（20120231 試験）Table 14-6.4 及び Table 14-6.8 改変］

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 1）**

**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 下痢 | 42/336.5 ( 12.5) | 11.0 | 46/342.4 ( 13.4) | 12.0 | 8/105.8 ( 7.6) | 6.5 | 96/784.6 ( 12.2) | 10.8 |
| 悪心 | 44/334.7 ( 13.1) | 11.5 | 27/354.6 ( 7.6) | 7.0 | 14/101.7 ( 13.8) | 11.4 | 85/791.0 ( 10.7) | 9.6 |
| 嘔吐 | 43/337.4 ( 12.7) | 11.2 | 38/350.5 ( 10.8) | 9.9 | 12/102.9 ( 11.7) | 9.8 | 93/790.8 ( 11.8) | 10.4 |
| 一般・全身障害および投与部位の状態 | | | | | | | | |
| 無力症 | 16/354.7 ( 4.5) | 4.2 | 11/363.4 ( 3.0) | 2.9 | 3/107.9 ( 2.8) | 2.4 | 30/826.0 ( 3.6) | 3.4 |
| 胸痛 | 11/357.2 ( 3.1) | 2.9 | 11/363.8 ( 3.0) | 2.9 | 4/107.6 ( 3.7) | 3.3 | 26/828.6 ( 3.1) | 2.9 |
| 末梢性浮腫 | 13/357.1 ( 3.6) | 3.4 | 4/368.7 ( 1.1) | 1.0 | 4/106.4 ( 3.8) | 3.3 | 21/832.3 ( 2.5) | 2.4 |
| 発熱 | 14/356.2 ( 3.9) | 3.7 | 16/362.2 ( 4.4) | 4.2 | 5/106.5 ( 4.7) | 4.1 | 35/824.9 ( 4.2) | 3.9 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 2）**

**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 非心臓性胸痛 | 13/354.8 ( 3.7) | 3.4 | 9/365.1 ( 2.5) | 2.3 | 3/107.7 ( 2.8) | 2.4 | 25/827.6 ( 3.0) | 2.8 |
| 感染症および寄生虫症 | | | | | | | | |
| 気管支炎 | 20/352.5 ( 5.7) | 5.2 | 6/365.6 ( 1.6) | 1.6 | 2/108.9 ( 1.8) | 1.6 | 28/827.0 ( 3.4) | 3.1 |
| 蜂巣炎 | 10/357.8 ( 2.8) | 2.6 | 11/365.4 ( 3.0) | 2.9 | 3/107.8 ( 2.8) | 2.4 | 24/830.9 ( 2.9) | 2.7 |
| 胃腸炎 | 10/357.0 ( 2.8) | 2.6 | 3/368.4 ( 0.8) | 0.8 | 5/106.1 ( 4.7) | 4.1 | 18/831.5 ( 2.2) | 2.0 |
| 鼻咽頭炎 | 19/352.9 ( 5.4) | 5.0 | 21/359.5 ( 5.8) | 5.5 | 3/107.8 ( 2.8) | 2.4 | 43/820.3 ( 5.2) | 4.8 |
| 肺炎 | 13/356.7 ( 3.6) | 3.4 | 7/367.4 ( 1.9) | 1.8 | 6/108.1 ( 5.6) | 4.9 | 26/832.1 ( 3.1) | 2.9 |
| 上気道感染 | 21/354.0 ( 5.9) | 5.5 | 14/362.0 ( 3.9) | 3.6 | 21/97.7 ( 21.5) | 17.1 | 56/813.8 ( 6.9) | 6.3 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 3）**

**解析対象集団：SAF**

| SOC | | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| | N | 383 | | 384 | | 123 | | 890 | |
| 尿路感染 | | 7/359.6 ( 1.9) | 1.8 | 13/360.5 ( 3.6) | 3.4 | 2/108.3 ( 1.8) | 1.6 | 22/828.4 ( 2.7) | 2.5 |
| 傷害、中毒および処置合併症 | | | | | | | | | |
| 動静脈瘻血栓症 | | 10/357.0 ( 2.8) | 2.6 | 15/360.9 ( 4.2) | 3.9 | 2/108.3 ( 1.8) | 1.6 | 27/826.2 ( 3.3) | 3.0 |
| 転倒 | | 22/351.5 ( 6.3) | 5.7 | 16/363.0 ( 4.4) | 4.2 | 7/105.8 ( 6.6) | 5.7 | 45/820.4 ( 5.5) | 5.1 |
| 裂傷 | | 8/358.3 ( 2.2) | 2.1 | 5/368.1 ( 1.4) | 1.3 | 5/107.0 ( 4.7) | 4.1 | 18/833.4 ( 2.2) | 2.0 |
| 挫傷 | | 12/355.5 ( 3.4) | 3.1 | 11/364.4 ( 3.0) | 2.9 | 2/108.0 ( 1.9) | 1.6 | 25/827.9 ( 3.0) | 2.8 |
| 動静脈瘻部位合併症 | | 27/345.2 ( 7.8) | 7.0 | 33/351.0 ( 9.4) | 8.6 | 8/103.6 ( 7.7) | 6.5 | 68/799.8 ( 8.5) | 7.6 |
| 動静脈瘻部位出血 | | 8/360.7 ( 2.2) | 2.1 | 13/362.1 ( 3.6) | 3.4 | 2/108.8 ( 1.8) | 1.6 | 23/831.7 ( 2.8) | 2.6 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 4）**

**解析対象集団：SAF**

| SOC / PT | | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| | N | 383 | | 384 | | 123 | | 890 | |
| 処置による低血圧 | | 17/352.5 ( 4.8) | 4.4 | 9/365.1 ( 2.5) | 2.3 | 8/103.9 ( 7.7) | 6.5 | 34/821.5 ( 4.1) | 3.8 |
| 移植血管合併症 | | 8/357.3 ( 2.2) | 2.1 | 10/363.0 ( 2.8) | 2.6 | 4/107.0 ( 3.7) | 3.3 | 22/827.4 ( 2.7) | 2.5 |
| 血管グラフト血栓症 | | 7/357.9 ( 2.0) | 1.8 | 7/367.8 ( 1.9) | 1.8 | 4/108.1 ( 3.7) | 3.3 | 18/833.8 ( 2.2) | 2.0 |
| 臨床検査 | | | | | | | | | |
| 血中カルシウム減少 | | 226/187.0 (120.8) | 59.0 | 129/278.5 ( 46.3) | 33.6 | 30/91.7 ( 32.7) | 24.4 | 385/557.3 ( 69.1) | 43.3 |
| 血中カルシウム増加 | | 10/359.0 ( 2.8) | 2.6 | 11/362.6 ( 3.0) | 2.9 | 4/107.0 ( 3.7) | 3.3 | 25/828.6 ( 3.0) | 2.8 |
| 代謝および栄養障害 | | | | | | | | | |
| 水分過負荷 | | 18/351.7 ( 5.1) | 4.7 | 15/361.0 ( 4.2) | 3.9 | 4/107.1 ( 3.7) | 3.3 | 37/819.8 ( 4.5) | 4.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 5）**

**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 高カリウム血症 | 24/350.6 ( 6.8) | 6.3 | 22/357.8 ( 6.1) | 5.7 | 10/104.7 ( 9.6) | 8.1 | 56/813.1 ( 6.9) | 6.3 |
| 高リン酸塩血症 | 14/352.3 ( 4.0) | 3.7 | 15/359.4 ( 4.2) | 3.9 | 6/107.0 ( 5.6) | 4.9 | 35/818.7 ( 4.3) | 3.9 |
| 低カルシウム血症 | 19/352.1 ( 5.4) | 5.0 | 14/362.0 ( 3.9) | 3.6 | 0/109.8 ( 0.0) | 0.0 | 33/824.0 ( 4.0) | 3.7 |
| 低血糖症 | 11/358.0 ( 3.1) | 2.9 | 11/363.1 ( 3.0) | 2.9 | 4/108.4 ( 3.7) | 3.3 | 26/829.5 ( 3.1) | 2.9 |
| 食欲減退 | 10/358.4 ( 2.8) | 2.6 | 8/365.5 ( 2.2) | 2.1 | 2/109.0 ( 1.8) | 1.6 | 20/833.0 ( 2.4) | 2.2 |
| 筋骨格系および結合組織障害 | | | | | | | | |
| 関節痛 | 19/349.8 ( 5.4) | 5.0 | 19/357.7 ( 5.3) | 4.9 | 11/103.8 ( 10.6) | 8.9 | 49/811.2 ( 6.0) | 5.5 |
| 背部痛 | 26/348.9 ( 7.5) | 6.8 | 20/358.0 ( 5.6) | 5.2 | 4/108.4 ( 3.7) | 3.3 | 50/815.2 ( 6.1) | 5.6 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 6）**

**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 筋痙縮 | 36/342.9 ( 10.5) | 9.4 | 33/349.3 ( 9.4) | 8.6 | 10/103.9 ( 9.6) | 8.1 | 79/796.1 ( 9.9) | 8.9 |
| 筋力低下 | 10/356.9 ( 2.8) | 2.6 | 5/367.2 ( 1.4) | 1.3 | 3/107.4 ( 2.8) | 2.4 | 18/831.4 ( 2.2) | 2.0 |
| 筋骨格痛 | 9/359.1 ( 2.5) | 2.3 | 14/364.8 ( 3.8) | 3.6 | 1/109.3 ( 0.9) | 0.8 | 24/833.1 ( 2.9) | 2.7 |
| 四肢痛 | 17/352.4 ( 4.8) | 4.4 | 24/353.6 ( 6.8) | 6.3 | 6/105.2 ( 5.7) | 4.9 | 47/811.3 ( 5.8) | 5.3 |
| 神経系障害 | | | | | | | | |
| 浮動性めまい | 14/353.5 ( 4.0) | 3.7 | 13/363.5 ( 3.6) | 3.4 | 3/108.4 ( 2.8) | 2.4 | 30/825.4 ( 3.6) | 3.4 |
| 頭痛 | 26/348.5 ( 7.5) | 6.8 | 25/356.0 ( 7.0) | 6.5 | 2/109.5 ( 1.8) | 1.6 | 53/814.0 ( 6.5) | 6.0 |
| 錯感覚 | 11/355.0 ( 3.1) | 2.9 | 8/365.5 ( 2.2) | 2.1 | 2/108.2 ( 1.8) | 1.6 | 21/828.7 ( 2.5) | 2.4 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 7）**

**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 失神 | 9/357.2 ( 2.5) | 2.3 | 6/367.7 ( 1.6) | 1.6 | 3/108.7 ( 2.8) | 2.4 | 18/833.6 ( 2.2) | 2.0 |
| 精神障害 | | | | | | | | |
| 不安 | 8/359.4 ( 2.2) | 2.1 | 10/364.6 ( 2.7) | 2.6 | 7/106.8 ( 6.6) | 5.7 | 25/830.8 ( 3.0) | 2.8 |
| 不眠症 | 9/358.5 ( 2.5) | 2.3 | 9/364.1 ( 2.5) | 2.3 | 3/108.7 ( 2.8) | 2.4 | 21/831.3 ( 2.5) | 2.4 |
| 呼吸器、胸郭および縦隔障害 | | | | | | | | |
| 咳嗽 | 22/350.1 ( 6.3) | 5.7 | 20/359.1 ( 5.6) | 5.2 | 13/100.7 ( 12.9) | 10.6 | 55/809.9 ( 6.8) | 6.2 |
| 呼吸困難 | 24/352.7 ( 6.8) | 6.3 | 20/359.3 ( 5.6) | 5.2 | 6/104.4 ( 5.7) | 4.9 | 50/816.5 ( 6.1) | 5.6 |
| 鼻出血 | 7/358.3 ( 2.0) | 1.8 | 9/364.8 ( 2.5) | 2.3 | 2/108.9 ( 1.8) | 1.6 | 18/832.0 ( 2.2) | 2.0 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 8）**

**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 皮膚および皮下組織障害 | | | | | | | | |
| そう痒症 | 10/357.1 ( 2.8) | 2.6 | 9/364.4 ( 2.5) | 2.3 | 2/107.8 ( 1.9) | 1.6 | 21/829.3 ( 2.5) | 2.4 |
| 皮膚潰瘍 | 8/357.5 ( 2.2) | 2.1 | 11/363.7 ( 3.0) | 2.9 | 1/109.0 ( 0.9) | 0.8 | 20/830.2 ( 2.4) | 2.2 |
| 血管障害 | | | | | | | | |
| 高血圧 | 34/344.1 ( 9.9) | 8.9 | 21/357.2 ( 5.9) | 5.5 | 10/103.3 ( 9.7) | 8.1 | 65/804.6 ( 8.1) | 7.3 |
| 低血圧 | 40/341.7 ( 11.7) | 10.4 | 28/354.9 ( 7.9) | 7.3 | 7/106.3 ( 6.6) | 5.7 | 75/802.9 ( 9.3) | 8.4 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
n = 有害事象発現例数.
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 9）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 血液およびリンパ系障害 | | | | | | | | |
| 貧血 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.2 ( 0.9) | 0.8 | 1/842.7 ( 0.1) | 0.1 |
| 心臓障害 | | | | | | | | |
| 心房細動 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| うっ血性心不全 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 胃腸障害 | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した.
n＝治験薬との因果関係が否定できない有害事象発現例数.
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率＝100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 10）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 腹痛 | 3/361.1 ( 0.8) | 0.8 | 1/369.5 ( 0.3) | 0.3 | 1/109.5 ( 0.9) | 0.8 | 5/840.0 ( 0.6) | 0.6 |
| 便秘 | 0/363.1 ( 0.0) | 0.0 | 1/369.5 ( 0.3) | 0.3 | 1/109.5 ( 0.9) | 0.8 | 2/842.1 ( 0.2) | 0.2 |
| 下痢 | 3/360.9 ( 0.8) | 0.8 | 4/367.4 ( 1.1) | 1.0 | 0/109.8 ( 0.0) | 0.0 | 7/838.2 ( 0.8) | 0.8 |
| 悪心 | 7/357.5 ( 2.0) | 1.8 | 7/366.6 ( 1.9) | 1.8 | 1/109.5 ( 0.9) | 0.8 | 15/833.7 ( 1.8) | 1.7 |
| 嘔吐 | 4/360.6 ( 1.1) | 1.0 | 2/369.7 ( 0.5) | 0.5 | 1/109.5 ( 0.9) | 0.8 | 7/839.9 ( 0.8) | 0.8 |
| 一般・全身障害および投与部位の状態 | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n = 治験薬との因果関係が否定できない有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 11）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 無力症 | 1/363.0 ( 0.3) | 0.3 | 1/369.7 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.6 ( 0.2) | 0.2 |
| 胸痛 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 末梢性浮腫 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 発熱 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 非心臓性胸痛 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 感染症および寄生虫症 | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 12）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 気管支炎 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 蜂巣炎 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 胃腸炎 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 鼻咽頭炎 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 肺炎 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 上気道感染 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 13）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 尿路感染 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 傷害、中毒および処置合併症 | | | | | | | | |
| 動静脈瘻血栓症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 転倒 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 裂傷 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 挫傷 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 14）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 動静脈瘻部位合併症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 動静脈瘻部位出血 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 処置による低血圧 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 移植血管合併症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 血管グラフト血栓症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 臨床検査 | | | | | | | | |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 15）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 血中カルシウム減少 | 196/206.7 ( 94.8) | 51.2 | 111/289.7 ( 38.3) | 28.9 | 23/96.4 ( 23.9) | 18.7 | 330/592.8 ( 55.7) | 37.1 |
| 血中カルシウム増加 | 2/362.2 ( 0.6) | 0.5 | 3/367.6 ( 0.8) | 0.8 | 1/108.8 ( 0.9) | 0.8 | 6/838.6 ( 0.7) | 0.7 |
| 代謝および栄養障害 | | | | | | | | |
| 水分過負荷 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 高カリウム血症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 高リン酸塩血症 | 3/360.5 ( 0.8) | 0.8 | 0/370.4 ( 0.0) | 0.0 | 2/108.7 ( 1.8) | 1.6 | 5/839.6 ( 0.6) | 0.6 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 16）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 低カルシウム血症 | 19/352.1 ( 5.4) | 5.0 | 12/363.2 ( 3.3) | 3.1 | 0/109.8 ( 0.0) | 0.0 | 31/825.2 ( 3.8) | 3.5 |
| 低血糖症 | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 食欲減退 | 2/361.3 ( 0.6) | 0.5 | 1/369.5 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 3/840.6 ( 0.4) | 0.3 |
| 筋骨格系および結合組織障害 | | | | | | | | |
| 関節痛 | 1/362.1 ( 0.3) | 0.3 | 1/369.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/841.2 ( 0.2) | 0.2 |
| 背部痛 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 17）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 筋痙縮 | 13/355.0 ( 3.7) | 3.4 | 10/364.8 ( 2.7) | 2.6 | 1/109.7 ( 0.9) | 0.8 | 24/829.5 ( 2.9) | 2.7 |
| 筋力低下 | 2/361.9 ( 0.6) | 0.5 | 2/369.4 ( 0.5) | 0.5 | 1/108.8 ( 0.9) | 0.8 | 5/840.1 ( 0.6) | 0.6 |
| 筋骨格痛 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 四肢痛 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 神経系障害 | | | | | | | | |
| 浮動性めまい | 0/363.1 ( 0.0) | 0.0 | 2/370.1 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 2/843.0 ( 0.2) | 0.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 18）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 頭痛 | 1/362.5 ( 0.3) | 0.3 | 1/369.7 ( 0.3) | 0.3 | 1/109.7 ( 0.9) | 0.8 | 3/842.0 ( 0.4) | 0.3 |
| 錯感覚 | 8/357.3 ( 2.2) | 2.1 | 5/367.0 ( 1.4) | 1.3 | 0/109.8 ( 0.0) | 0.0 | 13/834.2 ( 1.6) | 1.5 |
| 失神 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 精神障害 | | | | | | | | |
| 不安 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 不眠症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率＝100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 19）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 呼吸器、胸郭および縦隔障害 | | | | | | | | |
| 咳嗽 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 呼吸困難 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 鼻出血 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 皮膚および皮下組織障害 | | | | | | | | |
| そう痒症 | 1/362.7 ( 0.3) | 0.3 | 1/369.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/841.9 ( 0.2) | 0.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n = 治験薬との因果関係が否定できない有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率 = 100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

**表 2.7.4.7-17　発現率が 2%以上の有害事象及び治験薬との因果関係が否定できない有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 20）**

**解析対象集団：SAF**

| | 治験薬との因果関係が否定できない有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 皮膚潰瘍 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 0/843.3 ( 0.0) | 0.0 |
| 血管障害 | | | | | | | | |
| 高血圧 | 1/363.0 ( 0.3) | 0.3 | 2/369.7 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 3/842.5 ( 0.4) | 0.3 |
| 低血圧 | 0/363.1 ( 0.0) | 0.0 | 2/369.3 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 2/842.3 ( 0.2) | 0.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
因果関係の判断基準：因果関係は，「possibly related: yes」，「possibly related: no」の2段階で評価され，「possibly related: yes」と判定された場合に，治験薬との因果関係が否定できない有害事象として集計した．
n＝治験薬との因果関係が否定できない有害事象発現例数．
e＝曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による治験薬との因果関係が否定できない有害事象発現率＝100* n/ e.
**%=治験薬との因果関係が否定できない有害事象発現率 =100*n/N.

SAF = Safety Analysis Set
出典［総括報告書 5.3.5.2-4（20120231 試験）Table 14-6.4 及び Table 14-6.8 改変］

**表 2.7.4.7-18　死亡例の一覧表（20120231 試験）**

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22911003002 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | TINEA INFECTION BOTH GROIN [白癬感染] | 20[redacted]-12-15 * | -123 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-15 * | - |
| AMG 416 | 20120229-22911003002 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | OSTEOMYLITIS LEFT 5TH TOE [骨髄炎] | 20[redacted]-02-05 * | -71 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-07-31 * | - |
| AMG 416 | 20120229-22911003002 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | R LOWER LIMB CELLULITIS [蜂巣炎] | 20[redacted]-09-16T09:00 * | 153 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-11-21 * | - |
| AMG 416 | 20120229-22911003002 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CARDIAC ARREST [心停止] | 20[redacted]-11-21 * | 219 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | EMERGENCY ROOM VISIT, OTHER | NOT RELATED | 20[redacted]-11-21 * | - |
| AMG 416 | 20120229-22911003002 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PULMONARY EMBOLISM [肺塞栓症] | 20[redacted]-11-21 ** | 219 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-11-21 ### | - |
| AMG 416 | 20120229-22912003001 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | INSOMNIA [不眠症] | 20[redacted]-01-22 ** | -56 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-03-15 ** | - |
| AMG 416 | 20120229-22912003001 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | LOW SERUM CALCIUM [血中カルシウム減少] | 20[redacted]-04-30 | 43 | MODERATE | NO | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | RELATED | 20[redacted]-05-28 | - |

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する
＃＃＃　：「3年後」を意味する

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time ** | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time ** | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-2291200 3001 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | PERIPHERAL ARTERIAL DISEASE SINCE 5/20[redacted]; WORSENING SINCE 10/20[redacted]*; SCHEDULED REINTERVENTION [末梢動脈閉塞性疾患] | 20[redacted]-05-20 ** | 63 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-05-22 ** | - |
| AMG 416 | 20120229-2291200 3001 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | PNEUMONIA [肺炎] | 20[redacted]-10-06T12:00 ** | 202 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-10-18T15:00 ** | - |
| AMG 416 | 20120229-2291200 3001 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | PNEUMONIA [肺炎] | 20[redacted]-10-27T19:00 ** | 223 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-11-07T15:00 ** | - |
| AMG 416 | 20120229-2291200 3001 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | PAIN IN THE LEFT LEG [四肢痛] | 20[redacted]-12-15T12:35 ### | 272 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-15T14:35 ### | - |
| AMG 416 | 20120229-2291200 3001 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | WORSENING OF PERIPHERAL ARTERIAL DISEASE [末梢動脈閉塞性疾患] | 20[redacted]-01-09T09:00 | 297 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-02-06 | - |

年齢以外のマスキングにおいて，
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＊　　：「翌年」を意味する
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＃＃＃　：「3年後」を意味する

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time ### | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time ### | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-2291200 3001 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | CLOSTRIDIUM DIFFICILE COLITIS [クロストリジウム・ディフィシレ大腸炎] | 20[redacted]-02-20T15:00 ### | 339 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-03-04T15:00 ### | - |
| AMG 416 | 20120229-2291200 3001 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | INFLUENZA B [インフルエンザ] | 20[redacted]-03-11T21:50 ### | 358 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-15 ### | - |
| AMG 416 | 20120229-2291200 3001 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | ACUTE CARDIAL EVENT [心障害] | 20[redacted]-03-15T17:23 | 362 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | OTHER | NOT RELATED | 20[redacted]-03-15 ** | - |
| AMG 416 | 20120229-2292100 3002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | WORSENING OF CHRONIC HYPOTENSION [低血圧] | 20[redacted]-12-11 * | -112 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-01 ** | - |
| AMG 416 | 20120229-2292100 3002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | DEPRESION [うつ病] | 20[redacted]-01-06 * | -86 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-01 ** | - |
| AMG 416 | 20120229-2292100 3002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SHORT OF BRETH [呼吸困難] | 20[redacted]-02-05 * | -56 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-01 * | - |
| AMG 416 | 20120229-2292100 3002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SCAPULA FRACTURE [肩甲骨骨折] | 20[redacted]-03-27 * | -6 | MODERATE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-06-18 * | - |
| AMG 416 | 20120229-2292100 3002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | FRACTURE OF RIBBS [肋骨骨折] | 20[redacted]-04-09 | 8 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-06-18 | - |

年齢以外のマスキングにおいて，
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＃＃＃　：「3年後」を意味する

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time ** | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-2292100 3002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PROGRESSION OF ANEMIA [貧血] | 20[redacted]-04-28T13:00 ** | 27 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-01 ** | - |
| AMG 416 | 20120229-2292100 3002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LEFT FEMUR FRACTURE [大腿骨骨折] | 20[redacted]-01-18 ** | 292 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-01 ** | - |
| AMG 416 | 20120229-2292100 3002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SEPSIS [敗血症] | 20[redacted]-01-30 ** | 304 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-01T00:15 ** | - |
| AMG 416 | 20120229-2292100 3002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HYPERCALCEMIA [高カルシウム血症] | 20[redacted]-03-11T14:05 | 344 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-01T00:15 | - |
| AMG 416 | 20120229-2292100 5001 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PAIN OF TAIL BONE [尾骨痛] | 20[redacted]-04-02 | 85 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-11-03 | - |
| AMG 416 | 20120229-2292100 5001 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞] | 20[redacted]-11-05 | 302 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-05 * | - |
| AMG 416 | 20120229-2292100 5003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PYROSIS [消化不良] | 20[redacted]-09-30 | -100 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-05-21 | - |

年齢以外のマスキングにおいて,
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＊＊　：「翌々年」を意味する

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-2292100 5003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | VERTIGO SUBJECTIVE [回転性めまい] | 20[redacted]-10-20 * | -80 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-21 * | - |
| AMG 416 | 20120229-2292100 5003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | FEVER [発熱] | 20[redacted]-01-23 * | 16 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-21 * | - |
| AMG 416 | 20120229-2292100 5003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | DISORIENTATION [失見当識] | 20[redacted]-01-24 * | 17 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-24T12:56 * | - |
| AMG 416 | 20120229-2292100 5003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | UROSEPSIS [尿路性敗血症] | 20[redacted]-01-26 * | 19 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-27 * | - |
| AMG 416 | 20120229-2292100 5003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | RELAPS UROSEPSIS [尿路性敗血症] | 20[redacted]-04-09 * | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-21 * | - |
| AMG 416 | 20120229-2292100 5003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | BLEEDING [出血] | 20[redacted]-05-20 * | 133 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-21 * | - |
| AMG 416 | 20120229-2292100 5003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | RELAPSE UROSEPSIS [尿路性敗血症] | 20[redacted]-05-20 * | 133 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-20 * | - |

年齢以外のマスキングにおいて，
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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22921005003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | AC.HEART FAILURE [急性心不全] | 20[redacted]-05-21 | 134 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-21T00:02 * | - |
| AMG 416 | 20120229-22925007001 | 8[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PAROXYSMAL ATRIAL FIBRILLATION [心房細動] | 20[redacted]-07-10 * | -210 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-07-24 * | - |
| AMG 416 | 20120229-22925007001 | 8[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SHOULDER PAIN [筋骨格痛] | 20[redacted]-05 * | - | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-05 * | - |
| AMG 416 | 20120229-22925007001 | 8[redacted] | M | WHITE | NOT HISPANIC OR LATINO | WORSENING OF UNSTABLE ANGINA [不安定狭心症] | 20[redacted]-07-22 * | 168 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-07-24 * | - |
| AMG 416 | 20120229-22925007001 | 8[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CARDIOGENIC SHOCK [心原性ショック] | 20[redacted]-07-24 | 170 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-07-24 * | - |
| AMG 416 | 20120229-22926003003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LOW SERUM CALCIUM [血中カルシウム減少] | 20[redacted]-11-28 | -105 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-11 * | - |
| AMG 416 | 20120229-22926003003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ANXIETY STATE [不安] | 20[redacted]-12-31 | -72 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-08-05 | - |

年齢以外のマスキングにおいて,
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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22926003003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | COUGH [咳嗽] | 20[redacted]-03-04 * | -9 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-03-24 * | - |
| AMG 416 | 20120229-22926003003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PATELLA FRACTURE LEFT [膝蓋骨骨折] | 20[redacted]-06-07 * | 87 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER | NOT RELATED | 20[redacted]-08-05 * | - |
| AMG 416 | 20120229-22926003003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PAIN [疼痛] | 20[redacted]-06-10 * | 90 | SEVERE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-08-05 * | - |
| AMG 416 | 20120229-22926003003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | INFECTION SURGICAL WOUND AFTER PATELLA FRACTURE SURGERY [術後創感染] | 20[redacted]-06-25 * | 105 | LIFE THREATENING | YES | Is Life Threatening | DRUG WITHDRAWN | MEDICATION TAKEN, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-08-05 * | - |
| AMG 416 | 20120229-22926003003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SEPSIS AFTER AMPUTATION WOUND LEFT LEG [膿創] | 20[redacted]-08-05 | 146 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | NO ACTION TAKEN | NOT RELATED | 20[redacted]-08-05 | - |
| AMG 416 | 20120229-22926005008 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PERIPHERALARTERIALOCCLUSIVE DISEASE AGGRAVITED LEFT LEG [末梢動脈閉塞性疾患] | 20[redacted]-02-05 | -104 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-12 | - |
| AMG 416 | 20120229-22926005008 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | DYSNEA [呼吸困難] | 20[redacted]-06-23 | 35 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-06-23 | - |
| AMG 416 | 20120229-22926005008 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LOW SERUM CALCIUM [血中カルシウム減少] | 20[redacted]-07-08 | 50 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | RELATED | 20[redacted]-11-12 | - |

年齢以外のマスキングにおいて，
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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-2292600 5008 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | WORSENING OF CORONARY HEART DISEASE [冠動脈疾患] | 20[redacted]-07-30 | 72 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-01 | - |
| AMG 416 | 20120229-2292600 5008 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | WORSENING OF RIVA STENOSIS [冠動脈狭窄] | 20[redacted]-09-15 | 119 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-09-19 | - |
| AMG 416 | 20120229-2292600 5008 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | WORSENING OF PERIPHERAL VASCULAR DISEASE RIGHT LEG [末梢血管障害] | 20[redacted]-09-20 | 124 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-10 | - |
| AMG 416 | 20120229-2292600 5008 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SKIN NECROSIS OF RIGHT HELL [皮膚壊死] | 20[redacted]-10-16 | 150 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-11-12 | - |
| AMG 416 | 20120229-2292600 5008 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | DECOMPENSATION OF AORTIC VALVE STENOSIS [大動脈弁狭窄] | 20[redacted]-10-28 | 162 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-12 | - |
| AMG 416 | 20120229-2292600 5008 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PROTRACTED HYPOTENSION [低血圧] | 20[redacted]-10-28 | 162 | MODERATE | NO | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-11-12 | - |

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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-2292900 3006 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | CEREBRAL HAEMORRHAGIA [脳出血] | 20[redacted]-07-13T07:49 | 137 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-19 | - |
| AMG 416 | 20120229-2292900 7006 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | BLOOD CALCIUM DECREASED [血中カルシウム減少] | 20[redacted]-03-18 | 36 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | RELATED | 20[redacted]-08-14 | - |
| AMG 416 | 20120229-2292900 7006 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ACUTE ALCOHOL INTOXICATION [アルコール中毒] | 20[redacted]-03-21 | 39 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-21 | - |
| AMG 416 | 20120229-2292900 7006 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CRAMPS DURING DIALYSIS [筋痙縮] | 20[redacted]-05-27 | 106 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-05-27 | - |
| AMG 416 | 20120229-2292900 7006 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ILEUS [イレウス] | 20[redacted]-08-12T16:12 | 183 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-08-14T01:05 | - |
| AMG 416 | 20120229-2292900 7006 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SEPSIS [敗血症] | 20[redacted]-08-12T16:12 | 183 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-08-14T01:05 | - |

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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term[*1]] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22929007006 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | WORSENING ANAEMIA [貧血] | 20[redacted]-08-12T16:12 | 183 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-14T01:05 | - |
| AMG 416 | 20120229-22932001008 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LOW SERUM CALCIUM [血中カルシウム減少] | 20[redacted]-07-01T07:50 | 50 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | RELATED | 20[redacted]-07-24T09:00 | - |
| AMG 416 | 20120229-22932001008 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LOW SERUM CALCIUM [血中カルシウム減少] | 20[redacted]-08-21T07:20 | 101 | MODERATE | NO | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | RELATED | 20[redacted]-08-28T07:20 | - |
| AMG 416 | 20120229-22932001008 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | MYOCARDIAL INFARCTION/NSTEMI [急性心筋梗塞] | 20[redacted]-09-04T07:00 | 115 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-08T14:19 * | - |
| AMG 416 | 20120229-22932001008 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LOW SERUM CALCIUM [血中カルシウム減少] | 20[redacted]-12-16T07:20 * | 218 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | RELATED | 20[redacted]-01-20T09:11 * | - |
| AMG 416 | 20120229-22932001008 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | WEAKNESS [無力症] | 20[redacted]-03-08T09:00 * | 300 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-12T10:00 * | - |
| AMG 416 | 20120229-22932001008 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ARRHYTHMIA: VF STORM [心室細動] | 20[redacted]-05-06 * | 359 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-05-06 * | - |
| AMG 416 | 20120229-22932001008 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CARDIOPULMONARY ARREST [心肺停止] | 20[redacted]-05-06 | 359 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-06 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-2293301010 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | NAUSEA AND VOMITING [嘔吐] | 20[redacted]-03-09T12:00 | 19 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-03-19T12:00 | - |
| AMG 416 | 20120229-2293301010 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | ACCIDENTAL FALL OF UNKNOWN ORIGIN [転倒] | 20[redacted]-03-30T09:00 | 40 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-04-22T18:00 | - |
| AMG 416 | 20120229-2293301010 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | CERVICAL PAIN [頚部痛] | 20[redacted]-03-31T12:00 | 41 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-06-03 | - |
| AMG 416 | 20120229-2293301010 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | ACCIDENTAL FALL UNKNOWN ETIOLOGY [転倒] | 20[redacted]-04-16T12:00 | 57 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-04-29T18:00 | - |
| AMG 416 | 20120229-2293301010 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | LEFT FOOT SECOND AND FOURTH FINGER ULCERS DUE TO PERIPHERAL ARTERY DISEASE [末梢動脈閉塞性疾患] | 20[redacted]-04-23T14:00 | 64 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-06-03 | - |
| AMG 416 | 20120229-2293301010 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | WORSENING OF PERIPHERAL ARTERY DISEASE [末梢血管障害] | 20[redacted]-05-29T09:00 | 100 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-03 | - |
| AMG 416 | 20120229-2294800 3001 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SUDDEN DEATH - UNKNOWN REASON [突然死] | 20[redacted]-09-22 | 207 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-22* | - |
| AMG 416 | 20120229-2294800 3003 | 6[redacted] | F | WHITE | NOT HISPANIC OR LATINO | ANXIETY [不安] | 20[redacted]-08-28 | -182 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-07 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22948003003 | 6[redacted] | F | WHITE | NOT HISPANIC OR LATINO | BONE AND MUSCLE PAIN [筋骨格痛] | 20[redacted]-03-05T05:30 * | 8 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-12T09:30 * | - |
| AMG 416 | 20120229-22948003003 | 6[redacted] | F | WHITE | NOT HISPANIC OR LATINO | CONSTIPATION [便秘] | 20[redacted]-04-03 * | 37 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-03 * | - |
| AMG 416 | 20120229-22948003003 | 6[redacted] | F | WHITE | NOT HISPANIC OR LATINO | BRONCHOPNEUMONIA [気管支肺炎] | 20[redacted]-04-07 | 41 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-07 * | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | ARTERIAL HYPERTENSION WORSENING [高血圧] | 20[redacted]-09-25 | -140 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-12 ** | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DIABETIC FOOT ULCER [糖尿病性足病変] | 20[redacted]-12-17 * | -57 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-02-11 ** | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DEGENERATIVE DISC DISEASE OF THE SPINE [椎間板変性症] | 20[redacted]-01-21 * | -22 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-02-11 ** | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | OSTEOCHONDROSIS CERVICAL SPINE [骨端症] | 20[redacted]-01-21 * | -22 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-02-11 ** | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | VERTEBROBASILAR INSUFFICIENCY [椎骨脳底動脈不全] | 20[redacted]-01-21 * | -22 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-02-11 ** | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | TROPHIC ULCER OF RIGHT HEEL REGION [皮膚潰瘍] | 20[redacted]-02-19 | 8 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-02-11 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DRY GANGRENE OF THE FIRST AND THIRD TOES OF RIGHT FOOT [乾性壊疽] | 20[redacted]-03-04 * | 21 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-02-11 * | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DRY GANGRENE OF THE DISTAL PHALANX OF THE SECOND FINGER OF THE LEFT HAND [乾性壊疽] | 20[redacted]-03-12 * | 29 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-04-24 * | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DECREASED CORRECTED CALCIUM [血中カルシウム減少] | 20[redacted]-04-02 * | 50 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | RELATED | 20[redacted]-04-30 * | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | OCCLUSION LOWER EXTREMITY ARTERIES [末梢動脈再閉塞] | 20[redacted]-04-14 * | 62 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, NON-IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-04-30 * | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | OCCLUSION OF THE RADIAL AND ULNAR ARTERIES OF THE LEFT HAND [動脈閉塞性疾患] | 20[redacted]-05-08 * | 86 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, NON-IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-06-05 * | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | ANEMIA WORSENING [貧血] | 20[redacted]-05-14 | 92 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-12-12 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | PAIN IN THE STUMP OF THE SECOND FINGER OF THE LEFT HAND [断端痛] | 20[redacted]-05-19 * | 97 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-06-09 * | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DECREASED CORRECTED CALCIUM [血中カルシウム減少] | 20[redacted]-05-28 * | 106 | MODERATE | NO | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | RELATED | 20[redacted]-09-03 * | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | SYNDROME OF SYSTEMIC INFLAMMATORY RESPONSE [全身性炎症反応症候群] | 20[redacted]-07-21 * | 160 | MODERATE | NO | - | DOSE NOT CHANGED | IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-08-18 * | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DECREASED CORRECTED CALCIUM [血中カルシウム減少] | 20[redacted]-09-15 * | 216 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | RELATED | 20[redacted]-10-08 * | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | FISTULA THROMBOSIS ON THE RIGHT FOREARM [動静脈瘻血栓症] | 20[redacted]-09-15 * | 216 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, NON-IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-09-29 * | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DECREASED CORRECTED CALCIUM [血中カルシウム減少] | 20[redacted]-11-12 ** | 274 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | RELATED | 20[redacted]-11-19 ** | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DECREASED CORRECTED CALCIUM [血中カルシウム減少] | 20[redacted]-01-07 | 330 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | RELATED | 20[redacted]-01-21 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | PERMANENT CATHETER THROMBOSIS [医療機器関連の血栓症] | 20[redacted]-01-19 ** | 342 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-02-09 ** | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | HYPERGLYCEMIA [高血糖] | 20[redacted]-02-10 ** | 364 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-02-11 ** | - |
| AMG 416 | 20120229-22951007003 | 3[redacted] | F | WHITE | NOT HISPANIC OR LATINO | ACUTE CARDIOVASCULAR INSUFFICIENCY [心血管不全] | 20[redacted]-02-10T20:30 | 364 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-11T04:00 * | - |
| AMG 416 | 20120229-22958009018 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SYSTOLIC EJECTION FRACTION DECREASED (FE20%) [駆出率減少] | 20[redacted]-10-25 * | -108 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-07 * | - |
| AMG 416 | 20120229-22958009018 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | DYSPNOEA [呼吸困難] | 20[redacted]-02-10T07:30 * | 1 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-02-10 * | - |
| AMG 416 | 20120229-22958009018 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | OVERHYDRATION [水分過負荷] | 20[redacted]-02-10T07:30 * | 1 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-02-10 * | - |
| AMG 416 | 20120229-22958009018 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HEADACHE [頭痛] | 20[redacted]-03-26 | 45 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-26 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22958009018 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HEADACHE [頭痛] | 20[redacted]-03-28 * | 47 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-28 * | - |
| AMG 416 | 20120229-22958009018 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞] | 20[redacted]-04-06 * | 56 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-07 * | - |
| AMG 416 | 20120229-22958009018 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ISCHEMIC DELATED CARDIOMIOPATHY WITH SEVERAL DEPRESS LEFT VENTRICULAR DISFUNCTION [心筋虚血] | 20[redacted]-04-06 * | 56 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-07 * | - |
| AMG 416 | 20120229-22958009018 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | VENTRICULAR FIBRILATION [心室細動] | 20[redacted]-04-06 | 56 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-07 * | - |
| AMG 416 | 20120229-22966009014 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | BURN ON MIDDLE FINGER OF LEFT HAND [熱傷] | 20[redacted]-05-23 | -146 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-01-03 | - |
| AMG 416 | 20120229-22966009014 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-11-02 | 18 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-12 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966009014 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | FAILURE TO THRIVE [成長障害] | 20[redacted]-12-09 | 55 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-03 * | - |
| AMG 416 | 20120229-22966009014 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | COMPLETE HEART BLOCK [完全房室ブロック] | 20[redacted]-12-12 | 58 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-12-30 * | - |
| AMG 416 | 20120229-22966009014 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | HYPOTHYROIDISM, EXASPERATED [甲状腺機能低下症] | 20[redacted]-12-12 | 58 | MILD | NO | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-01-03 * | - |
| AMG 416 | 20120229-22966009014 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | A-V FISTULA BLEED [動静脈瘻部位出血] | 20[redacted]-12-17 | 63 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120229-22966009014 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | EXACERBATION OF ATRIAL FIBRILLATION [心房細動] | 20[redacted]-12-17 * | 63 | MODERATE | NO | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-01-03 * | - |
| AMG 416 | 20120229-22966009014 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | CARDIAC ARREST [心停止] | 20[redacted]-01-02 * | 79 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-01-02 * | - |
| AMG 416 | 20120229-22966009014 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | VENTRICULAR FIBRILLATION [心室細動] | 20[redacted]-01-03 | 80 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-03 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-2296601 3005 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | WORSENING PERIPHERAL VASCULAR DISEASE [末梢血管障害] | 20[redacted]-04-03T13:51 | 16 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-04-10 | - |
| AMG 416 | 20120229-2296601 3005 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | WORSENING PERIPHERAL VASCULAR DISEASE [末梢血管障害] | 20[redacted]-04-23 | 36 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-05-31 | - |
| AMG 416 | 20120229-2296601 3005 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | LEUKOPENIA [白血球減少症] | 20[redacted]-05-07 | 50 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-31 | - |
| AMG 416 | 20120229-2296601 3005 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | WORSENING CORONARY ARTERY DISEASE [冠動脈疾患] | 20[redacted]-05-15 | 58 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-31 | - |
| AMG 416 | 20120229-2296601 3005 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | CEREBRIAL VASCULAR ACCIDENT [脳血管発作] | 20[redacted]-05-21 | 64 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-31 | - |
| AMG 416 | 20120229-2296601 3005 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | CARDIOPULMONARY ARREST [心肺停止] | 20[redacted]-05-30 | 73 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-31 | - |
| AMG 416 | 20120229-2296601 3007 | 6[redacted] | F | WHITE | HISPANIC OR LATINO | WORSENING CORONARY ARTERY DISEASE [冠動脈疾患] | 20[redacted]-04-28 | 34 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-30 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966013007 | 6[redacted] | F | WHITE | HISPANIC OR LATINO | CARDIOPULMONARY ARREST [心肺停止] | 20[redacted]-04-30 | 36 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-30 | - |
| AMG 416 | 20120229-22966029005 | 3[redacted] | F | WHITE | HISPANIC OR LATINO | RONCHI [低音性連続性ラ音] | 20[redacted]-05-05T05:42 | 8 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-05T09:39 | - |
| AMG 416 | 20120229-22966029005 | 3[redacted] | F | WHITE | HISPANIC OR LATINO | CRACKLES IN LUNGS [ラ音] | 20[redacted]-05-09T05:35 | 12 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-09T09:31 | - |
| AMG 416 | 20120229-22966029005 | 3[redacted] | F | WHITE | HISPANIC OR LATINO | RHONCHI [低音性連続性ラ音] | 20[redacted]-05-12T05:42 | 15 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-12T09:38 | - |
| AMG 416 | 20120229-22966029005 | 3[redacted] | F | WHITE | HISPANIC OR LATINO | CRACKLES IN LUNGS [ラ音] | 20[redacted]-05-19T05:42 | 22 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-19T09:38 | - |
| AMG 416 | 20120229-22966029005 | 3[redacted] | F | WHITE | HISPANIC OR LATINO | CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-09-29T15:12 | 155 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-05 | - |
| AMG 416 | 20120229-22966029005 | 3[redacted] | F | WHITE | HISPANIC OR LATINO | SHORTNESS OF BREATH [呼吸困難] | 20[redacted]-10-13T05:52 | 169 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-10-13T09:50 | - |
| AMG 416 | 20120229-22966029005 | 3[redacted] | F | WHITE | HISPANIC OR LATINO | SHORTNESS OF BREATH [呼吸困難] | 20[redacted]-10-15T05:49 | 171 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-10-15T09:44 | - |
| AMG 416 | 20120229-22966029005 | 3[redacted] | F | WHITE | HISPANIC OR LATINO | BILATERAL CRACKLES [捻髪音] | 20[redacted]-11-05T05:51 | 192 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-11-05T09:38 | - |
| AMG 416 | 20120229-22966029005 | 3[redacted] | F | WHITE | HISPANIC OR LATINO | SUBJECT FELL GETTING INTO TAXI. [転倒] | 20[redacted]-11-28T05:00 | 215 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-11-28T05:05 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966029005 | 3[redacted] | F | WHITE | HISPANIC OR LATINO | ENCEPHALOPATHY SECONDARY TO ANOXIC EVENT [低酸素性虚血性脳症] | 20[redacted]-12-10 | 227 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-23 | - |
| AMG 416 | 20120229-22966041005 | 9[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | WORSENING HYPOTENSION [低血圧] | 20[redacted]-01-21 | -125 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-10-23 | - |
| AMG 416 | 20120229-22966041005 | 9[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | BILATERAL PLEURAL EFFUSION [胸水] | 20[redacted]-08-25 | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-18 | - |
| AMG 416 | 20120229-22966041005 | 9[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | IATROGENIC SPLENIC INJURY [脾臓損傷] | 20[redacted]-08-25 | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-09-05 | - |
| AMG 416 | 20120229-22966041005 | 9[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | POST-OP RESPIRATORY FAILURE [術後呼吸不全] | 20[redacted]-08-25 | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-18 | - |
| AMG 416 | 20120229-22966041005 | 9[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SYNCOPE [失神] | 20[redacted]-08-25 | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-08-25 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966041005 | 9[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | CELLULITIS OF LEFT FOOT [蜂巣炎] | 20[redacted]-10-17 | 145 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-23 | - |
| AMG 416 | 20120229-22966041005 | 9[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | WORSENING PERIPHERAL ARTERY DISEASE [末梢動脈閉塞性疾患] | 20[redacted]-10-17 | 145 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-23 | - |
| AMG 416 | 20120229-22966041005 | 9[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | CARDIAC ARREST [心停止] | 20[redacted]-10-23T00:45 | 151 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-23T00:45 | - |
| AMG 416 | 20120229-22966059001 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ACCESS SITE BLEEDING (AV FISTULA) [動静脈瘻部位出血] | 20[redacted]-03-02 | 110 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-03 | - |
| AMG 416 | 20120229-22966059001 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ISCHEMIC BOWEL [腸管虚血] | 20[redacted]-03-04 | 112 | LIFE THREATENING | YES | Is Life Threatening | DRUG WITHDRAWN | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-05 | - |
| AMG 416 | 20120229-22966059001 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SEPTIC SHOCK [敗血症性ショック] | 20[redacted]-03-04 | 112 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-03-05 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966059001 | 7[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | BILATERAL CEREBRAL STROKE [脳血管発作] | 20[redacted]-03-05 | 113 | LIFE THREATENING | YES | Is Life Threatening | DRUG WITHDRAWN | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-05 | - |
| AMG 416 | 20120229-22966117001 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LEFT HAND STEAL SYNDROME [スチール症候群] | 20[redacted]-05-07 | 41 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-10 | - |
| AMG 416 | 20120229-22966117001 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ASPIRATION [誤嚥] | 20[redacted]-05-11 | 45 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE ALTERED OR WITHHELD | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-05-11 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | POST DIALYSIS HYPOKALEMIA [低カリウム血症] | 20[redacted]-06-24 | -212 | MODERATE | NO | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PROLONGED QTC POST DIALYSIS [心電図ＱＴ延長] | 20[redacted]-06-24 * | -212 | MODERATE | NO | - | DOSE ALTERED OR WITHHELD | OTHER | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | NAUSEA [悪心] | 20[redacted]-03-21 * | 59 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | RELATED | 20[redacted]-03-21 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HYPOPHOSPHATEMIA [低リン酸血症] | 20[redacted]-03-24 * | 62 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LOW SERUM CALCIUM [血中カルシウム減少] | 20[redacted]-05-21 * | 120 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ALK ELEVATION (WORSENING) [血中アルカリホスファターゼ増加] | 20[redacted]-12-17 | 330 | MODERATE | YES | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-02-17 | - |

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| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ALT ELEVATION (WORSENING NO FURTHER INFORMATION AVAILABLE) [アラニンアミノトランスフェラーゼ増加] | 20[redacted]-12-17 * | 330 | MODERATE | YES | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | AST ELEVATION (WORSENING NO FURTHER INFORMATION AVAILABLE) [アスパラギン酸アミノトランスフェラーゼ増加] | 20[redacted]-12-17 * | 330 | MODERATE | YES | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | DIRECT BILIRUBIN ELEVATION [抱合ビリルビン増加] | 20[redacted]-12-17 * | 330 | SEVERE | YES | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | TOTAL BILIRUBIN ELEVATION [血中ビリルビン増加] | 20[redacted]-12-17 * | 330 | SEVERE | YES | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | INCREASE IN EOSINOPHILIA [好酸球数増加] | 20[redacted]-12-28 ** | 341 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER, OTHER | RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | FACIAL HEMATOMA [血腫] | 20[redacted]-01-08 ** | 352 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CHILLS [悪寒] | 20[redacted]-01-26 ** | 370 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | COUGH [咳嗽] | 20[redacted]-01-26 | 370 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 | - |

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time ** | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time ** | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | GENERALIZED WEAKNESS [無力症] | 20[redacted]-01-26 ** | 370 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | MILD FLUID OVERLOAD [水分過負荷] | 20[redacted]-01-26 ** | 370 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | MILD PERIHILAR INFILTRATES [肺浸潤] | 20[redacted]-01-26 ** | 370 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | NASAL CONGESTION [鼻閉] | 20[redacted]-01-26 ** | 370 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | UPPER RESPIRATORY SYMPTOMS [呼吸障害] | 20[redacted]-01-26 ** | 370 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HEMOSIDEROSIS PREDOMINANTLY RETICULOENDOTHELIAL [ヘモジデリン沈着症] | 20[redacted]-02-05 ** | 380 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | MILD PERIPORTAL FIBROSIS [肝線維症] | 20[redacted]-02-05 ** | 380 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ALTERED MENTAL STATUS [精神状態変化] | 20[redacted]-02-09 | 384 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HYPOGLYCEMIA [低血糖症] | 20[redacted]-02-09 ** | 384 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HYPOTHERMIA [低体温] | 20[redacted]-02-09 ** | 384 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ASCITES [腹水] | 20[redacted]-02-10 ** | 385 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CHOLELITHIASIS [胆石症] | 20[redacted]-02-10 ** | 385 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PANCREATIC CARCINOMA [膵癌] | 20[redacted]-02-10 ** | 385 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-2296616 7001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PANCREATIC DUCT OBSTRUCTION [膵管閉塞] | 20[redacted]-02-10 | 385 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-17 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HYPOKALEMIA [低カリウム血症] | 20[redacted]-02-11 ** | 386 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | PAIN [疼痛] | 20[redacted]-02-11 ** | 386 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SEVERE SEPSIS [敗血症] | 20[redacted]-02-11 ** | 386 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN, OTHER | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | BILATERAL LOWER EXTREMITY CELLULITIS [蜂巣炎] | 20[redacted]-02-13 ** | 388 | MODERATE | NO | - | DOSE NOT CHANGED | IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-02-17 ** | - |
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ACUTE RESPIRATORY FAILURE [急性呼吸不全] | 20[redacted]-02-15 | 390 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER | NOT RELATED | 20[redacted]-02-17 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966167001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ACINETOBACTER BACTEREMIA [アシネトバクター性菌血症] | 20[redacted]-02-16 | 391 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN, OTHER | NOT RELATED | 20[redacted]-02-17 | - |
| AMG 416 | 20120230-23021002001 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DUODENAL ULCUS FORREST IB, ENDOSCOPIC HEMOSTASIS [十二指腸潰瘍] | 20[redacted]-11-30T11:41 | 4 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, TRANSFUSION PERFORMED, OTHER | NOT RELATED | 20[redacted]-12-06 | - |
| AMG 416 | 20120230-23021002001 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-12-07T03:09 | 11 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-12-08T11:55 | - |
| AMG 416 | 20120230-23021012006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | FLU LIKE SYMPTOMS [インフルエンザ様疾患] | 20[redacted]-04-09 | -7 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-22 | - |
| AMG 416 | 20120230-23021012006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HYPOTHYREOSIS, DETECTED FROM LABOR.VALUES [甲状腺機能低下症] | 20[redacted]-04-16T08:00 | 1 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-09-04 | - |
| AMG 416 | 20120230-23021012006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HYPERHYDRATATION [水分過負荷] | 20[redacted]-07-28T05:00 | 104 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-07-28T11:30 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-2302101 2006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | DYSPNOE [呼吸困難] | 20[redacted]-07-30 | 106 | MODERATE | NO | - | DOSE NOT CHANGED | DEVICE EXPLANTATION | NOT RELATED | 20[redacted]-08-27 | - |
| AMG 416 | 20120230-2302101 2006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LOW BLOOD PRESSURE [低血圧] | 20[redacted]-07-30 | 106 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-09-04 | - |
| AMG 416 | 20120230-2302101 2006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SUPERFICIAL SKIN LESSIONS ON THE LEFT HAND [皮膚病変] | 20[redacted]-07-30 | 106 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-09-04 | - |
| AMG 416 | 20120230-2302101 2006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | TACHYCARDIA [頻脈] | 20[redacted]-07-30 | 106 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-08-08 | - |
| AMG 416 | 20120230-2302101 2006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | FALLING DOWN AT HOME [転倒] | 20[redacted]-08-06 | 113 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-08-06 | - |
| AMG 416 | 20120230-2302101 2006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HAEMATOMS ON THE BACK AND HANDS [血腫] | 20[redacted]-08-06 | 113 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-08-27 | - |
| AMG 416 | 20120230-2302101 2006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | INTERMITTENT DESORIENTATION [失見当識] | 20[redacted]-08-06 | 113 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-04 | - |
| AMG 416 | 20120230-2302101 2006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CARDIAC INSUFICENCE [心不全] | 20[redacted]-08-11 | 118 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-04T05:10 | - |
| AMG 416 | 20120230-2302101 2006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | UROINFECTION [尿路感染] | 20[redacted]-08-13 | 120 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-08-20 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23021012006 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | WHOLE BODY PAINS [疼痛] | 20[redacted]-09-01 | 139 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-09-01 | - |
| AMG 416 | 20120230-23029004001 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CARDIATIC FAILURE [心不全] | 20[redacted]-08-03 | 236 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-06 | - |
| AMG 416 | 20120230-23029004003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | OSTEOMYELITIS PEDIS LATERIS SINISTRI [骨髄炎] | 20[redacted]-07-08 | 216 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN, OTHER | NOT RELATED | 20[redacted]-08-15 | - |
| AMG 416 | 20120230-23029004003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SEPSIS [敗血症] | 20[redacted]-08-23 | 262 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-09-05 | - |
| AMG 416 | 20120230-23029004003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | DECUBITUS OF LEFT LEG [褥瘡性潰瘍] | 20[redacted]-09-05 | 275 | MILD | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-15 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23029004003 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SEPSIS [敗血症] | 20[redacted]-10-15 | 315 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-18 | - |
| AMG 416 | 20120230-23033008004 | 8[redacted] | F | WHITE | HISPANIC OR LATINO | FOOTS ARTHROSIS [変形性関節症] | 20[redacted]-08-11 * | -149 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-07 * | - |
| AMG 416 | 20120230-23033008004 | 8[redacted] | F | WHITE | HISPANIC OR LATINO | LOW SERUM CALCIUM [血中カルシウム減少] | 20[redacted]-02-21 * | 46 | MILD | NO | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-02-25 * | - |
| AMG 416 | 20120230-23033008004 | 8[redacted] | F | WHITE | HISPANIC OR LATINO | CHOLECISTITIS ALITIASICA [胆嚢炎] | 20[redacted]-08-28 * | 234 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-09-07 * | - |
| AMG 416 | 20120230-23033008004 | 8[redacted] | F | WHITE | HISPANIC OR LATINO | SEPSIS [敗血症] | 20[redacted]-08-28 * | 234 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-07 * | - |
| AMG 416 | 20120230-23033008004 | 8[redacted] | F | WHITE | HISPANIC OR LATINO | INFECTION DUE TO CLOSTRIDIUM DIFFICILE [クロストリジウム・ディフィシレ感染] | 20[redacted]-09-03 * | 240 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-09-07 * | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-2304800 2009 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | MECHANICAL SUBILEUS [亜イレウス] | 20[redacted]-05-24 | 33 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-10 | - |
| AMG 416 | 20120230-2304800 2009 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | ANGIOMA OF THE VERTEBRA THORAICUS ( TH 9 ) [骨血管腫] | 20[redacted]-05-29 | 38 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-17 | - |
| AMG 416 | 20120230-2304800 2009 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DEGENERATION OF THE SPINE. [変形性脊椎症] | 20[redacted]-05-29 | 38 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-17 | - |
| AMG 416 | 20120230-2304800 2009 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DIVERTICULOSIS OF INTESTINES [腸憩室] | 20[redacted]-05-29 | 38 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-17 | - |
| AMG 416 | 20120230-2304800 2009 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | TUMOR OF LEFT LUNG [肺新生物] | 20[redacted]-05-29 | 38 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-17 | - |
| AMG 416 | 20120230-2304800 2009 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | CHRONIC GASTRITIS [慢性胃炎] | 20[redacted]-05-30 | 39 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-09-17 | - |
| AMG 416 | 20120230-2304800 2009 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | PAIN OF LUMBAR SPINE [脊椎痛] | 20[redacted]-07-17 | 87 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-17 | - |
| AMG 416 | 20120230-2304800 2009 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | AGGRAVATED SECONDARY ANAEMIA [貧血] | 20[redacted]-08-19 | 120 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-17 | - |
| AMG 416 | 20120230-2304800 2009 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | PARAPARESIS BECOUSE OF METASTASES TO THE SPINE [脊椎転移] | 20[redacted]-08-28 | 129 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-17 | - |

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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23048002009 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | BREAST CANCER [乳癌] | 20[redacted]-09-12 | 144 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-17T21:25 | - |
| AMG 416 | 20120230-23048002009 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | CONSTIPATION [便秘] | 20[redacted]-09-13 | 145 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-09-17 | - |
| AMG 416 | 20120230-23048004020 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LOW SERUM CALCIUM [血中カルシウム減少] | 20[redacted]-04-29 | 57 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER, OTHER | RELATED | 20[redacted]-11-24 | - |
| AMG 416 | 20120230-23048004020 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SUDDEN DEATH [突然死] | 20[redacted]-11-24 | 266 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-11-24 | - |
| AMG 416 | 20120230-23048014001 | 6[redacted] | F | WHITE | NOT HISPANIC OR LATINO | AORTIC VALVE STENOSIS [大動脈弁狭窄] | 20[redacted]-01-21 | -57 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-09 | - |
| AMG 416 | 20120230-23048014001 | 6[redacted] | F | WHITE | NOT HISPANIC OR LATINO | VENTRICULAR FIBRILLATION [心室細動] | 20[redacted]-04-08 | 21 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-04-09T22:00 | - |
| AMG 416 | 20120230-23058004007 | 7[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SEPSIC SHOCK [敗血症性ショック] | 20[redacted]-09-12 | 164 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-12 | - |

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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CATHETER DYSFUNCTION [医療機器合併症] | 20[redacted]-11-27 | 3 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-02-21 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | VERTIGO [回転性めまい] | 20[redacted]-12-09 | 15 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | BLOOD CALCIUM DECREASED [血中カルシウム減少] | 20[redacted]-12-23 * | 29 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | RELATED | 20[redacted]-01-27 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | STROKE [脳血管発作] | 20[redacted]-01-17 * | 54 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-22 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | AVF HEMATOMA [動静脈瘻部位血腫] | 20[redacted]-02-14 * | 82 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-03-21 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | INSOMNIA [不眠症] | 20[redacted]-03-12 * | 108 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-11-21 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | AVF ARM EDEMA [動静脈瘻部位合併症] | 20[redacted]-03-14 * | 110 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-10-24 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | AVF EXTRAVASATION [動静脈瘻部位合併症] | 20[redacted]-03-19 * | 115 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-19 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CATHETER DYSFUNCTION [医療機器合併症] | 20[redacted]-05-26 | 183 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-06-13 | - |

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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | INFLAMMATION CATHETER [カテーテル留置部位炎症] | 20[redacted]-06-02 * | 190 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-06-04 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | AVF BLEEDING DURING HEMODIALYSIS TREATMENT [動静脈瘻部位出血] | 20[redacted]-06-16 * | 204 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-06-16 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | GENERAL MALAISE [倦怠感] | 20[redacted]-06-18 * | 206 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-06-20 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SICKNESS [倦怠感] | 20[redacted]-06-18 * | 206 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-06-18 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | VOMITING [嘔吐] | 20[redacted]-06-18 * | 206 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-06-20 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | DEHYDRATION [脱水] | 20[redacted]-06-20 * | 208 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-22 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | DIARREA [下痢] | 20[redacted]-06-20 * | 208 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-06-20 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | AVF HEMATOMA [動静脈瘻部位血腫] | 20[redacted]-08-22 * | 271 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-24 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | TACHYCARDIA [頻脈] | 20[redacted]-09-15 | 295 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-15 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | AVF ECCHYMOSIS [動静脈瘻部位出血] | 20[redacted]-09-19 * | 299 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-19 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | AVF INDURATION [動静脈瘻部位合併症] | 20[redacted]-09-19 * | 299 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-19 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CATHETER DYSFUNCTION [医療機器合併症] | 20[redacted]-10-24 * | 334 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-11-21 * | - |
| AMG 416 | 20120230-23058008002 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CARDIAC ARREST [心停止] | 20[redacted]-11-22 | 363 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-11-22 * | - |
| AMG 416 | 20120230-23066006010 | 6[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | RECURRENT WOUND ON LEFT UPPER EXTREMITY [創傷] | 20[redacted]-04-09 | -203 | MODERATE | NO | - | DOSE NOT CHANGED | IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-04-18 * | - |
| AMG 416 | 20120230-23066006010 | 6[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | SMALL ABSCESS NEAR LEFT UPPER EXTREMITY FISTULA [動静脈グラフト部位膿瘍] | 20[redacted]-05-28 | -154 | MODERATE | NO | - | DOSE NOT CHANGED | IV ANTIBIOTICS TAKEN, NON-IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-04-18 * | - |
| AMG 416 | 20120230-23066006010 | 6[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | RIGHT FOOT ULCER [皮膚潰瘍] | 20[redacted]-10-08 * | -21 | MILD | NO | - | DOSE NOT CHANGED | NON-IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-04-18 * | - |
| AMG 416 | 20120230-23066006010 | 6[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | LEFT ARM FISTULA INFILTRATION [動静脈瘻部位合併症] | 20[redacted]-01-07 * | 71 | MILD | NO | - | DOSE ALTERED OR WITHHELD | OTHER | NOT RELATED | 20[redacted]-01-07 * | - |
| AMG 416 | 20120230-23066006010 | 6[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | ASCITIS [腹水] | 20[redacted]-02-28 | 123 | MODERATE | NO | - | DOSE NOT CHANGED | DEVICE / PROCEDURE INTERVENTION, OTHER | NOT RELATED | 20[redacted]-04-18 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066006010 | 6[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | ACUTE CHOLECYSTITIS [急性胆嚢炎] | 20[redacted]-03-03 * | 126 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-18 * | - |
| AMG 416 | 20120230-23066006010 | 6[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | ACUTE CHOLECYSTITIS [急性胆嚢炎] | 20[redacted]-03-19 * | 142 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-18 * | - |
| AMG 416 | 20120230-23066006010 | 6[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | MULTIPLE GALLSTONES [胆石症] | 20[redacted]-03-19 * | 142 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-18 * | - |
| AMG 416 | 20120230-23066006010 | 6[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | LOW BLOOD IPTH [血中副甲状腺ホルモン減少] | 20[redacted]-03-22 * | 145 | MILD | NO | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | RELATED | 20[redacted]-04-18 * | - |
| AMG 416 | 20120230-23066006010 | 6[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | JAUNDICE [黄疸] | 20[redacted]-04-08 * | 162 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-04-18 * | - |
| AMG 416 | 20120230-23066006010 | 6[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | HYPOTENSION [低血圧] | 20[redacted]-04-09 | 163 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-04-18 | - |
| AMG 416 | 20120230-23066028006 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | COPD EXACERBATION [慢性閉塞性肺疾患] | 20[redacted]-05-26T22:09 | 34 | MODERATE | NO | - | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-12-29T12:00 | - |
| AMG 416 | 20120230-23066028006 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | NOSE BLEED [鼻出血] | 20[redacted]-05-26T22:09 | 34 | MODERATE | NO | - | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-05-27T12:00 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066028006 | 7[redacted] | F | WHITE | NOT HISPANIC OR LATINO | ACUTE RESPIRATORY FAILURE [急性呼吸不全] | 20[redacted]-12-15T12:00 | 237 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-29T12:00 * | - |
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | SHORTNESS OF BREATH [呼吸困難] | 20[redacted]-11-18 | -42 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-22 * | - |
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | RIGHT KNEE PAIN [関節痛] | 20[redacted]-11-26 * | -34 | MODERATE | NO | - | DOSE NOT CHANGED | UNKNOWN | NOT RELATED | 20[redacted]-03-22 * | - |
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | WORSENED LEG EDEMA [末梢性浮腫] | 20[redacted]-01-08 * | 10 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-01-10 * | - |
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | INJURY:ABRASIONS LEFT LEG [皮膚擦過傷] | 20[redacted]-02-21 * | 54 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-22 * | - |
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | INJURY:ABRASIONS RIGHT LEG [皮膚擦過傷] | 20[redacted]-02-21 * | 54 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-22 * | - |
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | ABNORMAL CARDIAC ENZYMES [心筋壊死マーカー上昇] | 20[redacted]-03-18 * | 79 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-22 * | - |
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE [心房細動] | 20[redacted]-03-18 | 79 | MODERATE | NO | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-03-20 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | CARDIOPULMONARY ARREST [心肺停止] | 20[redacted]-03-18 * | 79 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-18 * | - |
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | HYPERKALEMIA [高カリウム血症] | 20[redacted]-03-18 * | 79 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-18 * | - |
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | CORONARY ARTERY DISEASE [冠動脈疾患] | 20[redacted]-03-19 * | 80 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-03-22 * | - |
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | MILD LEFT VENTRIULAR HYPERTROPHY [左室肥大] | 20[redacted]-03-19 * | 80 | MILD | NO | - | DOSE NOT CHANGED | DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-03-22 * | - |
| AMG 416 | 20120230-23066032005 | 7[redacted] | F | WHITE | HISPANIC OR LATINO | CARDIAC ARREST [心停止] | 20[redacted]-03-22 | 83 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | MEDICATION TAKEN | NOT RELATED | 20[redacted]-03-22 | - |
| AMG 416 | 20120230-23066034010 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | GLAUCOMA [緑内障] | 20[redacted]-03-03T08:00 | -56 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-11-03 | - |
| AMG 416 | 20120230-23066034010 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | CARDIAC ARREST [心停止] | 20[redacted]-11-03T13:06 | 190 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-11-03T14:30 | - |

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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066046008 | 8[redacted] | F | WHITE | NOT HISPANIC OR LATINO | DIARRHEA [下痢] | 20[redacted]-01-06 | 10 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-13 | - |
| AMG 416 | 20120230-23066046008 | 8[redacted] | F | WHITE | NOT HISPANIC OR LATINO | ABDOMINAL PAIN [腹痛] | 20[redacted]-01-14 | 18 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-15 | - |
| AMG 416 | 20120230-23066046008 | 8[redacted] | F | WHITE | NOT HISPANIC OR LATINO | INTERMITTENT MODERATE DIARRHEA [下痢] | 20[redacted]-01-14 | 18 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-29 | - |
| AMG 416 | 20120230-23066046008 | 8[redacted] | F | WHITE | NOT HISPANIC OR LATINO | SUSPECTED METASTATIC LUNG CANCER [遠隔転移を伴う肺癌] | 20[redacted]-01-16 | 20 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-01-29 | - |
| AMG 416 | 20120230-23066046008 | 8[redacted] | F | WHITE | NOT HISPANIC OR LATINO | WORSENING ABDOMINAL PAIN [腹痛] | 20[redacted]-01-16 | 20 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-01-29 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HEMATURIA [血尿] | 20[redacted]-08-15 | -173 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | BRADYCARDIA [徐脈] | 20[redacted]-09-12 * | -145 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ANEMIA [貧血] | 20[redacted]-01-28 | -7 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-25 | - |

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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ACHILLES TENDINOPATHY [腱障害] | 20[redacted]-02-10 * | 7 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CONSTIPATION [便秘] | 20[redacted]-02-10 * | 7 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | WORSENING HYPERKALEMIA [高カリウム血症] | 20[redacted]-02-10 * | 7 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | DIARRHEA [下痢] | 20[redacted]-02-11 * | 8 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ACUTE RESPIRATORY FAILURE [急性呼吸不全] | 20[redacted]-02-14 * | 11 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-02-27 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | OBESITY HYPOVENTILATION SYNDROME [ピックウィック症候群] | 20[redacted]-02-14 * | 11 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | OBSTRUCTIVE SLEEP APNEA [睡眠時無呼吸症候群] | 20[redacted]-02-14 * | 11 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HYPERTENSION [高血圧] | 20[redacted]-02-18 * | 15 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | RECTAL BLEEDING [直腸出血] | 20[redacted]-03-08 | 33 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-25 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | INFECTION AT AV GRAFT EXIT SITE ON LEFT LEG POSITIVE FOR COAG-NEGATIVE STAPH [動静脈グラフト部位感染] | 20[redacted]-03-20 * | 45 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-03-29 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HYPOTESION [低血圧] | 20[redacted]-04-01 * | 57 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-11 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | RIGHT BASILAR ATELECTASIS [無気肺] | 20[redacted]-04-01 * | 57 | MILD | NO | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | BRADYCARDIC [徐脈] | 20[redacted]-04-01T15:15 * | 57 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-11 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CARDIOMEGALY [心拡大] | 20[redacted]-04-07 * | 63 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CLOTTED FEMORAL GRAFT [移植片血栓症] | 20[redacted]-04-12 * | 68 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-16 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | MULTIPLE POLYPOID LESIONS [ポリープ] | 20[redacted]-04-13 * | 69 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SIGMOID DIVERTICULOSIS [腸憩室] | 20[redacted]-04-13 | 69 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-25 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | RESPIRATORY FAILURE [呼吸不全] | 20[redacted]-04-16 * | 72 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-25 * | - |
| AMG 416 | 20120230-23066056005 | 6[redacted] | M | WHITE | NOT HISPANIC OR LATINO | RIGHT PLEURAL EFFUSION [胸水] | 20[redacted]-04-16 | 72 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-25 | - |
| AMG 416 | 20120230-23066078012 | 6[redacted] | F | WHITE | HISPANIC OR LATINO | LOW SERUM CALCIUM LEVEL [血中カルシウム減少] | 20[redacted]-04-16 | 10 | MODERATE | NO | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | RELATED | 20[redacted]-07-02 | - |
| AMG 416 | 20120230-23066078012 | 6[redacted] | F | WHITE | HISPANIC OR LATINO | UNCONTROLLED HYPERTENSION [高血圧] | 20[redacted]-04-23 | 17 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-26 * | - |
| AMG 416 | 20120230-23066078012 | 6[redacted] | F | WHITE | HISPANIC OR LATINO | HIGH SERUM CALCIUM LEVEL [血中カルシウム増加] | 20[redacted]-11-12 * | 220 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER, OTHER | RELATED | 20[redacted]-01-07 * | - |
| AMG 416 | 20120230-23066078012 | 6[redacted] | F | WHITE | HISPANIC OR LATINO | CEREBRAL VASCULAR ACCIDENT [脳血管発作] | 20[redacted]-03-07 | 335 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-03-13 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066078012 | 6[redacted] | F | WHITE | HISPANIC OR LATINO | ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞] | 20[redacted]-03-12 | 340 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-13 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | BILATERAL PLEURAL EFFUSION [胸水] | 20[redacted]-09-08 | 209 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | BLADDER WALL THICKENING [膀胱障害] | 20[redacted]-09-08 | 209 | SEVERE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | CONSTIPATION [便秘] | 20[redacted]-09-08 | 209 | MODERATE | YES | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | POORLY DIFFERENTIATED CARCINOMA; UNKNOWN PRIMARY [悪性新生物] | 20[redacted]-09-08 | 209 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | RENAL MASS [腎腫瘤] | 20[redacted]-09-08 | 209 | SEVERE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | UTI [尿路感染] | 20[redacted]-09-11 | 212 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | ACUTE RESPIRATORY FAIL [急性呼吸不全] | 20[redacted]-09-21 | 222 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HYPONATREMIA [低ナトリウム血症] | 20[redacted]-09-21 | 222 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | HYPOTENSION [低血圧] | 20[redacted]-09-21 | 222 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LACTIC ACIDOSIS [乳酸アシドーシス] | 20[redacted]-09-21 | 222 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | LEUKOCYTOSIS [白血球増加症] | 20[redacted]-09-21 | 222 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | SINUS TACHYCARDIA [洞性頻脈] | 20[redacted]-09-21 | 222 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | 5[redacted] | M | WHITE | NOT HISPANIC OR LATINO | RIGHT LOWER LOBE PULMONARY EMBOLUS [肺塞栓症] | 20[redacted]-09-23 | 224 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23* | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | PULMONARY HYPERTENSION [肺高血圧症] | 20[redacted]-11-18* | -63 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17* | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | GENERALIZED WEAKNESS [無力症] | 20[redacted]-01-23* | 4 | MODERATE | NO | - | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-01-26* | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SHORTNESS OF BREATH/DYSPNEA R/T VOLUME OVERLOAD [水分過負荷] | 20[redacted]-02-04T04:55 | 16 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-02-05T10:45 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | DIZZINESS [浮動性めまい] | 20[redacted]-02-04T11:00 * | 16 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-02-04T11:03 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | HEAD INJURY [頭部損傷] | 20[redacted]-02-04T11:00 * | 16 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-02-04T11:03 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | HEADACHE [頭痛] | 20[redacted]-02-04T11:00 * | 16 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-02-05T18:00 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | CONTUSION WITH INTACT SKIN- SCALP LEFT [挫傷] | 20[redacted]-02-04T11:30 * | 16 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER | NOT RELATED | 20[redacted]-02-07T10:00 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | FALL ACCIDENTAL [転倒] | 20[redacted]-02-04T11:30 * | 16 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-02-04T11:30 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SUBDURAL HEMATOMA [硬膜下血腫] | 20[redacted]-02-04T11:30 | 16 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-07T10:00 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ELEVATED INR WITH COUMADIN [国際標準比増加] | 20[redacted]-02-04T12:59 * | 16 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-05T04:32 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | NAUSEA [悪心] | 20[redacted]-02-05 * | 17 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-02-05 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | LEFT SPRAINED ANKLE [靭帯捻挫] | 20[redacted]-03-07T19:00 * | 47 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT, OTHER | NOT RELATED | 20[redacted]-03-14T08:00 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | LACERATIONS TO FOREHEAD [裂傷] | 20[redacted]-04-29 * | 100 | MILD | NO | - | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-05-19T11:30 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | LEFT EYE HEMATOMA [眼出血] | 20[redacted]-04-29 * | 100 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT, OTHER | NOT RELATED | 20[redacted]-05-19T11:30 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | LEFT SUBCONJUNCTIVAL HEMORRHAGE [結膜出血] | 20[redacted]-04-29 * | 100 | MODERATE | NO | - | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-05-19T11:30 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | RHABDOMYOLYSIS [横紋筋融解症] | 20[redacted]-05-22 | 123 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-06-12T02:20 | - |

年齢以外のマスキングにおいて,
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | FALL ACCIDENTAL [転倒] | 20[redacted]-05-23 * | 124 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-23 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | LEFT SHOULDER PAIN WITHOUT FRACTURE [筋骨格痛] | 20[redacted]-05-23 * | 124 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-06-30 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | HYPONATREMIA [低ナトリウム血症] | 20[redacted]-05-23T18:03 * | 124 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SUPRATHERAPUTIC INR [国際標準比増加] | 20[redacted]-05-24T05:04 * | 125 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-06-11 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ABNORMAL EJECTION FRACTION (40-50% DECREASE) [駆出率減少] | 20[redacted]-05-25 * | 126 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ACUTE HYPOXIC RESPIRATORY FAILURE RELATED TO UNRESPONSIVE EPISODE REQUIRING INTUBATION TO FOR AIRWAY PROTECTION [呼吸不全] | 20[redacted]-05-25 * | 126 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-05-27 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ATYPICAL PNEUMONIA [異型肺炎] | 20[redacted]-05-25 | 126 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-06-14 | - |

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
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＊新薬承認情報提供時に置換えた

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | BRADYCARDIA [徐脈] | 20[redacted]-05-25 * | 126 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-27 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | HYPOTENSION [低血圧] | 20[redacted]-05-25 * | 126 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-27 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | LEFT ATRIUM ENLARGEMENT [左房拡張] | 20[redacted]-05-25 * | 126 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | MODERATE DIASTOLIC DYSFUNCTION CONSISTENT WITH REDUCED LEFT VENTRICULAR COMPLIANCE [拡張機能障害] | 20[redacted]-05-25 * | 126 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | MODERATE TO SEVERE MITRAL VALVE REGURGITATION [僧帽弁閉鎖不全症] | 20[redacted]-05-25 * | 126 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | MODERATE TO SEVERE PULMONARY HYPERTENSION [肺高血圧症] | 20[redacted]-05-25 | 126 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |

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＊　　：「翌年」を意味する
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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | MODERATE TRICUSPID REGURGITATION [三尖弁閉鎖不全症] | 20[redacted]-05-25 * | 126 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | UNRESPONSIVE EPISODE [意識消失] | 20[redacted]-05-25 * | 126 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-27 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SHORTNESS OF BREATH [呼吸困難] | 20[redacted]-06-07 * | 139 | MODERATE | NO | - | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-06-13 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | CHEST PAIN-CARDIAC (ANGINA) [狭心症] | 20[redacted]-06-11T14:12 * | 143 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-11T17:53 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SENSATION OF PRESSURE ON CHEST [胸部不快感] | 20[redacted]-07-25T12:37 * | 187 | SEVERE | NO | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-07-25T14:59 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | COLON POLYPS [大腸ポリープ] | 20[redacted]-08-09 | 202 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER | NOT RELATED | 20[redacted]-12-17 | - |

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＊　　：「翌年」を意味する
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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term[*1]] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | GASTRITIS [胃炎] | 20[redacted]-08-15 * | 208 | MILD | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-08-20 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | HEMATURIA [血尿] | 20[redacted]-08-16 * | 209 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER | NOT RELATED | 20[redacted]-08-20 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SHORTNESS OF BREATH [呼吸困難] | 20[redacted]-10-01 * | 255 | MODERATE | NO | - | DOSE NOT CHANGED | UNKNOWN | NOT RELATED | 20[redacted]-10-06 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | INCREASED LOWER LEG EDEMA [末梢性浮腫] | 20[redacted]-10-20 * | 274 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | VENOUS STASIS [末梢静脈疾患] | 20[redacted]-10-25 * | 279 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | BILATERAL LEG PAIN R/T STASIS WOUNDS [創合併症] | 20[redacted]-11-03 * | 288 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | STASIS ULCERS [皮膚潰瘍] | 20[redacted]-11-03 | 288 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-12-17 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SHORTNESS OF BREATH [呼吸困難] | 20[redacted]-11-11T11:30 * | 296 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-11-11T16:00 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | DEMENTIA/ MEMORY LOSS PER FAMILY [認知症] | 20[redacted]-11-15 * | 300 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | DYSPNEA [呼吸困難] | 20[redacted]-12-05 * | 320 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | BRAIN ATROPHY (PER CT) [大脳萎縮] | 20[redacted]-12-11 * | 326 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | FAILURE TO THRIVE [成長障害] | 20[redacted]-12-11 * | 326 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | GLIOSIS (BRAIN) PER CT [グリオーシス] | 20[redacted]-12-11 * | 326 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |

年齢以外のマスキングにおいて，
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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | MALNUTRITION RELATED TO FAILURE TO THRIVE [栄養障害] | 20[redacted]-12-11 * | 326 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | INCREASED CONFUSION POSSIBLY R/T MEDICATION REACTION [錯乱状態] | 20[redacted]-12-11T11:30 * | 326 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT, CULTURE TAKEN | NOT RELATED | 20[redacted]-12-11T15:30 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ACUTE DELERIUM [譫妄] | 20[redacted]-12-11T18:00 * | 326 | SEVERE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120230-23066166005 | 7[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SHORTNESS OF BREATH [呼吸困難] | 20[redacted]-12-11T18:30 | 326 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-12-17 | - |
| AMG 416 | 20120359-35966002004 | 5[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | UPPER RESPIRATORY INFECTION [上気道感染] | 20[redacted]-01-03 | -5 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-01-13 | - |
| AMG 416 | 20120359-35966002004 | 5[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ISCHEMIC COLITIS [虚血性大腸炎] | 20[redacted]-01-10 | 3 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-01-26 | - |

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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120359-35966002004 | 5[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | HEMATEMESIS [吐血] | 20[redacted]-03-27 | 79 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-28 | - |
| AMG 416 | 20120359-35966002004 | 5[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | HEMORRHAGIC GASTRITIS [出血性胃炎] | 20[redacted]-03-27 | 79 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-31T15:04 | - |
| AMG 416 | 20120359-35966002004 | 5[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ACUTE PULMONARY EMBOLUS [肺塞栓症] | 20[redacted]-03-31T14:40 | 83 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-03-31T15:04 | - |
| AMG 416 | 20120359-35966025004 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | CARDIAC ARREST [心停止] | 20[redacted]-01-24T04:15 | 12 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-01-24T06:00 | - |
| AMG 416 | 20120359-35966028007 | 4[redacted] | M | WHITE | HISPANIC OR LATINO | ABDOMINAL DISCOMFORT [腹部不快感] | 20[redacted]-07-22 | 181 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-07-22 | - |
| AMG 416 | 20120359-35966028007 | 4[redacted] | M | WHITE | HISPANIC OR LATINO | ACUTE CORONARY SYNDROME [急性冠動脈症候群] | 20[redacted]-08-25 | 215 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-29 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120359-35966028007 | 4[redacted] | M | WHITE | HISPANIC OR LATINO | HYPOTENSION [低血圧] | 20[redacted]-08-25 | 215 | MODERATE | NO | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-08-29 | - |
| AMG 416 | 20120359-35966028007 | 4[redacted] | M | WHITE | HISPANIC OR LATINO | PNEUMONIA [肺炎] | 20[redacted]-08-25 | 215 | MODERATE | NO | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, IV ANTIBIOTICS TAKEN, CULTURE TAKEN, OTHER | NOT RELATED | 20[redacted]-08-29 | - |
| AMG 416 | 20120359-35966028007 | 4[redacted] | M | WHITE | HISPANIC OR LATINO | CARDIAC ARREST [心停止] | 20[redacted]-08-29 | 219 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE ALTERED OR WITHHELD | UNKNOWN | NOT RELATED | 20[redacted]08-29 | - |
| AMG 416 | 20120359-35966032004 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | SUDDEN DEATH [突然死] | 20[redacted]-06-28T12:00 | 146 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | NO ACTION TAKEN | NOT RELATED | 20[redacted]-06-28T12:00 ** | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SHOULDER DISCOMFORT [筋骨格不快感] | 20[redacted]-11-20 | -47 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-01-05 ** | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ERECTILE DYSFUNCTION [勃起不全] | 20[redacted]-12-02 * | -35 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-01-05 * | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | HEMATEMESIS [吐血] | 20[redacted]-01-19 * | 14 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-20 * | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | RIB CAGE PAIN [筋骨格系胸痛] | 20[redacted]-01-31 | 26 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-02-03 | - |

年齢以外のマスキングにおいて,
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time ** | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | PEYRONIE'S PLAQUE [ペイロニー病] | 20[redacted]-03-12 * | 66 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-05 ** | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | NODULAR SKIN LESIONS [皮膚病変] | 20[redacted]-04-07 * | 92 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-05 * | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | DENTAL CARIES [齲歯] | 20[redacted]-05-15 * | 130 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-05-21 ** | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | LUMBAR SPONDYLOSIS [変形性脊椎症] | 20[redacted]-07-29 * | 205 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-01-05 ** | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | RIGHT HIP PAIN [関節痛] | 20[redacted]-07-29 * | 205 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-01-05 ** | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SACRAL DISORDER (NO FURTHER INFORMATION AVAILABLE) [脊椎障害] | 20[redacted]-07-29 * | 205 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-01-05 * | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | WORSENING HYPERTENSION [高血圧] | 20[redacted]-08-04 * | 211 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-08-04 * | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | WORSENING NAUSEA [悪心] | 20[redacted]-08-04 | 211 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-08-04 | - |

年齢以外のマスキングにおいて,
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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time ** | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | NONPRODUCTIVE COUGH [咳嗽] | 20[redacted]-08-14 * | 221 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-05 * | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | MULTIPLE AREAS OF SKIN BREAKDOWN RIGHT FOOT [皮膚障害] | 20[redacted]-08-25 * | 232 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT, CULTURE TAKEN, IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-09-02 * | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | DIABETIC FOOT ULCER [糖尿病性足病変] | 20[redacted]-09-03 * | 241 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, CULTURE TAKEN, IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-09-09 * | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | OCCLUSION OF ANTERIOR TIBIAL ARTERY AT LEVEL OF RIGHT ANKLE [末梢動脈閉塞性疾患] | 20[redacted]-09-04 | 242 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-09-09 | - |

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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term[*1]] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time * | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | OCCLUSION OF POSTERIOR TIBIAL ARTERY AT LEVEL OF RIGHT ANKLE [末梢動脈閉塞性疾患] | 20[redacted]-09-04 * | 242 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-09-09 * | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | RESOLVING DIABETIC FOOT ULCER [糖尿病性足病変] | 20[redacted]-09-10 * | 248 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-10-29 ** | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | METABOLIC ALKALOSIS [代謝性アルカローシス] | 20[redacted]-09-22 * | 260 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-05 * | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | NON-HEALING DIABETIC FOOT ULCER, RIGHT FOOT [糖尿病性足病変] | 20[redacted]-10-30 * | 298 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-11-04 * | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | RESOLVING DIABETIC FOOT ULCER [糖尿病性足病変] | 20[redacted]-11-05 | 304 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-28 | - |

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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term[*1]] | Start Date/Time * | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time ** | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | NON-HEALING DIABETIC FOOT ULCER, RIGHT FOOT [糖尿病性足病変] | 20[redacted]-12-29 * | 358 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-01-05 ** | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SEPSIS [敗血症] | 20[redacted]-12-30 ** | 359 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-01-05 ** | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ACUTE ENCEPHALOPATHY [脳症] | 20[redacted]-01-02 ** | 362 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-05 ** | - |
| AMG 416 | 20120359-35966038004 | 3[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | VENTRICULAR FIBRILLATION [心室細動] | 20[redacted]-01-05 | 365 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-01-05 | - |
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | DYSPEPSIA [消化不良] | 20[redacted]-01-07 | 13 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-01-07 | - |
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | DIARRHEA [下痢] | 20[redacted]-01-19 | 25 | MODERATE | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-02-05 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | FATIGUE [疲労] | 20[redacted]-02-01 | 38 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-24 | - |
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | LOW SERUM CALCIUM [血中カルシウム減少] | 20[redacted]-02-27T10:50 | 64 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | RELATED | 20[redacted]-04-10T11:26 | - |
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | ABRASION LEFT WRIST [皮膚擦過傷] | 20[redacted]-04-02T16:00 | 98 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-16 | - |
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | ABRASION RIGHT ELBOW [皮膚擦過傷] | 20[redacted]-04-02T16:00 | 98 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-16 | - |
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | FRACTURE RIGHT 4TH FINGER [手骨折] | 20[redacted]-04-02T16:00 | 98 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-05-24 | - |
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | HEAD ABRASION - SMALL [皮膚擦過傷] | 20[redacted]-04-02T16:00 | 98 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-16 | - |
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | PAIN - RIGHT HAND FINGERS [四肢痛] | 20[redacted]-04-02T16:00 | 98 | MODERATE | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-04-16 | - |
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | DIARRHEA [下痢] | 20[redacted]-04-12 | 108 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-12 | - |
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | CARDIAC ARREST [心停止] | 20[redacted]-05-24 | 150 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-05-24 | - |
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | HYPOGLYCEMIA [低血糖症] | 20[redacted]-05-24 | 150 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-05-24 | - |

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| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120359-35966040006 | 6[redacted] | M | WHITE | HISPANIC OR LATINO | VENTRICULAR FIBRILLATION [心室細動] | 20[redacted]-05-24 | 150 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-05-24 | - |
| AMG 416 | 20120359-35966047003 | 8[redacted] | M | WHITE | HISPANIC OR LATINO | CELLULITIS [蜂巣炎] | 20[redacted]-12-31* | -41 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | ONGOING | - |
| AMG 416 | 20120359-35966047003 | 8[redacted] | M | WHITE | HISPANIC OR LATINO | INABILITY TO GET TO SLEEP [不眠症] | 20[redacted]-02-26* | 17 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | ONGOING* | - |
| AMG 416 | 20120359-35966047003 | 8[redacted] | M | WHITE | HISPANIC OR LATINO | UPPER RESPIRATORY FLUE-LIKE SYMPTOMS [インフルエンザ様疾患] | 20[redacted]-04-25* | 75 | MILD | NO | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-27 | - |
| AMG 416 | 20120359-35966047003 | 8[redacted] | M | WHITE | HISPANIC OR LATINO | FALL [転倒] | 20[redacted]-07-20T17:00* | 161 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | ONGOING* | - |
| AMG 416 | 20120359-35966047003 | 8[redacted] | M | WHITE | HISPANIC OR LATINO | WITHDRAWL FROM DIALYSIS [治療中断] | 20[redacted]-08-12 | 184 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-08-17* | - |
| AMG 416 | 20120359-35966057002 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | METABOLIC ACIDOSIS [代謝性アシドーシス] | 20[redacted]-10-18* | -117 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-09-14T06:00* | - |
| AMG 416 | 20120359-35966057002 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | BLEEDING HEMORRHOIDS [痔出血] | 20[redacted]-06-23T07:00* | 132 | MILD | NO | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-09-14* | - |
| AMG 416 | 20120359-35966057002 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | DECREASE IN HEMOGLOBIN [ヘモグロビン減少] | 20[redacted]-06-25 | 134 | MILD | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-09-14 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120359-35966057002 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | PLACEMENT OF RIGHT LEG STENT [ステント装着] | 20[redacted]-07-16 * | 155 | MODERATE | NO | - | DOSE NOT CHANGED | MEDICATION TAKEN, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-07-16 * | - |
| AMG 416 | 20120359-35966057002 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | LEFT LEG INFECTED GRAFT [移植片感染] | 20[redacted]-08-18T12:00 * | 188 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-09-14 * | - |
| AMG 416 | 20120359-35966057002 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | LEFT HIP FRACTURE [股関節部骨折] | 20[redacted]-08-25T10:00 * | 195 | SEVERE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-09-14 * | - |
| AMG 416 | 20120359-35966057002 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | NECROTIC BOWEL [消化管壊死] | 20[redacted]-09-12T12:00 * | 213 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-09-14T08:00 * | - |
| AMG 416 | 20120359-35966057002 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | PERFORATED BOWEL [腸管穿孔] | 20[redacted]-09-12T12:00 * | 213 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-09-14T08:00 * | - |
| AMG 416 | 20120359-35966057002 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | CARDIAC ARREST [心停止] | 20[redacted]-09-14T12:00 * | 215 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-14T14:46 * | - |
| AMG 416 | 20120359-35966057002 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | MEGAN COLON TOXIC [巨大結腸] | 20[redacted]-09-14T12:00 | 215 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-14T14:46 * | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120359-35966057002 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | SEPTIC SHOCK [敗血症性ショック] | 20[redacted]-09-14T12:00 | 215 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-14T14:46 | - |

*1:MedDRA Version 18.0J
AMG 416 = ONO-5163

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＊＊　：「翌々年」を意味する

**表 2.7.4.7-19　死亡例の一覧表（20130213 試験）**

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120360-36021004003 | 5[redacted] | F | WHITE | NOT HISPANIC OR LATINO | PROGRESSIVE SEPSIS [敗血症] | 20[redacted]-09-19 | 22 | LIFE THREATENING | YES | Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-09-26 | FATAL |
| AMG 416 | 20120360-36066059001 | 4[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | INTERNAL HEMORRHAGE (BRAIN) [脳出血] | 20[redacted]-09-22 | 19 | LIFE THREATENING | YES | Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG INTERRUPTED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-03 | FATAL |
| AMG 416 | 20120360-36066059001 | 4[redacted] | M | ASIAN | NOT HISPANIC OR LATINO | WORSENING HYPERTENSION [高血圧] | 20[redacted]-09-22 | 19 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG INTERRUPTED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-03 | NOT RECOVERED/NOT RESOLVED |
| AMG 416 | KAI-4169-005-0511-1515 | 5[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | CHEST PAIN [胸痛] | 20[redacted]-08-04 | 4 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG INTERRUPTED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-08 | RECOVERED/RESOLVED |

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | KAI-4169-005-0511-1515 | 5[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ANOXIC BRAIN INJURY [脳損傷] | 20[redacted]-08-22 | 22 | LIFE THREATENING | YES | Persist or Signif Disability/Incapacity, Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-09-08 | FATAL |
| AMG 416 | KAI-4169-005-0511-1515 | 5[redacted] | F | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | CARDIAC ARREST [心停止] | 20[redacted]-08-22 | 22 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening, Other Medically Important Serious Event | DRUG INTERRUPTED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-08 | RECOVERED/RESOLVED |
| AMG 416 | KAI-4169-005-0511-1532 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | MALFUNTIONING HEMODIALYSIS CATHETER [医療機器合併症] | 20[redacted]-07-14 | -2 | MODERATE | NO | - | DOSE NOT CHANGED | DEVICE / PROCEDURE INTERVENTION | - | 20[redacted]-07-14* | - |
| AMG 416 | KAI-4169-005-0511-1532 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | LOWER GASTROINTESTINAL BLEED [胃腸出血] | 20[redacted]-10-20* | 97 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG INTERRUPTED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-19* | RECOVERED/RESOLVED |
| AMG 416 | KAI-4169-005-0511-1532 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | CENTRAL VENOUS CATHETER ASSOCIATED MRSA BACTEREMIA [医療機器関連感染] | 20[redacted]-01-02 | 171 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG INTERRUPTED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-19* | RECOVERED/RESOLVED |

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | KAI-4169-005-0511-1532 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | ALTERED MENTAL STATUS [精神状態変化] | 20[redacted]-01-03 * | 172 | SEVERE | YES | Requires or Prolongs Hospitalization, Other Medically Important Serious Event | DRUG INTERRUPTED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-19 * | RECOVERED/RESOLVED |
| AMG 416 | KAI-4169-005-0511-1532 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | VENTILATOR DEPENDENT RESPIRATORY FAILURE [レスピレータ依存] | 20[redacted]-01-03 * | 172 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG INTERRUPTED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-19 * | FATAL |
| AMG 416 | KAI-4169-005-0511-1532 | 6[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | MITRAL VALVE ENDOCARDITIS [心内膜炎] | 20[redacted]-01-07 | 176 | SEVERE | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DRUG INTERRUPTED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-19 * | RECOVERED/RESOLVED |
| NOT TREATED | 20120359-35966031011 | 5[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | BOWEL OBSTRUCTION [腸閉塞] | 20[redacted]-01-27 | - | SEVERE | YES | Requires or Prolongs Hospitalization, Is Life Threatening | - | HOSPITALIZED / PROLONGED HOSPITALIZATION | - | 20[redacted]-01-30 | RECOVERED/RESOLVED |
| NOT TREATED | 20120359-35966031011 | 5[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | HYPERPOTASSEMIA [高カリウム血症] | 20[redacted]-01-27 | - | SEVERE | YES | Requires or Prolongs Hospitalization | - | HOSPITALIZED / PROLONGED HOSPITALIZATION | - | 20[redacted]-01-30 | RECOVERED/RESOLVED |
| NOT TREATED | 20120359-35966031011 | 5[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | HYPOTENSION [低血圧] | 20[redacted]-01-27 | - | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG INTERRUPTED | HOSPITALIZED / PROLONGED HOSPITALIZATION | - | 20[redacted]-01-30 | RECOVERED/RESOLVED |

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

| Treatment Group | Usubject ID | Age (years) | Sex | Race | Ethnicity | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| NOT TREATED | 20120359-35966031011 | 5[redacted] | M | BLACK OR AFRICAN AMERICAN | NOT HISPANIC OR LATINO | VENTRICULAR FIBRILLATION [心室細動] | 20[redacted]-01-30 | - | LIFE THREATENING | YES | Persist or Signif Disability/Incapacity, Results in Death, Is Life Threatening, Other Medically Important Serious Event | - | UNKNOWN | - | 20[redacted]-01-30 | FATAL |

*1:MedDRA Version 17.1J
AMG 416 = ONO-5163

年齢以外のマスキングにおいて,
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 全体 | 161/269.4 ( 59.8) | 42.0 | 142/293.8 ( 48.3) | 37.0 | 53/79.8 ( 66.4) | 43.1 | 356/643.0 ( 55.4) | 40.0 |
| 血液およびリンパ系障害 | 4/361.8 ( 1.1) | 1.0 | 3/368.6 ( 0.8) | 0.8 | 5/106.7 ( 4.7) | 4.1 | 12/837.1 ( 1.4) | 1.3 |
| 貧血 | 3/361.9 ( 0.8) | 0.8 | 1/369.7 ( 0.3) | 0.3 | 2/108.0 ( 1.9) | 1.6 | 6/839.6 ( 0.7) | 0.7 |
| 慢性疾患の貧血 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.2 ( 0.9) | 0.8 | 1/842.7 ( 0.1) | 0.1 |
| 出血性貧血 | 0/363.1 ( 0.0) | 0.0 | 1/369.6 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 白血球増加症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.3 ( 0.9) | 0.8 | 1/842.8 ( 0.1) | 0.1 |
| リンパ節症 | 0/363.1 ( 0.0) | 0.0 | 1/370.0 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 腎性貧血 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 1/843.2 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
n＝有害事象発現例数.
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.
出典［総括報告書 5.3.5.2-4（20120231 試験）Table 14-6.5 改変］

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 1）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 血小板減少症 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 心臓障害 | 46/343.8 ( 13.4) | 12.0 | 40/353.0 ( 11.3) | 10.4 | 14/104.6 ( 13.4) | 11.4 | 100/801.4 ( 12.5) | 11.2 |
| うっ血性心不全 | 8/357.9 ( 2.2) | 2.1 | 7/365.9 ( 1.9) | 1.8 | 3/108.1 ( 2.8) | 2.4 | 18/831.9 ( 2.2) | 2.0 |
| 心房細動 | 9/358.1 ( 2.5) | 2.3 | 4/368.5 ( 1.1) | 1.0 | 0/109.8 ( 0.0) | 0.0 | 13/836.4 ( 1.6) | 1.5 |
| 心停止 | 6/361.4 ( 1.7) | 1.6 | 2/370.4 ( 0.5) | 0.5 | 4/109.8 ( 3.6) | 3.3 | 12/841.6 ( 1.4) | 1.3 |
| 急性心筋梗塞 | 5/361.3 ( 1.4) | 1.3 | 6/367.1 ( 1.6) | 1.6 | 0/109.8 ( 0.0) | 0.0 | 11/838.2 ( 1.3) | 1.2 |
| 冠動脈疾患 | 3/362.7 ( 0.8) | 0.8 | 6/368.3 ( 1.6) | 1.6 | 0/109.8 ( 0.0) | 0.0 | 9/840.8 ( 1.1) | 1.0 |
| 狭心症 | 2/361.6 ( 0.6) | 0.5 | 3/368.8 ( 0.8) | 0.8 | 2/108.7 ( 1.8) | 1.6 | 7/839.2 ( 0.8) | 0.8 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 2）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 心筋梗塞 | 2/361.9 ( 0.6) | 0.5 | 4/368.2 ( 1.1) | 1.0 | 1/109.3 ( 0.9) | 0.8 | 7/839.4 ( 0.8) | 0.8 |
| 心室細動 | 2/363.1 ( 0.6) | 0.5 | 2/370.4 ( 0.5) | 0.5 | 2/109.8 ( 1.8) | 1.6 | 6/843.3 ( 0.7) | 0.7 |
| 徐脈 | 2/362.5 ( 0.6) | 0.5 | 2/369.5 ( 0.5) | 0.5 | 1/108.9 ( 0.9) | 0.8 | 5/840.9 ( 0.6) | 0.6 |
| 心不全 | 2/363.0 ( 0.6) | 0.5 | 3/369.5 ( 0.8) | 0.8 | 0/109.8 ( 0.0) | 0.0 | 5/842.4 ( 0.6) | 0.6 |
| 急性冠動脈症候群 | 3/362.1 ( 0.8) | 0.8 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 4/842.3 ( 0.5) | 0.4 |
| 心肺停止 | 1/363.1 ( 0.3) | 0.3 | 3/370.4 ( 0.8) | 0.8 | 0/109.8 ( 0.0) | 0.0 | 4/843.3 ( 0.5) | 0.4 |
| 完全房室ブロック | 1/363.1 ( 0.3) | 0.3 | 1/369.6 ( 0.3) | 0.3 | 1/109.1 ( 0.9) | 0.8 | 3/841.8 ( 0.4) | 0.3 |
| 冠動脈狭窄 | 3/361.7 ( 0.8) | 0.8 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 3/842.0 ( 0.4) | 0.3 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 3）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 上室性頻脈 | 1/363.0 ( 0.3) | 0.3 | 2/370.1 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 3/843.0 ( 0.4) | 0.3 |
| 不安定狭心症 | 1/363.1 ( 0.3) | 0.3 | 1/369.9 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.8 ( 0.2) | 0.2 |
| 心房粗動 | 1/362.6 ( 0.3) | 0.3 | 1/369.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/841.8 ( 0.2) | 0.2 |
| 心原性ショック | 1/363.1 ( 0.3) | 0.3 | 1/369.6 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.6 ( 0.2) | 0.2 |
| 心筋虚血 | 2/362.2 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/842.4 ( 0.2) | 0.2 |
| 洞結節機能不全 | 0/363.1 ( 0.0) | 0.0 | 2/370.3 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 2/843.2 ( 0.2) | 0.2 |
| 大動脈弁疾患 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 大動脈弁閉鎖不全症 | 1/362.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 4）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 大動脈弁狭窄 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 不整脈 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.1 ( 0.9) | 0.8 | 1/842.6 ( 0.1) | 0.1 |
| 心障害 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 急性心不全 | 0/363.1 ( 0.0) | 0.0 | 1/370.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 慢性心不全 | 1/362.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 心臓弁膜疾患 | 1/362.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 心筋症 | 1/362.6 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| 心血管不全 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 5）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 僧帽弁閉鎖不全症 | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 動悸 | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 心嚢液貯留 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 1/843.3 ( 0.1) | 0.1 |
| 頻脈 | 1/362.7 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| トルサード　ド　ポアント | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 三尖弁閉鎖不全症 | 1/362.4 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |
| 耳および迷路障害 | 2/361.9 ( 0.6) | 0.5 | 2/369.6 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 4/841.3 ( 0.5) | 0.4 |
| 回転性めまい | 2/361.9 ( 0.6) | 0.5 | 1/369.6 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 3/841.3 ( 0.4) | 0.3 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 6）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 感音性難聴 | 0/363.1 ( 0.0) | 0.0 | 1/370.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 内分泌障害 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 甲状腺腫 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 眼障害 | 3/361.9 ( 0.8) | 0.8 | 1/370.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 4/842.1 ( 0.5) | 0.4 |
| 白内障 | 0/363.1 ( 0.0) | 0.0 | 1/370.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 複視 | 1/362.4 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 水晶体脱臼 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 視神経症 | 1/362.7 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 7）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 胃腸障害 | 35/344.3 ( 10.2) | 9.1 | 21/359.2 ( 5.8) | 5.5 | 11/102.7 ( 10.7) | 8.9 | 67/806.3 ( 8.3) | 7.5 |
| 胃腸出血 | 2/361.1 ( 0.6) | 0.5 | 4/368.4 ( 1.1) | 1.0 | 4/107.6 ( 3.7) | 3.3 | 10/837.1 ( 1.2) | 1.1 |
| 腹痛 | 3/362.1 ( 0.8) | 0.8 | 3/368.8 ( 0.8) | 0.8 | 1/109.0 ( 0.9) | 0.8 | 7/839.9 ( 0.8) | 0.8 |
| 嘔吐 | 3/361.4 ( 0.8) | 0.8 | 1/369.5 ( 0.3) | 0.3 | 1/108.9 ( 0.9) | 0.8 | 5/839.8 ( 0.6) | 0.6 |
| 下痢 | 2/362.1 ( 0.6) | 0.5 | 2/369.1 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 4/841.0 ( 0.5) | 0.4 |
| 小腸閉塞 | 1/362.6 ( 0.3) | 0.3 | 2/368.5 ( 0.5) | 0.5 | 1/109.1 ( 0.9) | 0.8 | 4/840.1 ( 0.5) | 0.4 |
| びらん性胃炎 | 1/362.7 ( 0.3) | 0.3 | 2/369.9 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 3/842.4 ( 0.4) | 0.3 |
| 出血性胃炎 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 2/108.9 ( 1.8) | 1.6 | 3/842.0 ( 0.4) | 0.3 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 8）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 腸管虚血 | 3/361.2 ( 0.8) | 0.8 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 3/841.4 ( 0.4) | 0.3 |
| 急性膵炎 | 2/361.4 ( 0.6) | 0.5 | 1/369.8 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 3/841.0 ( 0.4) | 0.3 |
| 下腹部痛 | 1/363.0 ( 0.3) | 0.3 | 1/369.5 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.4 ( 0.2) | 0.2 |
| 虚血性大腸炎 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 1/109.6 ( 0.9) | 0.8 | 2/842.3 ( 0.2) | 0.2 |
| 便秘 | 1/362.2 ( 0.3) | 0.3 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.3 ( 0.2) | 0.2 |
| 胃炎 | 2/362.2 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/842.4 ( 0.2) | 0.2 |
| 吐血 | 0/363.1 ( 0.0) | 0.0 | 1/369.6 ( 0.3) | 0.3 | 1/109.8 ( 0.9) | 0.8 | 2/842.5 ( 0.2) | 0.2 |
| 悪心 | 1/362.6 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 1/108.9 ( 0.9) | 0.8 | 2/841.8 ( 0.2) | 0.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 9）**
**解析対象集団：SAF**

| SOC | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 上部消化管出血 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 1/109.3 ( 0.9) | 0.8 | 2/842.0 ( 0.2) | 0.2 |
| 腹部癒着 | 0/363.1 ( 0.0) | 0.0 | 1/369.6 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 上腹部痛 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.0 ( 0.9) | 0.8 | 1/842.5 ( 0.1) | 0.1 |
| 腹壁血腫 | 1/362.5 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |
| 肛門直腸静脈瘤出血 | 1/362.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 腹水 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.2 ( 0.9) | 0.8 | 1/842.7 ( 0.1) | 0.1 |
| 大腸炎 | 0/363.1 ( 0.0) | 0.0 | 1/370.1 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 齲歯 | 0/363.1 ( 0.0) | 0.0 | 1/370.1 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 10）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 糖尿病性胃不全麻痺 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/108.8 ( 0.9) | 0.8 | 1/842.3 ( 0.1) | 0.1 |
| 憩室穿孔 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 腸憩室 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 十二指腸潰瘍 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 小腸炎 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 腸管皮膚瘻 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 胃前庭部毛細血管拡張症 | 0/363.1 ( 0.0) | 0.0 | 1/369.5 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 胃障害 | 1/362.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 11）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 胃出血 | 0/363.1 ( 0.0) | 0.0 | 1/369.8 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |
| 消化管壊死 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 1/843.3 ( 0.1) | 0.1 |
| 胃腸血管奇形 | 0/363.1 ( 0.0) | 0.0 | 1/369.5 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 胃食道逆流性疾患 | 1/362.7 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| 痔出血 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| 痔核 | 0/363.1 ( 0.0) | 0.0 | 1/370.1 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| イレウス | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 鼠径ヘルニア | 1/362.5 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.8 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 12）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 腸管穿孔 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 1/843.3 ( 0.1) | 0.1 |
| 大腸穿孔 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 大腸ポリープ | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 巨大結腸 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 1/843.3 ( 0.1) | 0.1 |
| 食道炎 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 膵管閉塞 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 膵炎 | 0/363.1 ( 0.0) | 0.0 | 1/369.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 直腸出血 | 1/362.7 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 13）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 亜イレウス | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 一般・全身障害および投与部位の状態 | 20/351.2 ( 5.7) | 5.2 | 18/359.6 ( 5.0) | 4.7 | 10/105.1 ( 9.5) | 8.1 | 48/815.9 ( 5.9) | 5.4 |
| 非心臓性胸痛 | 6/358.6 ( 1.7) | 1.6 | 5/367.4 ( 1.4) | 1.3 | 1/109.4 ( 0.9) | 0.8 | 12/835.4 ( 1.4) | 1.3 |
| 胸痛 | 3/361.7 ( 0.8) | 0.8 | 7/366.4 ( 1.9) | 1.8 | 1/109.3 ( 0.9) | 0.8 | 11/837.4 ( 1.3) | 1.2 |
| 発熱 | 2/361.6 ( 0.6) | 0.5 | 2/369.4 ( 0.5) | 0.5 | 3/107.3 ( 2.8) | 2.4 | 7/838.2 ( 0.8) | 0.8 |
| 無力症 | 2/362.3 ( 0.6) | 0.5 | 2/368.4 ( 0.5) | 0.5 | 1/109.5 ( 0.9) | 0.8 | 5/840.2 ( 0.6) | 0.6 |
| 突然死 | 1/363.1 ( 0.3) | 0.3 | 1/370.4 ( 0.3) | 0.3 | 1/109.8 ( 0.9) | 0.8 | 3/843.3 ( 0.4) | 0.3 |
| 医療機器関連の血栓症 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 2/109.2 ( 1.8) | 1.6 | 3/842.7 ( 0.4) | 0.3 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 14）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 医薬品副作用 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 医療機器閉塞 | 1/362.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 薬剤耐性 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 出血性嚢胞 | 0/363.1 ( 0.0) | 0.0 | 1/369.6 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 高熱 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 悪性高熱 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.7 ( 0.9) | 0.8 | 1/843.2 ( 0.1) | 0.1 |
| 低体温 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 治癒不良 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 15）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 肝胆道系障害 | 4/360.8 ( 1.1) | 1.0 | 8/368.2 ( 2.2) | 2.1 | 0/109.8 ( 0.0) | 0.0 | 12/838.8 ( 1.4) | 1.3 |
| 胆嚢炎 | 2/362.4 ( 0.6) | 0.5 | 3/369.5 ( 0.8) | 0.8 | 0/109.8 ( 0.0) | 0.0 | 5/841.7 ( 0.6) | 0.6 |
| 胆石症 | 1/362.4 ( 0.3) | 0.3 | 2/370.2 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 3/842.4 ( 0.4) | 0.3 |
| 胆管結石 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 胆道仙痛 | 1/362.5 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |
| 急性胆管炎 | 0/363.1 ( 0.0) | 0.0 | 1/369.7 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |
| 肝硬変 | 0/363.1 ( 0.0) | 0.0 | 1/370.1 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 急性肝炎 | 0/363.1 ( 0.0) | 0.0 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 16）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 肝毒性 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 免疫系障害 | 3/362.1 ( 0.8) | 0.8 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 3/842.3 ( 0.4) | 0.3 |
| 薬物過敏症 | 1/362.6 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.8 ( 0.1) | 0.1 |
| 過敏症 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 季節性アレルギー | 1/362.7 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| 感染症および寄生虫症 | 57/332.7 ( 17.1) | 14.9 | 39/353.5 ( 11.0) | 10.2 | 16/102.2 ( 15.7) | 13.0 | 112/788.4 ( 14.2) | 12.6 |
| 肺炎 | 7/359.9 ( 1.9) | 1.8 | 5/368.4 ( 1.4) | 1.3 | 3/109.0 ( 2.8) | 2.4 | 15/837.3 ( 1.8) | 1.7 |
| 敗血症 | 10/359.1 ( 2.8) | 2.6 | 2/369.9 ( 0.5) | 0.5 | 3/108.8 ( 2.8) | 2.4 | 15/837.9 ( 1.8) | 1.7 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 17）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 蜂巣炎 | 8/358.7 ( 2.2) | 2.1 | 4/369.1 ( 1.1) | 1.0 | 1/109.4 ( 0.9) | 0.8 | 13/837.1 ( 1.6) | 1.5 |
| 骨髄炎 | 4/360.4 ( 1.1) | 1.0 | 3/369.7 ( 0.8) | 0.8 | 1/109.4 ( 0.9) | 0.8 | 8/839.6 ( 1.0) | 0.9 |
| 胃腸炎 | 6/359.1 ( 1.7) | 1.6 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 6/839.3 ( 0.7) | 0.7 |
| インフルエンザ | 3/362.4 ( 0.8) | 0.8 | 1/369.5 ( 0.3) | 0.3 | 2/108.4 ( 1.8) | 1.6 | 6/840.3 ( 0.7) | 0.7 |
| 敗血症性ショック | 3/362.9 ( 0.8) | 0.8 | 1/370.4 ( 0.3) | 0.3 | 2/109.1 ( 1.8) | 1.6 | 6/842.3 ( 0.7) | 0.7 |
| 動静脈グラフト部位感染 | 1/362.5 ( 0.3) | 0.3 | 1/369.7 ( 0.3) | 0.3 | 2/108.8 ( 1.8) | 1.6 | 4/840.9 ( 0.5) | 0.4 |
| 菌血症 | 2/361.4 ( 0.6) | 0.5 | 2/369.2 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 4/840.5 ( 0.5) | 0.4 |
| 感染性皮膚潰瘍 | 3/362.4 ( 0.8) | 0.8 | 1/369.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 4/841.6 ( 0.5) | 0.4 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 18）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 尿路感染 | 1/362.8 ( 0.3) | 0.3 | 2/369.6 ( 0.5) | 0.5 | 1/109.2 ( 0.9) | 0.8 | 4/841.6 ( 0.5) | 0.4 |
| 医療機器関連敗血症 | 1/362.7 ( 0.3) | 0.3 | 1/369.5 ( 0.3) | 0.3 | 1/109.5 ( 0.9) | 0.8 | 3/841.7 ( 0.4) | 0.3 |
| 上気道感染 | 1/362.9 ( 0.3) | 0.3 | 1/370.2 ( 0.3) | 0.3 | 1/109.1 ( 0.9) | 0.8 | 3/842.3 ( 0.4) | 0.3 |
| 尿路性敗血症 | 1/362.2 ( 0.3) | 0.3 | 2/369.8 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 3/841.8 ( 0.4) | 0.3 |
| 気管支肺炎 | 1/362.4 ( 0.3) | 0.3 | 1/370.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.6 ( 0.2) | 0.2 |
| 医療機器関連感染 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 1/109.2 ( 0.9) | 0.8 | 2/842.4 ( 0.2) | 0.2 |
| 糖尿病性壊疽 | 0/363.1 ( 0.0) | 0.0 | 1/369.6 ( 0.3) | 0.3 | 1/108.8 ( 0.9) | 0.8 | 2/841.6 ( 0.2) | 0.2 |
| 憩室炎 | 1/362.8 ( 0.3) | 0.3 | 1/369.9 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.5 ( 0.2) | 0.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 19）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 壊疽 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 2/108.1 ( 1.8) | 1.6 | 2/841.6 ( 0.2) | 0.2 |
| 帯状疱疹 | 2/362.3 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/842.5 ( 0.2) | 0.2 |
| 椎間板炎 | 2/361.5 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/841.7 ( 0.2) | 0.2 |
| 限局性感染 | 0/363.1 ( 0.0) | 0.0 | 1/369.9 ( 0.3) | 0.3 | 1/109.1 ( 0.9) | 0.8 | 2/842.1 ( 0.2) | 0.2 |
| 下気道感染 | 2/361.3 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/841.5 ( 0.2) | 0.2 |
| 皮膚感染 | 1/363.0 ( 0.3) | 0.3 | 1/369.5 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.3 ( 0.2) | 0.2 |
| ブドウ球菌性菌血症 | 1/362.5 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 1/108.9 ( 0.9) | 0.8 | 2/841.7 ( 0.2) | 0.2 |
| ブドウ球菌性敗血症 | 1/362.5 ( 0.3) | 0.3 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.5 ( 0.2) | 0.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 20）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 気管気管支炎 | 2/362.0 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/842.2 ( 0.2) | 0.2 |
| 創傷感染 | 2/362.1 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/842.3 ( 0.2) | 0.2 |
| 腹壁膿瘍 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 四肢膿瘍 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| アシネトバクター性菌血症 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| アシネトバクター感染 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| 虫垂炎 | 1/362.6 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.8 ( 0.1) | 0.1 |
| 細菌性敗血症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 1/843.2 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 21）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 細菌性気管炎 | 1/362.7 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| 気管支炎 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| カンピロバクター胃腸炎 | 0/363.1 ( 0.0) | 0.0 | 1/369.9 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.8 ( 0.1) | 0.1 |
| クロストリジウム・ディフィシレ大腸炎 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| クロストリジウム・ディフィシレ感染 | 0/363.1 ( 0.0) | 0.0 | 1/370.1 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 膀胱炎 | 0/363.1 ( 0.0) | 0.0 | 1/369.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 心内膜炎 | 1/362.4 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 感染性腸炎 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 22）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 丹毒 | 0/363.1 ( 0.0) | 0.0 | 1/369.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 大腸菌性菌血症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.0 ( 0.9) | 0.8 | 1/842.4 ( 0.1) | 0.1 |
| ウイルス性胃腸炎 | 1/362.6 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.8 ( 0.1) | 0.1 |
| 性器膿瘍 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| 移植片感染 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 1/843.3 ( 0.1) | 0.1 |
| ヘリコバクター性胃炎 | 0/363.1 ( 0.0) | 0.0 | 1/369.9 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| 伝染性単核症 | 0/363.1 ( 0.0) | 0.0 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 急性骨髄炎 | 1/362.5 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 23）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 直腸周囲膿瘍 | 0/363.1 ( 0.0) | 0.0 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 腹膜炎 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 細菌性肺炎 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| 術後創感染 | 0/363.1 ( 0.0) | 0.0 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 腎嚢胞感染 | 0/363.1 ( 0.0) | 0.0 | 1/369.6 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 気道感染 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| シャント感染 | 0/363.1 ( 0.0) | 0.0 | 1/370.1 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 皮下組織膿瘍 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 24）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 気管炎 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| ウイルス感染 | 1/362.4 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| ウイルス性上気道感染 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 膿創 | 0/363.1 ( 0.0) | 0.0 | 1/370.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 傷害、中毒および処置合併症 | 34/342.3 ( 9.9) | 8.9 | 40/350.5 ( 11.4) | 10.4 | 12/104.2 ( 11.5) | 9.8 | 86/797.0 ( 10.8) | 9.7 |
| 動静脈瘻部位合併症 | 7/358.0 ( 2.0) | 1.8 | 6/367.5 ( 1.6) | 1.6 | 0/109.8 ( 0.0) | 0.0 | 13/835.4 ( 1.6) | 1.5 |
| 動静脈瘻血栓症 | 4/360.5 ( 1.1) | 1.0 | 6/366.2 ( 1.6) | 1.6 | 0/109.8 ( 0.0) | 0.0 | 10/836.6 ( 1.2) | 1.1 |
| 動静脈瘻部位出血 | 3/362.3 ( 0.8) | 0.8 | 4/367.8 ( 1.1) | 1.0 | 1/109.0 ( 0.9) | 0.8 | 8/839.0 ( 1.0) | 0.9 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
n＝有害事象発現例数.
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 25）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 血管グラフト血栓症 | 4/360.1 ( 1.1) | 1.0 | 2/369.9 ( 0.5) | 0.5 | 2/109.1 ( 1.8) | 1.6 | 8/839.1 ( 1.0) | 0.9 |
| 移植血管合併症 | 0/363.1 ( 0.0) | 0.0 | 2/369.2 ( 0.5) | 0.5 | 2/108.7 ( 1.8) | 1.6 | 4/841.0 ( 0.5) | 0.4 |
| 転倒 | 0/363.1 ( 0.0) | 0.0 | 2/370.0 ( 0.5) | 0.5 | 1/109.8 ( 0.9) | 0.8 | 3/842.8 ( 0.4) | 0.3 |
| 足骨折 | 3/361.3 ( 0.8) | 0.8 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 3/841.5 ( 0.4) | 0.3 |
| 足関節部骨折 | 0/363.1 ( 0.0) | 0.0 | 1/370.1 ( 0.3) | 0.3 | 1/109.1 ( 0.9) | 0.8 | 2/842.4 ( 0.2) | 0.2 |
| 動静脈瘻閉塞 | 0/363.1 ( 0.0) | 0.0 | 2/369.0 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 2/841.9 ( 0.2) | 0.2 |
| 股関節部骨折 | 1/362.9 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 2/843.0 ( 0.2) | 0.2 |
| 橈骨骨折 | 0/363.1 ( 0.0) | 0.0 | 2/368.4 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 2/841.4 ( 0.2) | 0.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 26）**
**解析対象集団：SAF**

| SOC | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 硬膜下血腫 | 1/362.3 ( 0.3) | 0.3 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.3 ( 0.2) | 0.2 |
| 血管確保合併症 | 0/363.1 ( 0.0) | 0.0 | 2/369.5 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 2/842.4 ( 0.2) | 0.2 |
| 血管偽動脈瘤 | 1/362.6 ( 0.3) | 0.3 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.6 ( 0.2) | 0.2 |
| 頚椎骨折 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.4 ( 0.9) | 0.8 | 1/842.9 ( 0.1) | 0.1 |
| 鎖骨骨折 | 0/363.1 ( 0.0) | 0.0 | 1/369.7 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 移植腎の合併症 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 圧迫骨折 | 1/362.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 挫傷 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 27）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 冠動脈バイパス血栓症 | 0/363.1 ( 0.0) | 0.0 | 1/370.0 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| 透析関連合併症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.2 ( 0.9) | 0.8 | 1/842.7 ( 0.1) | 0.1 |
| 顔面骨骨折 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 大腿骨頚部骨折 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| 大腿骨骨折 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| 移植片血栓症 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 血液透析誘発症状 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/108.9 ( 0.9) | 0.8 | 1/842.4 ( 0.1) | 0.1 |
| 上腕骨骨折 | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 28）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 企図的過量投与 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 1/843.2 ( 0.1) | 0.1 |
| 顎の骨折 | 0/363.1 ( 0.0) | 0.0 | 1/369.7 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 下肢骨折 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 腰椎骨折 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 多発骨折 | 0/363.1 ( 0.0) | 0.0 | 1/370.0 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 膝蓋骨骨折 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 末梢動脈再閉塞 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 腎周囲血腫 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 29）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 処置後合併症 | 0/363.1 ( 0.0) | 0.0 | 1/369.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 処置後血腫 | 1/362.5 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |
| 術後呼吸不全 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 処置による低血圧 | 0/363.1 ( 0.0) | 0.0 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| シャント狭窄 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| シャント血栓症 | 0/363.1 ( 0.0) | 0.0 | 1/369.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 軟部組織損傷 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 脾臓損傷 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 30）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| ストーマ部疼痛 | 1/362.4 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 熱傷 | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 脛骨骨折 | 0/363.1 ( 0.0) | 0.0 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 各種物質毒性 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 1/843.2 ( 0.1) | 0.1 |
| 創傷 | 1/362.7 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| 創合併症 | 1/362.4 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 創離開 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.2 ( 0.9) | 0.8 | 1/842.7 ( 0.1) | 0.1 |
| 創傷出血 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 31）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 臨床検査 | 7/360.5 ( 1.9) | 1.8 | 3/368.9 ( 0.8) | 0.8 | 1/109.5 ( 0.9) | 0.8 | 11/838.9 ( 1.3) | 1.2 |
| 抗凝固薬濃度治療量以下 | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 1/109.5 ( 0.9) | 0.8 | 2/842.1 ( 0.2) | 0.2 |
| アスパラギン酸アミノトランスフェラーゼ増加 | 2/362.9 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/843.1 ( 0.2) | 0.2 |
| 国際標準比増加 | 1/362.3 ( 0.3) | 0.3 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.4 ( 0.2) | 0.2 |
| アラニンアミノトランスフェラーゼ増加 | 1/362.9 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 抱合ビリルビン増加 | 1/362.9 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 血中アルカリホスファターゼ増加 | 1/362.9 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 血中ビリルビン増加 | 1/362.9 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 32）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 血中カルシウム減少 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 血圧上昇 | 0/363.1 ( 0.0) | 0.0 | 1/369.9 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| C型肝炎抗体陽性 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| トロポニン増加 | 0/363.1 ( 0.0) | 0.0 | 1/369.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 体重減少 | 1/362.7 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| 代謝および栄養障害 | 25/350.9 ( 7.1) | 6.5 | 21/357.7 ( 5.9) | 5.5 | 8/105.4 ( 7.6) | 6.5 | 54/813.9 ( 6.6) | 6.1 |
| 高カリウム血症 | 14/356.1 ( 3.9) | 3.7 | 10/364.6 ( 2.7) | 2.6 | 5/107.1 ( 4.7) | 4.1 | 29/827.7 ( 3.5) | 3.3 |
| 水分過負荷 | 3/361.1 ( 0.8) | 0.8 | 8/365.4 ( 2.2) | 2.1 | 4/107.1 ( 3.7) | 3.3 | 15/833.6 ( 1.8) | 1.7 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 33）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 低血糖症 | 5/361.9 ( 1.4) | 1.3 | 4/368.0 ( 1.1) | 1.0 | 1/109.8 ( 0.9) | 0.8 | 10/839.7 ( 1.2) | 1.1 |
| 血液量増加症 | 1/362.2 ( 0.3) | 0.3 | 1/369.6 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/841.7 ( 0.2) | 0.2 |
| 低カルシウム血症 | 2/362.1 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/842.3 ( 0.2) | 0.2 |
| 脱水 | 1/362.7 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| 糖尿病 | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 糖尿病性ケトアシドーシス | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 成長障害 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 低リン酸血症 | 0/363.1 ( 0.0) | 0.0 | 1/369.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
n＝有害事象発現例数.
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 34）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 栄養障害 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 代謝性アシドーシス | 0/363.1 ( 0.0) | 0.0 | 1/369.6 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 筋骨格系および結合組織障害 | 9/359.7 ( 2.5) | 2.3 | 7/368.3 ( 1.9) | 1.8 | 3/107.9 ( 2.8) | 2.4 | 19/835.8 ( 2.3) | 2.1 |
| 関節痛 | 0/363.1 ( 0.0) | 0.0 | 1/369.3 ( 0.3) | 0.3 | 1/109.2 ( 0.9) | 0.8 | 2/841.6 ( 0.2) | 0.2 |
| 筋骨格痛 | 0/363.1 ( 0.0) | 0.0 | 2/369.8 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 2/842.7 ( 0.2) | 0.2 |
| 四肢痛 | 1/363.1 ( 0.3) | 0.3 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/843.1 ( 0.2) | 0.2 |
| 変形性脊椎症 | 2/361.3 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/841.5 ( 0.2) | 0.2 |
| 脊椎痛 | 2/362.1 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/842.3 ( 0.2) | 0.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 35）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 関節炎 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 骨痛 | 0/363.1 ( 0.0) | 0.0 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 滑液包炎 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 側腹部痛 | 0/363.1 ( 0.0) | 0.0 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 関節腫脹 | 1/362.9 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| 筋骨格系胸痛 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 神経障害性関節症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.1 ( 0.9) | 0.8 | 1/842.6 ( 0.1) | 0.1 |
| 変形性関節症 | 1/362.7 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 36）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 横紋筋融解症 | 1/362.5 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.8 ( 0.1) | 0.1 |
| 肩回旋筋腱板症候群 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.2 ( 0.9) | 0.8 | 1/842.7 ( 0.1) | 0.1 |
| 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） | 8/361.4 ( 2.2) | 2.1 | 4/368.2 ( 1.1) | 1.0 | 1/109.7 ( 0.9) | 0.8 | 13/839.3 ( 1.5) | 1.5 |
| 脊椎転移 | 2/362.9 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/843.1 ( 0.2) | 0.2 |
| 結腸腺癌 | 1/362.6 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.8 ( 0.1) | 0.1 |
| 膀胱腺癌、病期不明 | 0/363.1 ( 0.0) | 0.0 | 1/369.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 乳癌 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 腎明細胞癌 | 1/362.5 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 37）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 結腸癌第２期 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 遠隔転移を伴う肺癌 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 悪性新生物 | 0/363.1 ( 0.0) | 0.0 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 膵癌 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 前立腺癌 | 1/362.9 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| 肉腫 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.7 ( 0.9) | 0.8 | 1/843.1 ( 0.1) | 0.1 |
| 皮膚有棘細胞癌 | 0/363.1 ( 0.0) | 0.0 | 1/369.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 甲状腺新生物 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 38）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 神経系障害 | 19/354.6 ( 5.4) | 5.0 | 17/363.0 ( 4.7) | 4.4 | 7/105.9 ( 6.6) | 5.7 | 43/823.6 ( 5.2) | 4.8 |
| 失神 | 6/359.5 ( 1.7) | 1.6 | 2/369.5 ( 0.5) | 0.5 | 3/108.7 ( 2.8) | 2.4 | 11/837.7 ( 1.3) | 1.2 |
| 脳血管発作 | 3/362.3 ( 0.8) | 0.8 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 4/842.4 ( 0.5) | 0.4 |
| 脳症 | 0/363.1 ( 0.0) | 0.0 | 3/369.7 ( 0.8) | 0.8 | 1/109.8 ( 0.9) | 0.8 | 4/842.7 ( 0.5) | 0.4 |
| 痙攣発作 | 3/361.7 ( 0.8) | 0.8 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 4/841.8 ( 0.5) | 0.4 |
| 意識変容状態 | 0/363.1 ( 0.0) | 0.0 | 2/368.9 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 2/841.9 ( 0.2) | 0.2 |
| 頭痛 | 2/361.5 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/841.7 ( 0.2) | 0.2 |
| 感覚鈍麻 | 0/363.1 ( 0.0) | 0.0 | 2/369.4 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 2/842.4 ( 0.2) | 0.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 39）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 失神寸前の状態 | 0/363.1 ( 0.0) | 0.0 | 2/369.4 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 2/842.4 ( 0.2) | 0.2 |
| 一過性脳虚血発作 | 1/363.0 ( 0.3) | 0.3 | 1/369.8 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.7 ( 0.2) | 0.2 |
| 運動失調 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/108.8 ( 0.9) | 0.8 | 1/842.3 ( 0.1) | 0.1 |
| 頚動脈狭窄 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 脳出血 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 脳梗塞 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 浮動性めまい | 0/363.1 ( 0.0) | 0.0 | 1/369.7 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 全身性強直性間代性発作 | 1/362.7 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 40）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 頭蓋内出血 | 0/363.1 ( 0.0) | 0.0 | 1/370.0 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 不全片麻痺 | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 低酸素性虚血性脳症 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 意識消失 | 1/362.6 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.8 ( 0.1) | 0.1 |
| 感覚異常性大腿神経痛 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/108.9 ( 0.9) | 0.8 | 1/842.4 ( 0.1) | 0.1 |
| 代謝性脳症 | 0/363.1 ( 0.0) | 0.0 | 1/369.6 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 片頭痛 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.0 ( 0.9) | 0.8 | 1/842.5 ( 0.1) | 0.1 |
| くも膜下出血 | 0/363.1 ( 0.0) | 0.0 | 1/369.5 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 41）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 振戦 | 0/363.1 ( 0.0) | 0.0 | 1/370.2 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 精神障害 | 9/358.2 ( 2.5) | 2.3 | 2/369.2 ( 0.5) | 0.5 | 3/108.8 ( 2.8) | 2.4 | 14/836.2 ( 1.7) | 1.6 |
| 精神状態変化 | 6/359.6 ( 1.7) | 1.6 | 0/370.4 ( 0.0) | 0.0 | 2/108.8 ( 1.8) | 1.6 | 8/838.8 ( 1.0) | 0.9 |
| うつ病 | 0/363.1 ( 0.0) | 0.0 | 2/369.8 ( 0.5) | 0.5 | 1/109.8 ( 0.9) | 0.8 | 3/842.7 ( 0.4) | 0.3 |
| 錯乱状態 | 2/362.5 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/842.7 ( 0.2) | 0.2 |
| 譫妄 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 希死念慮を有するうつ病 | 0/363.1 ( 0.0) | 0.0 | 1/369.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 幻視 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 42）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 腎および尿路障害 | 4/361.3 ( 1.1) | 1.0 | 5/368.6 ( 1.4) | 1.3 | 2/109.2 ( 1.8) | 1.6 | 11/839.1 ( 1.3) | 1.2 |
| 高窒素血症 | 2/361.7 ( 0.6) | 0.5 | 2/369.9 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 4/841.4 ( 0.5) | 0.4 |
| 腎結石症 | 0/363.1 ( 0.0) | 0.0 | 1/369.7 ( 0.3) | 0.3 | 1/109.3 ( 0.9) | 0.8 | 2/842.1 ( 0.2) | 0.2 |
| 慢性腎臓病 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 血尿 | 1/362.8 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |
| 腎硬化症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 1/843.2 ( 0.1) | 0.1 |
| 腎仙痛 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.3 ( 0.9) | 0.8 | 1/842.8 ( 0.1) | 0.1 |
| 腎嚢胞出血 | 0/363.1 ( 0.0) | 0.0 | 1/369.8 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 43）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 腎機能障害 | 0/363.1 ( 0.0) | 0.0 | 1/370.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 生殖系および乳房障害 | 0/363.1 ( 0.0) | 0.0 | 4/367.9 ( 1.1) | 1.0 | 0/109.8 ( 0.0) | 0.0 | 4/840.9 ( 0.5) | 0.4 |
| 良性前立腺肥大症 | 0/363.1 ( 0.0) | 0.0 | 1/369.7 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 月経過多 | 0/363.1 ( 0.0) | 0.0 | 1/369.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 骨盤内出血 | 0/363.1 ( 0.0) | 0.0 | 1/369.6 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 閉経後出血 | 0/363.1 ( 0.0) | 0.0 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 呼吸器、胸郭および縦隔障害 | 19/352.5 ( 5.4) | 5.0 | 16/364.2 ( 4.4) | 4.2 | 3/108.8 ( 2.8) | 2.4 | 38/825.5 ( 4.6) | 4.3 |
| 呼吸不全 | 3/361.9 ( 0.8) | 0.8 | 2/369.8 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 5/841.6 ( 0.6) | 0.6 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 44）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 呼吸困難 | 0/363.1 ( 0.0) | 0.0 | 3/369.3 ( 0.8) | 0.8 | 1/109.0 ( 0.9) | 0.8 | 4/841.5 ( 0.5) | 0.4 |
| 胸水 | 2/362.0 ( 0.6) | 0.5 | 2/370.2 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 4/842.1 ( 0.5) | 0.4 |
| 肺塞栓症 | 1/362.1 ( 0.3) | 0.3 | 2/370.4 ( 0.5) | 0.5 | 1/109.8 ( 0.9) | 0.8 | 4/842.3 ( 0.5) | 0.4 |
| 肺水腫 | 1/362.3 ( 0.3) | 0.3 | 3/369.2 ( 0.8) | 0.8 | 0/109.8 ( 0.0) | 0.0 | 4/841.4 ( 0.5) | 0.4 |
| 急性呼吸不全 | 2/362.3 ( 0.6) | 0.5 | 1/370.3 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 3/842.5 ( 0.4) | 0.3 |
| 鼻出血 | 1/362.4 ( 0.3) | 0.3 | 1/369.7 ( 0.3) | 0.3 | 1/109.7 ( 0.9) | 0.8 | 3/841.8 ( 0.4) | 0.3 |
| 急性肺水腫 | 1/362.2 ( 0.3) | 0.3 | 1/369.9 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.0 ( 0.2) | 0.2 |
| 慢性閉塞性肺疾患 | 1/362.3 ( 0.3) | 0.3 | 1/370.0 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 2/842.1 ( 0.2) | 0.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
n = 有害事象発現例数.
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 45）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 誤嚥 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 喘息 | 1/362.3 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.5 ( 0.1) | 0.1 |
| 気管支痙攣 | 1/362.9 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| 咳嗽 | 1/362.5 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |
| 労作性呼吸困難 | 0/363.1 ( 0.0) | 0.0 | 1/369.9 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.9 ( 0.1) | 0.1 |
| 低酸素症 | 0/363.1 ( 0.0) | 0.0 | 1/369.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 誤嚥性肺炎 | 1/362.6 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.8 ( 0.1) | 0.1 |
| 肺空洞形成 | 0/363.1 ( 0.0) | 0.0 | 1/370.0 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.0 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 46）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 肺うっ血 | 1/362.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 肺梗塞 | 1/362.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.3 ( 0.1) | 0.1 |
| 肺腫瘤 | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 呼吸停止 | 0/363.1 ( 0.0) | 0.0 | 1/369.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 上気道性喘鳴 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 咽喉絞扼感 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 皮膚および皮下組織障害 | 6/360.5 ( 1.7) | 1.6 | 8/366.4 ( 2.2) | 2.1 | 2/109.2 ( 1.8) | 1.6 | 16/836.1 ( 1.9) | 1.8 |
| 皮膚潰瘍 | 1/362.3 ( 0.3) | 0.3 | 5/367.9 ( 1.4) | 1.3 | 0/109.8 ( 0.0) | 0.0 | 6/840.1 ( 0.7) | 0.7 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 47）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 糖尿病性足病変 | 1/362.1 ( 0.3) | 0.3 | 2/369.1 ( 0.5) | 0.5 | 2/109.2 ( 1.8) | 1.6 | 5/840.4 ( 0.6) | 0.6 |
| 血管浮腫 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 褥瘡性潰瘍 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| ヘノッホ・シェーンライン紫斑病 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 紫斑 | 0/363.1 ( 0.0) | 0.0 | 1/370.1 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.1 ( 0.1) | 0.1 |
| 血管炎性皮疹 | 1/362.6 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.8 ( 0.1) | 0.1 |
| 外科および内科処置 | 0/363.1 ( 0.0) | 0.0 | 1/369.5 ( 0.3) | 0.3 | 1/109.8 ( 0.9) | 0.8 | 2/842.4 ( 0.2) | 0.2 |
| 動静脈グラフト | 0/363.1 ( 0.0) | 0.0 | 1/369.5 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n = 有害事象発現例数．
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 48）**
**解析対象集団：SAF**

| | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| SOC | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| PT | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 治療中断 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.8 ( 0.9) | 0.8 | 1/843.3 ( 0.1) | 0.1 |
| 血管障害 | 23/350.9 ( 6.6) | 6.0 | 20/360.5 ( 5.5) | 5.2 | 7/105.8 ( 6.6) | 5.7 | 50/817.2 ( 6.1) | 5.6 |
| 低血圧 | 5/361.1 ( 1.4) | 1.3 | 4/367.9 ( 1.1) | 1.0 | 2/108.0 ( 1.9) | 1.6 | 11/837.1 ( 1.3) | 1.2 |
| 高血圧 | 5/359.3 ( 1.4) | 1.3 | 4/367.7 ( 1.1) | 1.0 | 1/108.8 ( 0.9) | 0.8 | 10/835.9 ( 1.2) | 1.1 |
| 末梢血管障害 | 2/362.9 ( 0.6) | 0.5 | 4/368.7 ( 1.1) | 1.0 | 0/109.8 ( 0.0) | 0.0 | 6/841.5 ( 0.7) | 0.7 |
| 末梢動脈閉塞性疾患 | 2/361.7 ( 0.6) | 0.5 | 1/370.4 ( 0.3) | 0.3 | 1/109.5 ( 0.9) | 0.8 | 4/841.6 ( 0.5) | 0.4 |
| 深部静脈血栓症 | 2/361.6 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/841.9 ( 0.2) | 0.2 |
| 血腫 | 2/362.2 ( 0.6) | 0.5 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 2/842.4 ( 0.2) | 0.2 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
n＝有害事象発現例数.
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 49）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 高血圧クリーゼ | 0/363.1 ( 0.0) | 0.0 | 1/370.0 ( 0.3) | 0.3 | 1/109.7 ( 0.9) | 0.8 | 2/842.8 ( 0.2) | 0.2 |
| 悪性高血圧 | 0/363.1 ( 0.0) | 0.0 | 2/369.5 ( 0.5) | 0.5 | 0/109.8 ( 0.0) | 0.0 | 2/842.4 ( 0.2) | 0.2 |
| 起立性低血圧 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 1/109.5 ( 0.9) | 0.8 | 2/842.8 ( 0.2) | 0.2 |
| 大動脈瘤 | 1/362.5 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |
| 大動脈狭窄 | 1/362.2 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.4 ( 0.1) | 0.1 |
| 動脈閉塞性疾患 | 1/362.4 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 乾性壊疽 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |
| 四肢壊死 | 1/363.0 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.2 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた.
n = 有害事象発現例数.
e = 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間，非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした.
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率 = 100* n/ e.
**%=有害事象発現率 = 100*n/N.

**表 2.7.4.7-20　重篤な有害事象の SOC・PT 別発現頻度（20120231 試験）（続き 50）**
**解析対象集団：SAF**

| SOC / PT | 有害事象 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 親試験（20120229試験及び20120230試験） | | | | 親試験（20120359試験） | | 合計 | |
| | プラセボ | | ONO-5163 | | ONO-5163 | | ONO-5163 | |
| | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** | n/e(r)* | (%)** |
| N | 383 | | 384 | | 123 | | 890 | |
| 出血 | 0/363.1 ( 0.0) | 0.0 | 1/370.4 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 高血圧緊急症 | 0/363.1 ( 0.0) | 0.0 | 1/369.6 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.6 ( 0.1) | 0.1 |
| 頚静脈血栓症 | 0/363.1 ( 0.0) | 0.0 | 0/370.4 ( 0.0) | 0.0 | 1/109.5 ( 0.9) | 0.8 | 1/843.0 ( 0.1) | 0.1 |
| 出血性ショック | 0/363.1 ( 0.0) | 0.0 | 1/369.7 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.7 ( 0.1) | 0.1 |
| スチール症候群 | 1/363.1 ( 0.3) | 0.3 | 0/370.4 ( 0.0) | 0.0 | 0/109.8 ( 0.0) | 0.0 | 1/843.3 ( 0.1) | 0.1 |
| 血管炎 | 0/363.1 ( 0.0) | 0.0 | 1/369.8 ( 0.3) | 0.3 | 0/109.8 ( 0.0) | 0.0 | 1/842.8 ( 0.1) | 0.1 |

医師から報告された有害事象名は，MedDRA ver18.0Jを用いて読み替えた．
n＝有害事象発現例数．
e＝ 曝露期間の合計を年換算した値．有害事象発現者においては治験薬投与開始日から有害事象の初発日までの期間， 非発現者においては治験薬投与開始日から治験薬最終投与日+30日又は死亡日の早い方までの期間を各被験者の曝露期間とした．
*n/e=n/e(yrs); r=曝露期間で調整した人年法（100人年）による有害事象発現率＝100* n/ e.
**%=有害事象発現率＝100*n/N.

SAF＝Safety Analysis Set
出典［総括報告書 5.3.5.2-4（20120231 試験）Table 14-6.5 改変］

## 表 2.7.4.7-21　重篤な有害事象の一覧表（20120231 試験）

| Treatment Group | Usubject ID | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-229110010 03 | ATYPICAL NON-CARDIOGENIC CHEST PAIN [非心臓性胸痛] | 20[redacted]-06-19 | 22 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-20 | - |
| AMG 416 | 20120229-229110010 03 | LEFT ARM CELLULITIS [蜂巣炎] | 20[redacted]-10-28 | 153 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-12 * | - |
| AMG 416 | 20120229-229110010 03 | RIGHT 1ST-3RD TOE NECROSIS [四肢壊死] | 20[redacted]-04-07 * | 314 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-06-05 * | - |
| AMG 416 | 20120229-229110010 03 | DRY GANGRENE [乾性壊疽] | 20[redacted]-04-21 | 328 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-06-05 | - |
| AMG 416 | 20120229-229110010 06 | BACTERAEMIA [菌血症] | 20[redacted]-06-29 | 25 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-07-15 | - |
| AMG 416 | 20120229-229110010 10 | INFECTED ARTERIO-VENOUS GRAFT [動静脈グラフト部位感染] | 20[redacted]-10-31 | 156 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-11-18 | - |
| AMG 416 | 20120229-229110010 10 | MSSA SEPSIS [ブドウ球菌性敗血症] | 20[redacted]-10-31 | 156 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-11-04 | - |

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

| Treatment Group | Usubject ID | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22911001010 | VASCULITIC RASH [血管炎性皮疹] | 20[redacted]-12-05 | 191 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22911001010 | CEPHAZOLIN ALLERGY [薬物過敏症] | 20[redacted]-12-07 | 193 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-20 | - |
| AMG 416 | 20120229-22911001010 | VANCOMYCIN ALLERGY [薬物過敏症] | 20[redacted]-12-16* | 202 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-20* | - |
| AMG 416 | 20120229-22911001010 | TACHYCARDIA [頻脈] | 20[redacted]-01-11* | 228 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-16* | - |
| AMG 416 | 20120229-22911001010 | INFECTION OF CHRONIC LEFT LOWER LIMB ULCER [感染性皮膚潰瘍] | 20[redacted]-06-16 | 384 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-22 | - |
| AMG 416 | 20120229-22911003002 | R LOWER LIMB CELLULITIS [蜂巣炎] | 20[redacted]-09-16T09:00 | 153 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-11-21 | - |
| AMG 416 | 20120229-22911003002 | CARDIAC ARREST [心停止] | 20[redacted]-11-21 | 219 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | EMERGENCY ROOM VISIT, OTHER | NOT RELATED | 20[redacted]-11-21 | - |
| AMG 416 | 20120229-22911003002 | PULMONARY EMBOLISM [肺塞栓症] | 20[redacted]-11-21 | 219 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-11-21 | - |
| AMG 416 | 20120229-22911003003 | RIGHT SURGICAL NECK OF HUMERUS FRACTURE [上腕骨骨折] | 20[redacted]-05-11* | 53 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING* | - |
| AMG 416 | 20120229-22911003003 | LABIAL ABSESS [性器膿瘍] | 20[redacted]-01-06 | 293 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-29 | - |
| AMG 416 | 20120229-22911003006 | TERTIARY HYPER-PARATHYROIDISM [三次性副甲状腺機能亢進症] | 20[redacted]-12-17 | 253 | SEVERE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-12-22 | - |

年齢以外のマスキングにおいて,
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する

| Treatment Group | Usubject ID | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22911013001 | RIGHT SIDED CHEST PAIN [胸痛] | 20[redacted]-05-28T12:10 | 85 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-05-29 | - |
| AMG 416 | 20120229-22912001003 | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-11-19 * | 204 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22912001003 | OPTICUSNEUROPATHY [視神経症] | 20[redacted]-01 | - | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22912001005 | WORSENING OF PRE-EXISTING PERIPHERAL VASCULAR DISEASE [末梢血管障害] | 20[redacted]-09-24 ** | 141 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-10-01 ** | - |
| AMG 416 | 20120229-22912003001 | PERIPHERAL ARTERIAL DISEASE SINCE 5/20[redacted]; * WORSENING SINCE 10/20[redacted]; SCHEDULED REINTERVENTION [末梢動脈閉塞性疾患] | 20[redacted]-05-20 ** | 63 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-05-22 ** | - |
| AMG 416 | 20120229-22912003001 | PNEUMONIA [肺炎] | 20[redacted]-10-06T12:00 ** | 202 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-10-18T15:00 ** | - |
| AMG 416 | 20120229-22912003001 | PNEUMONIA [肺炎] | 20[redacted]-10-27T19:00 ### | 223 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-11-07T15:00 ### | - |
| AMG 416 | 20120229-22912003001 | WORSENING OF PERIPHERAL ARTERIAL DISEASE [末梢動脈閉塞性疾患] | 20[redacted]-01-09T09:00 ### | 297 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-02-06 ### | - |
| AMG 416 | 20120229-22912003001 | CLOSTRIDIUM DIFFICILE COLITIS [クロストリジウム・ディフィシレ大腸炎] | 20[redacted]-02-20T15:00 | 339 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-03-04T15:00 | - |

年齢以外のマスキングにおいて，
＊なし：「同年」を意味する
＊　　：「翌年」を意味する
＊＊　：「翌々年」を意味する
＃＃＃　：「3年後」を意味する

| Treatment Group | Usubject ID | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time ###Event (days) | Study Day of Start of Adverse | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time ### | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22912003001 | INFLUENZA B [インフルエンザ] | 20[redacted]-03-11T21:50 ### | 358 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-15 ### | - |
| AMG 416 | 20120229-22912003001 | ACUTE CARDIAL EVENT [心障害] | 20[redacted]-03-15T17:23 | 362 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | OTHER | NOT RELATED | 20[redacted]-03-15 | - |
| AMG 416 | 20120229-22913001001 | HEMORROIDAL BLEEDING [痔出血] | 20[redacted]-10-22T08:00 | 316 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-29T14:00 | - |
| AMG 416 | 20120229-22913001004 | ACUTE CHOLANGITIS [急性胆管炎] | 20[redacted]-07-21T20:00 | 148 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-07-24T09:30 | - |
| AMG 416 | 20120229-22913003006 | CARDIAC BYPASS THROMBOSIS [冠動脈バイパス血栓症] | 20[redacted]-01-21 | 254 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22913005001 | OCCLUSION OF ARTERY POPLITEA LEFT [末梢動脈閉塞性疾患] | 20[redacted]-07-08 | 77 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-07-10 | - |
| AMG 416 | 20120229-22913005001 | PSEUDO-ANEURYSM OF ARTERIA POPLITEA LEFT [血管偽動脈瘤] | 20[redacted]-07-08 | 77 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-07-10 | - |
| AMG 416 | 20120229-22913005005 | MYOCARDIAL INFARCTION [心筋梗塞] | 20[redacted]-03-24 | 328 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22913007006 | MESENTERIC ISCHEMIA [腸管虚血] | 20[redacted]-01-25 | 2 | SEVERE | YES | - | DOSE NOT CHANGED | DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-02-05 | - |
| AMG 416 | 20120229-22913009002 | RECURRENT FALLS [転倒] | 20[redacted]-10-21 | 337 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-01 | - |

年齢以外のマスキングにおいて，
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＊　　：「翌年」を意味する
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＃＃＃　：「3年後」を意味する

| Treatment Group | Usubject ID | Reported Term for the Adverse Event [Preferred Term*1] | Start Date/Time | Study Day of Start of Adverse Event (days) | Severity/ Intensity | Serious | Serious Criteria | Action Taken with Study Treatment | Other Action Taken | Causality | End Date/Time | Outcome of Serious Adverse Event |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22913009002 | TREMOR [振戦] | 20[redacted]-10-21 | 337 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22916001003 | NON COMPLICATED DIVERTICULITIS [憩室炎] | 20[redacted]-12-23T09:26 | 266 | MODERATE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-12-24 | - |
| AMG 416 | 20120229-22916001004 | CONFUSION [錯乱状態] | 20[redacted]-05-09 | 37 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22916001004 | HYPOCALCEMIA [低カルシウム血症] | 20[redacted]-05-09 | 37 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | RELATED | 20[redacted]-05-15 | - |
| AMG 416 | 20120229-22916001004 | SEIZURE [痙攣発作] | 20[redacted]-05-09 | 37 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-09 | - |
| AMG 416 | 20120229-22916001004 | SEVERE HYPOGLYCEMIA [低血糖症] | 20[redacted]-05-09 | 37 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-09 | - |
| AMG 416 | 20120229-22916001007 | OSTEITIS LEFT FIRST TOE [骨炎] | 20[redacted]-01-26 | 292 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-03-11 | - |
| AMG 416 | 20120229-22921003001 | PNEUMONIA [肺炎] | 20[redacted]-01-14T16:00 | 344 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN, IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-02-13 | - |
| AMG 416 | 20120229-22921003002 | SCAPULA FRACTURE [肩甲骨骨折] | 20[redacted]-03-27* | -6 | MODERATE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-06-18* | - |
| AMG 416 | 20120229-22921003002 | LEFT FEMUR FRACTURE [大腿骨骨折] | 20[redacted]-01-18 | 292 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-01 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-229210030 02 | SEPSIS [敗血症] | 20[redacted]-01-30 | 304 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-01T00:15 | - |
| AMG 416 | 20120229-229210050 01 | ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞] | 20[redacted]-11-05 | 302 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-05 | - |
| AMG 416 | 20120229-229210050 03 | UROSEPSIS [尿路性敗血症] | 20[redacted]-01-26 | 19 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-27 | - |
| AMG 416 | 20120229-229210050 03 | RELAPS UROSEPSIS [尿路性敗血症] | 20[redacted]-04-09 | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-21 | - |
| AMG 416 | 20120229-229210050 03 | BLEEDING [出血] | 20[redacted]-05-20 | 133 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-21 | - |
| AMG 416 | 20120229-229210050 03 | RELAPSE UROSEPSIS [尿路性敗血症] | 20[redacted]-05-20 | 133 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-20 | - |
| AMG 416 | 20120229-229210050 03 | AC.HEART FAILURE [急性心不全] | 20[redacted]-05-21 | 134 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-21T00:02 | - |
| AMG 416 | 20120229-229250010 02 | BONE PAIN [骨痛] | 20[redacted]-04-15 | 97 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | RELATED | 20[redacted]-04-19 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22925001002 | DEPRESSION [うつ病] | 20[redacted]-04-15 | 97 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-19 | - |
| AMG 416 | 20120229-22925001003 | BLOOD HYPER-FLUX OF ARTERIO-VENOUS FESTULA. [動静脈瘻部位合併症] | 20[redacted]-10-10T13:30 | 269 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-11-03 | - |
| AMG 416 | 20120229-22925001005 | ANGINA PECTORIS [狭心症] | 20[redacted]-05-24 | 18 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-09-19 | - |
| AMG 416 | 20120229-22925007001 | WORSENING OF UNSTABLE ANGINA [不安定狭心症] | 20[redacted]-07-22 | 168 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-07-24 | - |
| AMG 416 | 20120229-22925007001 | CARDIOGENIC SHOCK [心原性ショック] | 20[redacted]-07-24 | 170 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-07-24 | - |
| AMG 416 | 20120229-22926003003 | PATELLA FRACTURE LEFT [膝蓋骨骨折] | 20[redacted]-06-07 | 87 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER | NOT RELATED | 20[redacted]-08-05 | - |
| AMG 416 | 20120229-22926003003 | INFECTION SURGICAL WOUND AFTER PATELLA FRACTURE SURGERY [術後創感染] | 20[redacted]-06-25 | 105 | LIFE THREATENING | YES | Is Life Threatening | DRUG WITHDRAWN | MEDICATION TAKEN, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-08-05 | - |
| AMG 416 | 20120229-22926003003 | SEPSIS AFTER AMPUTATION WOUND LEFT LEG [膿創] | 20[redacted]-08-05 | 146 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | NO ACTION TAKEN | NOT RELATED | 20[redacted]-08-05 | - |
| AMG 416 | 20120229-22926005001 | THROMBOSIS OF ATERIOVENOUS GRAFT [血管グラフト血栓症] | 20[redacted]-06-13 | 39 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-18 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22926005001 | THROMBOSIS OF ATERIOVENOUS GRAFT [血管グラフト血栓症] | 20[redacted]-07-15T14:30 | 71 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-19 | - |
| AMG 416 | 20120229-22926005001 | THROMBOSIS OF ARTERIO-VENOUS GRAFT [血管グラフト血栓症] | 20[redacted]-07-26 | 82 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-28 | - |
| AMG 416 | 20120229-22926005001 | THROMBOSIS OF ARTERIO VENOUS GRAFT [血管グラフト血栓症] | 20[redacted]-08-07 | 94 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-10 | - |
| AMG 416 | 20120229-22926005001 | THROMBOSIS OF ARTERIO-VENOUS GRAFT [血管グラフト血栓症] | 20[redacted]-08-14 | 101 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-20 | - |
| AMG 416 | 20120229-22926005001 | THROMBOSIS OF ARTERIO-VENOUS GRAFT [血管グラフト血栓症] | 20[redacted]-11-29 | 208 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-04 | - |
| AMG 416 | 20120229-22926005003 | WORSENING OF ARTERIO-VENOUSIS SHUNT STENOSIS [シャント狭窄] | 20[redacted]-01-07 | 260 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-01-08 | - |
| AMG 416 | 20120229-22926005004 | DIAGNOSTIC OF DIVERTICULOSIS ON COLON [腸憩室] | 20[redacted]-02-11 | 288 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-14 | - |
| AMG 416 | 20120229-22926005006 | PARTIAL THROMBOSIS OF AV-FISTULA [動静脈瘻血栓症] | 20[redacted]-03-25 | 309 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-30 | - |
| AMG 416 | 20120229-22926005008 | PERIPHERALARTERIALOCCLUSIVE DISEASE AGGRAVITED LEFT LEG [末梢動脈閉塞性疾患] | 20[redacted]-02-05 | -104 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-12 | - |
| AMG 416 | 20120229-22926005008 | WORSENING OF CORONARY HEART DISEASE [冠動脈疾患] | 20[redacted]-07-30 | 72 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-01 | - |
| AMG 416 | 20120229-22926005008 | WORSENING OF RIVA STENOSIS [冠動脈狭窄] | 20[redacted]-09-15 | 119 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-09-19 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22926005008 | WORSENING OF PERIPHERAL VASCULAR DISEASE RIGHT LEG [末梢血管障害] | 20[redacted]-09-20 | 124 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-10 | - |
| AMG 416 | 20120229-22926005008 | DECOMPENSATION OF AORTIC VALVE STENOSIS [大動脈弁狭窄] | 20[redacted]-10-28 | 162 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-12 | - |
| AMG 416 | 20120229-22929001003 | WORSENING AV FISTULA FUNCTION [動静脈瘻部位合併症] | 20[redacted]-09-02T08:00 * | 225 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-09-04T08:00 * | - |
| AMG 416 | 20120229-22929001003 | PROGRESSING CATARACT OF LEFT EYE [白内障] | 20[redacted]-02-11T07:18 | 387 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE EXPLANTATION | NOT RELATED | 20[redacted]-02-12T07:00 | - |
| AMG 416 | 20120229-22929003006 | CEREBRAL HAEMORRHAGIA [脳出血] | 20[redacted]-07-13T07:49 | 137 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-19 | - |
| AMG 416 | 20120229-22929007002 | ANGINA PECTORIS [狭心症] | 20[redacted]-10-28T12:00 | 29 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-29 | - |
| AMG 416 | 20120229-22929007004 | PROBLEMATIC PUNCTURE OF THE AV FISTULA [動静脈瘻部位合併症] | 20[redacted]-04-15T11:13 | 100 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | ONGOING | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22929007004 | GASTROENTERITIS [胃腸炎] | 20[redacted]-08-14T15:00 | 221 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-18T10:00 | - |
| AMG 416 | 20120229-22929007005 | ACUTE GASTROENTERITIS [胃腸炎] | 20[redacted]-02-21T08:00 | 33 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-26T16:00 | - |
| AMG 416 | 20120229-22929007005 | CIMINO'S FITULE STENOSIS [動静脈瘻部位合併症] | 20[redacted]-03-11T22:32 | 51 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-13T14:07 | - |
| AMG 416 | 20120229-22929007006 | ILEUS [イレウス] | 20[redacted]-08-12T16:12 | 183 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-08-14T01:05 | - |
| AMG 416 | 20120229-22929007006 | SEPSIS [敗血症] | 20[redacted]-08-12T16:12 | 183 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-08-14T01:05 | - |
| AMG 416 | 20120229-22929007006 | WORSENING ANAEMIA [貧血] | 20[redacted]-08-12T16:12 | 183 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-14T01:05 | - |
| AMG 416 | 20120229-22929007008 | THE WOUND OF THE LEFT FOURTH TOE ABLATION INFLAMMATION (SAME AS IN 229 SAE 003 [創傷] | 20[redacted]-01-23T16:50 | -54 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-01T11:14 | - |
| AMG 416 | 20120229-22929007008 | PERIFERAL ARTERY DISEASE [末梢血管障害] | 20[redacted]-03-11T13:58 | -7 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-18T09:58 | - |
| AMG 416 | 20120229-22929007008 | LEFT III. AND V. FINGER OSTEOMYELITIS [骨髄炎] | 20[redacted]-05-01T16:48 | 45 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-17T08:00 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22929007008 | LEFT HALLUX OSTEOMYELITIS [骨髄炎] | 20[redacted]-09-02T11:26 | 169 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-11T08:26 | - |
| AMG 416 | 20120229-22929007017 | ERYTHROPOETIN RESISTANCE [薬剤耐性] | 20[redacted]-06-10T10:03 | 86 | SEVERE | YES | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-06-16T11:00 | - |
| AMG 416 | 20120229-22929007017 | TRANSPLANTED KIDNEY PAIN (COMPLICATION) [移植腎の合併症] | 20[redacted]-06-10T10:03 | 86 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-06-16T11:00 | - |
| AMG 416 | 20120229-22929007018 | CIMINO FISTULE STENOSIS [動静脈瘻部位合併症] | 20[redacted]-03-03 | 300 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-05 | - |
| AMG 416 | 20120229-22932001008 | MYOCARDIAL INFARCTION/NSTEMI [急性心筋梗塞] | 20[redacted]-09-04T07:00 * | 115 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-08T14:19 * | - |
| AMG 416 | 20120229-22932001008 | ARRHYTHMIA: VF STORM [心室細動] | 20[redacted]-05-06 * | 359 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-05-06 * | - |
| AMG 416 | 20120229-22932001008 | CARDIOPULMONARY ARREST [心肺停止] | 20[redacted]-05-06 | 359 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-06 | - |
| AMG 416 | 20120229-22932003004 | SEPSIS [敗血症] | 20[redacted]-06-03 | 20 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-06-29 | - |
| AMG 416 | 20120229-22933001002 | WORSENING OF RENAL FUNCTION [腎機能障害] | 20[redacted]-01-03T10:30 | 31 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-01-23T17:30 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22933011008 | CHOLELITIASIS [胆石症] | 20[redacted]-05-29T09:00 | 114 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-31 | - |
| AMG 416 | 20120229-22933011010 | WORSENING OF PERIPHERAL ARTERY DISEASE [末梢血管障害] | 20[redacted]-05-29T09:00 | 100 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-03 | - |
| AMG 416 | 20120229-22933011011 | SUSPECT CENTRAL VENOUS CATHETER RELATED SEPSIS [医療機器関連敗血症] | 20[redacted]-05-19T17:00 | 76 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-05-30 | - |
| AMG 416 | 20120229-22933011011 | BLEEDING FROM THE ARTERIOVENOUS FISTULA [動静脈瘻部位出血] | 20[redacted]-06-25T18:00 | 113 | SEVERE | YES | - | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-06-25T19:51 | - |
| AMG 416 | 20120229-22933011011 | SUSPECT CENTRAL VENOUS CATHETER-RELATED SEPSIS [医療機器関連敗血症] | 20[redacted]-07-02 | 120 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-09 | - |
| AMG 416 | 20120229-22948001001 | SEIZURES [痙攣発作] | 20[redacted]-03-07T08:15 | 75 | LIFE THREATENING | YES | Is Life Threatening | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, OTHER | RELATED | 20[redacted]-03-07 | - |
| AMG 416 | 20120229-22948001005 | THROMBOSIS OF AV FISTULA [動静脈瘻血栓症] | 20[redacted]-02-23 | 391 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-02-23 | - |
| AMG 416 | 20120229-22948003001 | SUDDEN DEATH - UNKNOWN REASON [突然死] | 20[redacted]-09-22 | 207 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-22 | - |
| AMG 416 | 20120229-22948003002 | WORSENING SPINA PAIN [脊椎痛] | 20[redacted]-04-17 | 52 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-05-24 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22948003002 | AGGRAVATED HYPERTENSION [高血圧] | 20[redacted]-05-17 | 82 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-24 | - |
| AMG 416 | 20120229-22948003002 | SPONDYLOSIS [変形性脊椎症] | 20[redacted]-05-17T17:30 | 82 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-24T23:00 | - |
| AMG 416 | 20120229-22948003002 | BRONCHOPNEUMONIA [気管支肺炎] | 20[redacted]-06-17 * | 113 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-26 | - |
| AMG 416 | 20120229-22948003002 | WORSENING SPINAL PAIN [脊椎痛] | 20[redacted]-02-05 | 346 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-19 * | - |
| AMG 416 | 20120229-22948003003 | BONE AND MUSCLE PAIN [筋骨格痛] | 20[redacted]-03-05T05:30 | 8 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-12T09:30 | - |
| AMG 416 | 20120229-22948003003 | BRONCHOPNEUMONIA [気管支肺炎] | 20[redacted]-04-07 | 41 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-07 | - |
| AMG 416 | 20120229-22948005006 | BODY WEIGHT LOSS [体重減少] | 20[redacted]-09-03T07:51 | 238 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-09-04T12:00 | - |
| AMG 416 | 20120229-22948005006 | UNCONTROLLED HYPERTENSION [高血圧] | 20[redacted]-09-29 | 264 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22948005007 | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-11-20 | 330 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22948005008 | SEIZURE [痙攣発作] | 20[redacted]-02-21T14:00 | 121 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22948005009 | INFLAMMATION OF A-V FISTULA REGION [動静脈瘻部位合併症] | 20[redacted]-07-01 | 181 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-04 | - |
| AMG 416 | 20120229-22948005009 | DYSFUNCTION OF ARTERIO-VENOUS FISTULA [動静脈瘻部位合併症] | 20[redacted]-09-17 | 259 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER, OTHER | NOT RELATED | 20[redacted]-09-24 | - |
| AMG 416 | 20120229-22948005010 | NON-CARDIAC CHEST PAIN [非心臓性胸痛] | 20[redacted]-04-12 | 101 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-13 | - |
| AMG 416 | 20120229-22948005011 | EXACERBATION OF CHRONIC HEART FAILURE [慢性心不全] | 20[redacted]-01-07 | 6 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-13 | - |
| AMG 416 | 20120229-22948005013 | STAPHYLOCOCCUS AUREUS SEPSIS [ブドウ球菌性敗血症] | 20[redacted]-06-09 | 61 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, CULTURE TAKEN | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22951001004 | ACUTE CORPOREAL GASTRIC EROSION [びらん性胃炎] | 20[redacted]-01-08T01:00 | 347 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, OTHER | NOT RELATED | 20[redacted]-01-19 | - |
| AMG 416 | 20120229-22951003004 | METASTATIC LESIONS OF VERTEBREA [脊椎転移] | 20[redacted]-05-25 | 89 | SEVERE | YES | - | DRUG WITHDRAWN | MEDICATION TAKEN | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22951003004 | INCREASING AST [アスパラギン酸アミノトランスフェラーゼ増加] | 20[redacted]-06-23 | 118 | SEVERE | YES | - | DOSE NOT CHANGED | NO ACTION TAKEN | RELATED | 20[redacted]-07-24 | - |
| AMG 416 | 20120229-22951003004 | VERTEBROGENIC PAIN WORSERING [脊椎痛] | 20[redacted]-07-06 | 131 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22951003004 | WEAKNESS [無力症] | 20[redacted]-07-06 | 131 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22951003005 | OD INITIAL CATARACT LENS SUBLUXATION IMPAIRMENT [水晶体脱臼] | 20[redacted]-05-14 | 78 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-19 | - |
| AMG 416 | 20120229-22951007003 | OCCLUSION LOWER EXTREMITY ARTERIES [末梢動脈再閉塞] | 20[redacted]-04-14 | 62 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, NON-IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-04-30 | - |
| AMG 416 | 20120229-22951007003 | OCCLUSION OF THE RADIAL AND ULNAR ARTERIES OF THE LEFT HAND [動脈閉塞性疾患] | 20[redacted]-05-08 | 86 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN, NON-IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-06-05 | - |
| AMG 416 | 20120229-22951007003 | FISTULA THROMBOSIS ON THE RIGHT FOREARM [動静脈瘻血栓症] | 20[redacted]-09-15 * | 216 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, NON-IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-09-29 * | - |
| AMG 416 | 20120229-22951007003 | PERMANENT CATHETER THROMBOSIS [医療機器関連の血栓症] | 20[redacted]-01-19 * | 342 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-02-09 * | - |
| AMG 416 | 20120229-22951007003 | ACUTE CARDIOVASCULAR INSUFFICIENCY [心血管不全] | 20[redacted]-02-10T20:30 | 364 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-11T04:00 | - |

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| AMG 416 | 20120229-22951009004 | FRACTURE OF THE RIGHT RADIUS [橈骨骨折] | 20[redacted]-04-22T12:00 | 63 | SEVERE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION, EMERGENCY ROOM VISIT | RELATED | 20[redacted]-06-30T12:00 | - |
| AMG 416 | 20120229-22958003008 | FRACTURE OF RADIUS [橈骨骨折] | 20[redacted]-12-22 | 11 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-25 | - |
| AMG 416 | 20120229-22958009002 | LITHIASIC CHOLECISTITIS [胆嚢炎] | 20[redacted]-05-06 | 139 | LIFE THREATENING | YES | Is Life Threatening | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-05-21 | - |
| AMG 416 | 20120229-22958009002 | HEPATIC COLIC [胆道仙痛] | 20[redacted]-06-10 | 174 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-30 | - |
| AMG 416 | 20120229-22958009006 | INFECTION OF SACRAL ULCER [感染性皮膚潰瘍] | 20[redacted]-11-18 | 327 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-11-25 | - |
| AMG 416 | 20120229-22958009006 | SEPTIC SHOCK [敗血症性ショック] | 20[redacted]-11-18 | 327 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-11-25 | - |
| AMG 416 | 20120229-22958009009 | STENT OCCLUSION OF THE LEFT SUPERFICIAL FEMORAL ARTERY [医療機器閉塞] | 20[redacted]-03-17 | 13 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER | NOT RELATED | 20[redacted]-04-16 | - |
| AMG 416 | 20120229-22958009009 | DEEP VEIN THROMBOSIS (RIGHT LOWER EXTREMITY [深部静脈血栓症] | 20[redacted]-03-31 | 27 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-04-09 | - |
| AMG 416 | 20120229-22958009009 | GASTROENTERITIS [胃腸炎] | 20[redacted]-04-18* | 45 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-23* | - |
| AMG 416 | 20120229-22958009009 | ORTOSTATIC HYPOTENSION [起立性低血圧] | 20[redacted]-02-15* | 348 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-02-16* | - |
| AMG 416 | 20120229-22958009009 | TOXIC HYPERKALEMIA [高カリウム血症] | 20[redacted]-02-15 | 348 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-16 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22958009018 | ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞] | 20[redacted]-04-06 | 56 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-04-07 | - |
| AMG 416 | 20120229-22958009018 | ISCHEMIC DELATED CARDIOMIOPATHY WITH SEVERAL DEPRESS LEFT VENTRICULAR DISFUNCTION [心筋虚血] | 20[redacted]-04-06 | 56 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-07 | - |
| AMG 416 | 20120229-22958009018 | VENTRICULAR FIBRILATION [心室細動] | 20[redacted]-04-06 | 56 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-07 | - |
| AMG 416 | 20120229-22965003004 | SUPRA VENTRICULAR TACCHYCARDIA [上室性頻脈] | 20[redacted]-08-19T16:00 | 83 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-19 | - |
| AMG 416 | 20120229-22965003006 | DIARRHOEA [下痢] | 20[redacted]-04-27 | 355 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-28 | - |
| AMG 416 | 20120229-22965003006 | LOW ABDOMINAL PAIN [下腹部痛] | 20[redacted]-04-27T05:00 | 355 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-28 | - |
| AMG 416 | 20120229-22965005002 | DIARRHOEA [下痢] | 20[redacted]-06-30T05:00 | 69 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-01T05:00 | - |
| AMG 416 | 20120229-22965005002 | INFECTED FOOT LESION [皮膚感染] | 20[redacted]-06-30T05:00 | 69 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22965005002 | NUMB RIGHT LEG [感覚鈍麻] | 20[redacted]-06-30T05:00 | 69 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-07T05:00 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22965005002 | PURPURIC ERUPTIONS ON UPPER AND LOWER EXTREMITIES AND TO LOWER ABDOMEN, BUTTOCKS AND BACK [紫斑] | 20[redacted]-02-24 | 308 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | RELATED | 20[redacted]-06-05 | - |
| AMG 416 | 20120229-22965007003 | SOFT TISSUE INJURY TO RIGHT THIGH [軟部組織損傷] | 20[redacted]-03-26T07:00 | 332 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22965007003 | BILATERAL LEG ULCERS [皮膚潰瘍] | 20[redacted]-04-14T07:00 | 351 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966001002 | ATRIAL FIB W RVR [心房細動] | 20[redacted]-06-09 | 85 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-11 | - |
| AMG 416 | 20120229-22966001002 | DIABETIC FOOT ULCER RIGHT 2ND TOE [糖尿病性足病変] | 20[redacted]-07-29 | 135 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-01 | - |
| AMG 416 | 20120229-22966003023 | SUPRAVENTRICULAR TACHYCARDIA [上室性頻脈] | 20[redacted]-09-02 | 106 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966005002 | EROSIVE GASTRITIS [びらん性胃炎] | 20[redacted]-09-01 | 230 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-03 | - |
| AMG 416 | 20120229-22966005002 | LEFT LOWER LEG CELLULITIS [蜂巣炎] | 20[redacted]-09-01 | 230 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-03 | - |
| AMG 416 | 20120229-22966005004 | WORSENING ANXIETY [不安] | 20[redacted]-03-25 | -6 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-26 | - |
| AMG 416 | 20120229-22966005004 | NON CARDIAC ATYPICAL CHEST PAIN [非心臓性胸痛] | 20[redacted]-08-26 | 149 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-27 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966009003 | EXASCERBATION OF BILATERAL KIDNEY STONES [腎結石症] | 20[redacted]-04-09 | 162 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-16 | - |
| AMG 416 | 20120229-22966009003 | PNEUMONIA [肺炎] | 20[redacted]-06-02 | 216 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-14 | - |
| AMG 416 | 20120229-22966009003 | ATRIAL FIBRILLATION, TRANSIENT [心房細動] | 20[redacted]-06-04 | 218 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-06-05 | - |
| AMG 416 | 20120229-22966009003 | EXACERBATION OF CORONARY ARTERY DISEASE [冠動脈疾患] | 20[redacted]-10-24 | 360 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-29 | - |
| AMG 416 | 20120229-22966009003 | KIDNEY STONE EXACERBATION [腎結石症] | 20[redacted]-10-24 | 360 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-10-29 | - |
| AMG 416 | 20120229-22966009003 | EXACERBATION OF LEFT FLANK PAIN [側腹部痛] | 20[redacted]-11-03 | 370 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-04 | - |
| AMG 416 | 20120229-22966009003 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-11-03 | 370 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-04 | - |
| AMG 416 | 20120229-22966009004 | PNEUMONIA [肺炎] | 20[redacted]-06-14 | 235 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-17 | - |
| AMG 416 | 20120229-22966009004 | CAVITARY LESSION OF LUNG [肺空洞形成] | 20[redacted]-07-18 | 269 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966009004 | LYMPHADENOPATHY [リンパ節症] | 20[redacted]-07-18 | 269 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966009008 | EPISTAXIS [鼻出血] | 20[redacted]-02-16 | 116 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-02-25 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966009008 | SEVERE HYPERKALEMIA [高カリウム血症] | 20[redacted]-02-17 | 117 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-25 | - |
| AMG 416 | 20120229-22966009008 | ANEMIA [貧血] | 20[redacted]-08-09 | 290 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-12 | - |
| AMG 416 | 20120229-22966009008 | EPISTAXIS [鼻出血] | 20[redacted]-08-09 | 290 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-12 | - |
| AMG 416 | 20120229-22966009009 | FLUID OVERLOAD [水分過負荷] | 20[redacted]-01-04 | 45 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-01-08 | - |
| AMG 416 | 20120229-22966009009 | SEVERE HYPERKALEMIA [高カリウム血症] | 20[redacted]-01-04 | 45 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-01-08 | - |
| AMG 416 | 20120229-22966009009 | UREMIA [高窒素血症] | 20[redacted]-01-04 | 45 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-01-08 | - |
| AMG 416 | 20120229-22966009009 | PULMONARY EDEMA [肺水腫] | 20[redacted]-02-28 | 100 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-03-02 | - |
| AMG 416 | 20120229-22966009009 | FLUID OVERLOAD [水分過負荷] | 20[redacted]-07-29 | 251 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-31 | - |
| AMG 416 | 20120229-22966009010 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-06-16 | 229 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-19 | - |
| AMG 416 | 20120229-22966009010 | INCREASED BLOOD PRESSURE [血圧上昇] | 20[redacted]-06-16 | 229 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-19 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966009010 | A-V GRAFT STENOSIS [移植血管合併症] | 20[redacted]-10-16 | 351 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-10-17 | - |
| AMG 416 | 20120229-22966009010 | PRESYNCOPE [失神寸前の状態] | 20[redacted]-10-28 | 363 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-31 | - |
| AMG 416 | 20120229-22966009010 | BRADYCARDIA [徐脈] | 20[redacted]-11-13 | 379 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-16 | - |
| AMG 416 | 20120229-22966009011 | EXACERBATION OF POST-MENOPAUSAL BLEEDING [閉経後出血] | 20[redacted]-10-31 | 359 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-03 | - |
| AMG 416 | 20120229-22966009011 | HYPOTENSION [低血圧] | 20[redacted]-10-31 | 359 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-03 | - |
| AMG 416 | 20120229-22966009011 | SEIZURE [痙攣発作] | 20[redacted]-10-31 | 359 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-03 | - |
| AMG 416 | 20120229-22966009014 | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-11-02 | 18 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-12 | - |
| AMG 416 | 20120229-22966009014 | COMPLETE HEART BLOCK [完全房室ブロック] | 20[redacted]-12-12 | 58 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-12-30 | - |
| AMG 416 | 20120229-22966009014 | A-V FISTULA BLEED [動静脈瘻部位出血] | 20[redacted]-12-17 * | 63 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-12-17 * | - |
| AMG 416 | 20120229-22966009014 | CARDIAC ARREST [心停止] | 20[redacted]-01-02 * | 79 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-01-02 * | - |
| AMG 416 | 20120229-22966009014 | VENTRICULAR FIBRILLATION [心室細動] | 20[redacted]-01-03 | 80 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-01-03 | - |

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| AMG 416 | 20120229-22966009015 | GASTROINTESTINAL BLEED [胃腸出血] | 20[redacted]-02-04 | 41 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-02-06 | - |
| AMG 416 | 20120229-22966009015 | MODERATE ANEMIA [貧血] | 20[redacted]-02-25 | 62 | MODERATE | YES | - | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-26 | - |
| AMG 416 | 20120229-22966009015 | RECURRENCE OF ATRIAL FIBRILLATION [心房細動] | 20[redacted]-05-01 | 127 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-05-02 | - |
| AMG 416 | 20120229-22966009015 | RECURRENCE OF GASTROINTESTINAL BLEED [胃腸出血] | 20[redacted]-05-03 | 129 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-05-09 | - |
| AMG 416 | 20120229-22966009017 | ACUTE OSTEOMYELITIS LEFT FOOT [急性骨髄炎] | 20[redacted]-11-04 | 154 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-11-17 | - |
| AMG 416 | 20120229-22966009017 | STAPH AUREUS BACTEREMIA [ブドウ球菌性菌血症] | 20[redacted]-11-04 * | 154 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-17 * | - |
| AMG 416 | 20120229-22966009017 | DEEP VEIN THROMBOSIS [深部静脈血栓症] | 20[redacted]-01-11 * | 222 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-16 * | - |
| AMG 416 | 20120229-22966009017 | INFLUENZA [インフルエンザ] | 20[redacted]-01-22 * | 233 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-28 * | - |
| AMG 416 | 20120229-22966009017 | VIRAL UPPER RESPIRATORY INFECTION [ウイルス性上気道感染] | 20[redacted]-02-17 | 259 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-20 | - |
| AMG 416 | 20120229-22966011004 | ACUTE ON CHRONIC SYSTOLIC CHF [うっ血性心不全] | 20[redacted]-03-03 | 75 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-03-07 | - |

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| AMG 416 | 20120229-22966011010 | CLOTTED AV GRAFT [血管グラフト血栓症] | 20[redacted]-02-23 | 295 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-25 | - |
| AMG 416 | 20120229-22966011018 | ISCHEMIC COLITIS [虚血性大腸炎] | 20[redacted]-09-14 | 110 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-10-01 | - |
| AMG 416 | 20120229-22966011018 | ACUTE RESPIRATORY FAILURE [急性呼吸不全] | 20[redacted]-09-16 | 112 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-16 | - |
| AMG 416 | 20120229-22966011018 | CARDIAC ARREST [心停止] | 20[redacted]-09-16 | 112 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-16 | - |
| AMG 416 | 20120229-22966011018 | ENTEROCUTANEOUS FISTULA [腸管皮膚瘻] | 20[redacted]-09-16 | 112 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966011018 | GENERALIZED WEAKNESS [無力症] | 20[redacted]-10-02 | 128 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966013005 | WORSENING PERIPHERAL VASCULAR DISEASE [末梢血管障害] | 20[redacted]-04-03T13:51 | 16 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-04-10 | - |
| AMG 416 | 20120229-22966013005 | WORSENING CORONARY ARTERY DISEASE [冠動脈疾患] | 20[redacted]-05-15 | 58 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-31 | - |
| AMG 416 | 20120229-22966013005 | CEREBRIAL VASCULAR ACCIDENT [脳血管発作] | 20[redacted]-05-21 | 64 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-31 | - |
| AMG 416 | 20120229-22966013005 | CARDIOPULMONARY ARREST [心肺停止] | 20[redacted]-05-30 | 73 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-31 | - |

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| AMG 416 | 20120229-22966013007 | WORSENING CORONARY ARTERY DISEASE [冠動脈疾患] | 20[redacted]-04-28 | 34 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-30 | - |
| AMG 416 | 20120229-22966013007 | CARDIOPULMONARY ARREST [心肺停止] | 20[redacted]-04-30 | 36 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-30 | - |
| AMG 416 | 20120229-22966019007 | WORSENING OF INFECTED DIALYSIS CATHETER [医療機器関連感染] | 20[redacted]-09-29 | 181 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-03 | - |
| AMG 416 | 20120229-22966019007 | INFECTED DIALYSIS CATHETER [医療機器関連感染] | 20[redacted]-12-13 | 256 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-12-20 | - |
| AMG 416 | 20120229-22966019007 | WORSENING OF INFECTED DIALYSIS CATHETER [医療機器関連感染] | 20[redacted]-12-27 | 270 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966019011 | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-12-08T16:24 | 196 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-13 | - |
| AMG 416 | 20120229-22966021003 | EXCESS FLUID IN BLOOD DUE TO MISSING HEMODIALYSIS ON NOV-8-20[redacted] [水分過負荷] | 20[redacted]-11-11T19:00 | 302 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-13 | - |
| AMG 416 | 20120229-22966021003 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-11-11T19:00 | 302 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-13 | - |
| AMG 416 | 20120229-22966023004 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-09-06 | 264 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-07 | - |
| AMG 416 | 20120229-22966023004 | SEVERE HEADACHE THIS TERM CHANGED TO WORSENING OF HYPERTENSION [高血圧] | 20[redacted]-11-20 | 339 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-11-21 | - |
| AMG 416 | 20120229-22966023005 | AORTIC STENOSIS [大動脈狭窄] | 20[redacted]-12-19 | 56 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-24 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966023005 | ISCHEMIC HEART DISEASE [心筋虚血] | 20[redacted]-12-19 | 56 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-24 | - |
| AMG 416 | 20120229-22966023005 | URO SEPSIS [尿路性敗血症] | 20[redacted]-12-19 | 56 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-24 | - |
| AMG 416 | 20120229-22966023005 | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-12-27T01:49 | 64 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-30T07:08 | - |
| AMG 416 | 20120229-22966023005 | CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-12-27T01:49 | 64 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-30T07:08 | - |
| AMG 416 | 20120229-22966023005 | MITRAL VALVE REGURGITATION [僧帽弁閉鎖不全症] | 20[redacted]-12-27T01:49 * | 64 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-30T07:08 * | - |
| AMG 416 | 20120229-22966023005 | HYPERVOLEMIC CONGESTIVE CARDIAC FAILURE. [うっ血性心不全] | 20[redacted]-08-11T05:00 * | 291 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-12T11:26 * | - |
| AMG 416 | 20120229-22966023005 | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-09-04T16:06 | 315 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-09T11:44 | - |
| AMG 416 | 20120229-22966023010 | CONGESTIVE CARDIAC FAILURE [うっ血性心不全] | 20[redacted]-05-06T10:31 | 113 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-10T12:51 | - |
| AMG 416 | 20120229-22966023010 | HYPERVOLEMIA [血液量増加症] | 20[redacted]-05-06T10:31 | 113 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-10T12:51 | - |
| AMG 416 | 20120229-22966023010 | POST TRAUMATIC SUBDURAL HEMATOMA [硬膜下血腫] | 20[redacted]-11-22 | 313 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-04 * | - |
| AMG 416 | 20120229-22966023010 | HYPERVOLEMIA [血液量増加症] | 20[redacted]-12-27 | 348 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-08 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966027007 | MITRAL VALVE PROLAPSE [僧帽弁逸脱] | 20[redacted]-11-26 * | -50 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-02-04 * | - |
| AMG 416 | 20120229-22966027007 | MITRAL/ TRICUSPID VALVE DISEASE [心臓弁膜疾患] | 20[redacted]-02-04 * | 21 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-17 * | - |
| AMG 416 | 20120229-22966027007 | ALTERED MENTAL STATUS [精神状態変化] | 20[redacted]-02-08 * | 25 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-11 * | - |
| AMG 416 | 20120229-22966027007 | TRACHEOBRONCHITIS [気管気管支炎] | 20[redacted]-02-12 * | 29 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966027007 | INFECTED ABSCESS STERNAL WOUND [創傷感染] | 20[redacted]-02-15 * | 32 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-02-22 * | - |
| AMG 416 | 20120229-22966027007 | CARDIAC ARREST [心停止] | 20[redacted]-02-26 * | 43 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-26 * | - |
| AMG 416 | 20120229-22966027007 | TORSADES DE POINTES [トルサード　ド　ポアント] | 20[redacted]-02-26 * | 43 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-26 * | - |
| AMG 416 | 20120229-22966027007 | PALPITATIONS [動悸] | 20[redacted]-03-24 * | 69 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-27 * | - |
| AMG 416 | 20120229-22966027007 | SUBTHERAPEUTIC INR [抗凝固薬濃度治療量以下] | 20[redacted]-03-24 * | 69 | SEVERE | YES | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-31 * | - |
| AMG 416 | 20120229-22966027007 | INTERMITTENT CHEST PAIN [胸痛] | 20[redacted]-06-16 | 153 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-19 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966027007 | LEFT SIDED MUSCULOSKELETAL CHEST PAIN [筋骨格系胸痛] | 20[redacted]-12-15 * | 335 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-18 * | - |
| AMG 416 | 20120229-22966029001 | CHEST PAIN - CARDIAC NON MI [狭心症] | 20[redacted]-08-18T16:58 * | -192 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-09-06 * | - |
| AMG 416 | 20120229-22966029001 | GASTROENTERITIS [胃腸炎] | 20[redacted]-02-17T05:33 * | -9 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-24T18:55 ** | - |
| AMG 416 | 20120229-22966029001 | OSTEOMYELITIS [骨髄炎] | 20[redacted]-12-03T06:57 | 281 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-01-05 | - |
| AMG 416 | 20120229-22966029005 | CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-09-29T15:12 | 155 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-05 | - |
| AMG 416 | 20120229-22966029005 | ENCEPHALOPATHY SECONDARY TO ANOXIC EVENT [低酸素性虚血性脳症] | 20[redacted]-12-10 | 227 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-23 | - |
| AMG 416 | 20120229-22966031004 | FLUID OVERLOAD [水分過負荷] | 20[redacted]-09-16T14:11 | 147 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-20T18:36 * | - |
| AMG 416 | 20120229-22966031004 | CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION [慢性閉塞性肺疾患] | 20[redacted]-12-26 | 248 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-06 * | - |
| AMG 416 | 20120229-22966031004 | PNEUMONIA [肺炎] | 20[redacted]-12-26 | 248 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-09 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966031004 | PNEUMONIA [肺炎] | 20[redacted]-05-01 | 374 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-04 | - |
| AMG 416 | 20120229-22966031006 | FLUID OVERLOAD [水分過負荷] | 20[redacted]-05-18T19:42 * | 54 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-19T12:30 * | - |
| AMG 416 | 20120229-22966031006 | INFECTIOUS MONONUCLEOSIS [伝染性単核症] | 20[redacted]-03-01 | 341 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-06 | - |
| AMG 416 | 20120229-22966033003 | NON CARDIAC CHEST PAIN [非心臓性胸痛] | 20[redacted]-03-30 | 75 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-31 | - |
| AMG 416 | 20120229-22966033003 | HYPOGLYCEMIA [低血糖症] | 20[redacted]-04-17 | 93 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-04-19 | - |
| AMG 416 | 20120229-22966035004 | INFECTED SKIN ULCER [感染性皮膚潰瘍] | 20[redacted]-01-07 | 28 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-02-07 | - |
| AMG 416 | 20120229-22966035004 | MALIGNANT HTN [悪性高血圧] | 20[redacted]-12-01 | 356 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966035005 | ANGINA PECTORIS [狭心症] | 20[redacted]-05-01T23:00 | 95 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966035005 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-05-14 | 108 | MODERATE | YES | - | DOSE ALTERED OR WITHHELD | OTHER | NOT RELATED | 20[redacted]-05-29 | - |
| AMG 416 | 20120229-22966035005 | MALIGNANT HYPERTENSION [悪性高血圧] | 20[redacted]-05-14 | 108 | MODERATE | YES | - | DOSE ALTERED OR WITHHELD | OTHER | NOT RELATED | 20[redacted]-05-29 | - |
| AMG 416 | 20120229-22966035005 | RIGHT FOOT CELLULITIS [蜂巣炎] | 20[redacted]-05-14 | 108 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-29 | - |
| AMG 416 | 20120229-22966035005 | RIGHT FOOT ULCER [皮膚潰瘍] | 20[redacted]-05-14 | 108 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-29 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966035005 | ACUTE PULMONARY EDEMA [急性肺水腫] | 20[redacted]-08-31 | 217 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-01 | - |
| AMG 416 | 20120229-22966035005 | CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-11-30 | 308 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-02 | - |
| AMG 416 | 20120229-22966035005 | VOLUME OVERLOAD [水分過負荷] | 20[redacted]-11-30 | 308 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-02 | - |
| AMG 416 | 20120229-22966035005 | LEFT TOE OSTEOMYELITIS [骨髄炎] | 20[redacted]-12-18 | 326 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-23 | - |
| AMG 416 | 20120229-22966035005 | LEFT FOOT PAIIN [四肢痛] | 20[redacted]-12-19 * | 327 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-23 | - |
| AMG 416 | 20120229-22966035005 | LIVER TOXICITY [肝毒性] | 20[redacted]-01-02 * | 341 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966035005 | CELLULITIS OF BOTH LEGS [蜂巣炎] | 20[redacted]-01-21 * | 360 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966035005 | SHORTNESS OF BREATH [呼吸困難] | 20[redacted]-02-15 * | 385 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966035005 | ULCER OF FOOT [皮膚潰瘍] | 20[redacted]-02-25 | 395 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966035010 | CHEST PAIN(NON CARDIAC ORIGIN) [非心臓性胸痛] | 20[redacted]-03-26 | 13 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-01 | - |
| AMG 416 | 20120229-22966037001 | PANCREATITIS [膵炎] | 20[redacted]-07-23T10:00 * | 55 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-27T12:00 | - |
| AMG 416 | 20120229-22966037001 | HYPOGLYCEMIA [低血糖症] | 20[redacted]-01-24 * | 240 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING * | - |
| AMG 416 | 20120229-22966037001 | DIARRHOEA [下痢] | 20[redacted]-01-25 | 241 | MODERATE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-01-26 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966037001 | ARTERIO-VENOUS FISTULA SITE BLEEDING. [動静脈瘻部位出血] | 20[redacted]-03-03 | 278 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-04 | - |
| AMG 416 | 20120229-22966041005 | BILATERAL PLEURAL EFFUSION [胸水] | 20[redacted]-08-25 | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-18 | - |
| AMG 416 | 20120229-22966041005 | IATROGENIC SPLENIC INJURY [脾臓損傷] | 20[redacted]-08-25 | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-09-05 | - |
| AMG 416 | 20120229-22966041005 | POST-OP RESPIRATORY FAILURE [術後呼吸不全] | 20[redacted]-08-25 | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-18 | - |
| AMG 416 | 20120229-22966041005 | SYNCOPE [失神] | 20[redacted]-08-25 | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-08-25 | - |
| AMG 416 | 20120229-22966041005 | CELLULITIS OF LEFT FOOT [蜂巣炎] | 20[redacted]-10-17 | 145 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-23 | - |
| AMG 416 | 20120229-22966041005 | WORSENING PERIPHERAL ARTERY DISEASE [末梢動脈閉塞性疾患] | 20[redacted]-10-17 | 145 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-23 | - |
| AMG 416 | 20120229-22966041005 | CARDIAC ARREST [心停止] | 20[redacted]-10-23T00:45 | 151 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-23T00:45 | - |
| AMG 416 | 20120229-22966045001 | NSTEMI [急性心筋梗塞] | 20[redacted]-06-09 | 69 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-17 | - |
| AMG 416 | 20120229-22966045001 | HYPOTENSION [低血圧] | 20[redacted]-06-30 | 90 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-07-02 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966047002 | OCCLUDED FISTULA [動静脈瘻閉塞] | 20[redacted]-03-21 | 17 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-22 | - |
| AMG 416 | 20120229-22966049004 | CELLULITIS - BLLATERAL LEGS [蜂巣炎] | 20[redacted]-05-16 | 8 | MODERATE | YES | - | DRUG WITHDRAWN | MEDICATION TAKEN | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966049006 | ACUTE BILIARY PANCREATITIS [急性膵炎] | 20[redacted]-05-17 | 23 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-21 | - |
| AMG 416 | 20120229-22966049006 | CHOLECYSTITIS [胆嚢炎] | 20[redacted]-05-17 | 23 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-21 | - |
| AMG 416 | 20120229-22966051009 | COLON CANCER STAGE II [結腸癌第２期] | 20[redacted]-03-31T11:00 | 102 | SEVERE | YES | - | DRUG WITHDRAWN | SURGICAL INTERVENTION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966051016 | FEVER [発熱] | 20[redacted]-02-19 | 284 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-21 | - |
| AMG 416 | 20120229-22966053002 | CHEST PAIN [胸痛] | 20[redacted]-08-18 | 242 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-21 | - |
| AMG 416 | 20120229-22966053002 | ANTRAL EROSIONS [びらん性胃炎] | 20[redacted]-09-07 | 262 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-10 | - |
| AMG 416 | 20120229-22966053002 | RESPIRATORY INSUFFICENCEY [呼吸不全] | 20[redacted]-09-22 | 277 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-25 | - |
| AMG 416 | 20120229-22966053002 | SHORTNESS OF BREATH [呼吸困難] | 20[redacted]-10-05 | 290 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-22 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966053002 | WORSENING HEART FAILURE [心不全] | 20[redacted]-10-06 | 291 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-10-22 | - |
| AMG 416 | 20120229-22966055002 | NONCARDIAC CHEST PAIN [非心臓性胸痛] | 20[redacted]-01-25T00:12 | 20 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-26T00:12 | - |
| AMG 416 | 20120229-22966055002 | GI BLEED SECONDARY TO GASTRITIS [出血性胃炎] | 20[redacted]-10-02 | 270 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | RELATED | 20[redacted]-10-06 | - |
| AMG 416 | 20120229-22966055002 | ABDOMINAL PAIN, SECONDARY TO ENTERITIS [小腸炎] | 20[redacted]-12-15 | 344 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-12-19 | - |
| AMG 416 | 20120229-22966057002 | CELLULITIS [蜂巣炎] | 20[redacted]-11-28T11:00 | 390 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-12-08 | - |
| AMG 416 | 20120229-22966057002 | HEMATOMA [血腫] | 20[redacted]-11-28T11:00 | 390 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-12-08 | - |
| AMG 416 | 20120229-22966057002 | LEFT LEG PAIN [四肢痛] | 20[redacted]-11-28T11:00 | 390 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-12-08 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966057007 | LOW BLOOD PRESSURE [低血圧] | 20[redacted]-10-27T11:25 | 251 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-10-28T09:00 | - |
| AMG 416 | 20120229-22966059001 | ACCESS SITE BLEEDING (AV FISTULA) [動静脈瘻部位出血] | 20[redacted]-03-02 | 110 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-03 | - |
| AMG 416 | 20120229-22966059001 | ISCHEMIC BOWEL [腸管虚血] | 20[redacted]-03-04 | 112 | LIFE THREATENING | YES | Is Life Threatening | DRUG WITHDRAWN | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-05 | - |
| AMG 416 | 20120229-22966059001 | SEPTIC SHOCK [敗血症性ショック] | 20[redacted]-03-04 | 112 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-03-05 | - |
| AMG 416 | 20120229-22966059001 | BILATERAL CEREBRAL STROKE [脳血管発作] | 20[redacted]-03-05 | 113 | LIFE THREATENING | YES | Is Life Threatening | DRUG WITHDRAWN | NO ACTION TAKEN | NOT RELATED | 20[redacted]-03-05 | - |
| AMG 416 | 20120229-22966061004 | ALLERGY [過敏症] | 20[redacted]-02-03 | 376 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-05 | - |
| AMG 416 | 20120229-22966061004 | ANGIOEDEMA [血管浮腫] | 20[redacted]-02-03 | 376 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-05 | - |
| AMG 416 | 20120229-22966061004 | BACK OF THROAT WAS CLOSING OUT [咽喉絞扼感] | 20[redacted]-02-03 | 376 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-05 | - |
| AMG 416 | 20120229-22966061004 | STRIDOR [上気道性喘鳴] | 20[redacted]-02-03 | 376 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-05 | - |
| AMG 416 | 20120229-22966061008 | HYPOTENSION [低血圧] | 20[redacted]-06-14T17:19 | 11 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-18T19:40 | - |
| AMG 416 | 20120229-22966061008 | WEAKNESS [無力症] | 20[redacted]-06-14T17:19 | 11 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-18T19:40 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966079005 | ARTERIOVENOUS GRAFT THROMBOSIS [血管グラフト血栓症] | 20[redacted]-08-11 | 197 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-08-13 | - |
| AMG 416 | 20120229-22966081002 | DEPRESSION WITH SUICIDAL IDEATION [希死念慮を有するうつ病] | 20[redacted]-02-05 | 17 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-06 | - |
| AMG 416 | 20120229-22966081002 | MAXILLARY SINUS FRACTURE [顎の骨折] | 20[redacted]-06-04 | 136 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-13 | - |
| AMG 416 | 20120229-22966081002 | SYNCOPAL EPISODE [失神] | 20[redacted]-06-04 | 136 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-13 | - |
| AMG 416 | 20120229-22966081002 | DEPRESSION [うつ病] | 20[redacted]-09-05 | 229 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-17 | - |
| AMG 416 | 20120229-22966081002 | HELICOBACTER PYLORI GASTRITIS WITH EROSION [ヘリコバクター性胃炎] | 20[redacted]-09-09 | 233 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-09-17 | - |
| AMG 416 | 20120229-22966081006 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-05-27 | 51 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-07 | - |
| AMG 416 | 20120229-22966081006 | HYPOCALCEMIA [低カルシウム血症] | 20[redacted]-05-27 | 51 | MODERATE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | RELATED | 20[redacted]-06-09 | - |
| AMG 416 | 20120229-22966081006 | HYPOTENSION [低血圧] | 20[redacted]-05-27 | 51 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-07 | - |
| AMG 416 | 20120229-22966081006 | SYNCOPE [失神] | 20[redacted]-08-25 | 141 | SEVERE | YES | - | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-08-25 | - |
| AMG 416 | 20120229-22966081006 | COUGH [咳嗽] | 20[redacted]-09-29 | 176 | MODERATE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966081006 | GASTROESOPHAGEAL REFLUX DISEASE [胃食道逆流性疾患] | 20[redacted]-11-20 | 228 | MODERATE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | ONGOING | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966081006 | SEASONAL ALLERGIES [季節性アレルギー] | 20[redacted]-11-21 | 229 | MODERATE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966087005 | COMPRESSION FRACTURE [圧迫骨折] | 20[redacted]-03-17T17:00 | 34 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-04-10T18:00 | - |
| AMG 416 | 20120229-22966087005 | BACTEREMIA [菌血症] | 20[redacted]-03-17T18:00 | 34 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, CULTURE TAKEN, IV ANTIMICROBIAL TAKEN | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966087005 | BACTEREMIA [菌血症] | 20[redacted]-05-06T09:00 | 84 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-05-09T15:00 | - |
| AMG 416 | 20120229-22966087005 | ALTERED MENTAL STATUS [精神状態変化] | 20[redacted]-05-06T12:30 | 84 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966087005 | LEFT FOOT FRACTURE [足骨折] | 20[redacted]-08-06T09:00 | 176 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-08-11T12:20 | - |
| AMG 416 | 20120229-22966087006 | CHEST PAIN (NON-CARDIAC) [非心臓性胸痛] | 20[redacted]-10-22T21:14 | 204 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-10-23T19:57 | - |
| AMG 416 | 20120229-22966089001 | CELLULITIS LEFT SECOND TOE [蜂巣炎] | 20[redacted]-05-19 | 102 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-20 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966089001 | LEFT ANKLE SWELLING [関節腫脹] | 20[redacted]-12-08 | 305 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-10 | - |
| AMG 416 | 20120229-22966089001 | BRONCHOSPASM [気管支痙攣] | 20[redacted]-12-26 | 323 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-27 | - |
| AMG 416 | 20120229-22966089006 | CHEST PAIN [胸痛] | 20[redacted]-11-11 | 223 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-13 | - |
| AMG 416 | 20120229-22966089006 | EXERTIONAL DYSPNEA [労作性呼吸困難] | 20[redacted]-11-11 | 223 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-13 | - |
| AMG 416 | 20120229-22966089006 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-11-11 | 223 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-15 | - |
| AMG 416 | 20120229-22966113006 | DIALYSIS ACCESS HEMORRHAGE [動静脈瘻部位出血] | 20[redacted]-05-13* | 14 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-15* | - |
| AMG 416 | 20120229-22966113006 | DIALYSIS ACCESS HEMORRHAGE [動静脈瘻部位出血] | 20[redacted]-03-31T23:00* | 336 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-04-01T08:00* | - |
| AMG 416 | 20120229-22966113006 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-04-21 | 357 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-04-22 | - |
| AMG 416 | 20120229-22966117001 | LEFT HAND STEAL SYNDROME [スチール症候群] | 20[redacted]-05-07 | 41 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-10 | - |
| AMG 416 | 20120229-22966117001 | ASPIRATION [誤嚥] | 20[redacted]-05-11 | 45 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE ALTERED OR WITHHELD | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-05-11 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966121002 | CORNARY ARTERY DISEASE [冠動脈疾患] | 20[redacted]-06-26 | 24 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966121002 | LARGE NONHEMORRHAGIC RIGHT MCA DISTRIBUTION INFARCTION WITHOUT HEMORRHAGE OR MIDLINE SHIFT [脳梗塞] | 20[redacted]-06-27 | 25 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966121007 | ALTERED MENTAL STATUS [精神状態変化] | 20[redacted]-03-28T15:30 | -6 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-01 | - |
| AMG 416 | 20120229-22966121007 | FALSE POSITIVE ELEVATION OF TROPONIN (NO FURTHER INFORMATION AVAILABLE) [トロポニン増加] | 20[redacted]-05-27 | 55 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-28 | - |
| AMG 416 | 20120229-22966121007 | ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE [心房細動] | 20[redacted]-12-06* | 248 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-09 | - |
| AMG 416 | 20120229-22966121007 | FALL [転倒] | 20[redacted]-01-23 | 296 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966133004 | RUPTURED DIALYSIS ACCESS [血管確保合併症] | 20[redacted]-09-29 | 252 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-10-01 | - |
| AMG 416 | 20120229-22966133009 | ABDOMINAL WALL CELLULITIS [蜂巣炎] | 20[redacted]-03-02 | 6 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-03-24 | - |
| AMG 416 | 20120229-22966133009 | CHEST PAIN [胸痛] | 20[redacted]-12-23T18:00 | 302 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-12-28 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966133014 | PNEUMONIA [肺炎] | 20[redacted]-05-14 | -2 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-19 | - |
| AMG 416 | 20120229-22966133014 | FLUID OVERLOAD [水分過負荷] | 20[redacted]-08-18T12:00 | 95 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-08-21 | - |
| AMG 416 | 20120229-22966133014 | FLUID OVERLOAD [水分過負荷] | 20[redacted]-09-06 * | 114 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-09 * | - |
| AMG 416 | 20120229-22966133014 | RIGHT GLUTEAL ABCESS [皮下組織膿瘍] | 20[redacted]-03-02 | 291 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-06 * | - |
| AMG 416 | 20120229-22966167001 | ALK ELEVATION (WORSENING) [血中アルカリホスファターゼ増加] | 20[redacted]-12-17 | 330 | MODERATE | YES | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | ALT ELEVATION (WORSENING NO FURTHER INFORMATION AVAILABLE) [アラニンアミノトランスフェラーゼ増加] | 20[redacted]-12-17 | 330 | MODERATE | YES | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | AST ELEVATION (WORSENING NO FURTHER INFORMATION AVAILABLE) [アスパラギン酸アミノトランスフェラーゼ増加] | 20[redacted]-12-17 | 330 | MODERATE | YES | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | DIRECT BILIRUBIN ELEVATION [抱合ビリルビン増加] | 20[redacted]-12-17 | 330 | SEVERE | YES | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | TOTAL BILIRUBIN ELEVATION [血中ビリルビン増加] | 20[redacted]-12-17 * | 330 | SEVERE | YES | - | DOSE NOT CHANGED | OTHER, OTHER | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | ALTERED MENTAL STATUS [精神状態変化] | 20[redacted]-02-09 | 384 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966167001 | HYPOGLYCEMIA [低血糖症] | 20[redacted]-02-09 * | 384 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | HYPOTHERMIA [低体温] | 20[redacted]-02-09 * | 384 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | PANCREATIC CARCINOMA [膵癌] | 20[redacted]-02-10 * | 385 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | PANCREATIC DUCT OBSTRUCTION [膵管閉塞] | 20[redacted]-02-10 * | 385 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | SEVERE SEPSIS [敗血症] | 20[redacted]-02-11 * | 386 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN, OTHER | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | ACUTE RESPIRATORY FAILURE [急性呼吸不全] | 20[redacted]-02-15 * | 390 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER | NOT RELATED | 20[redacted]-02-17 * | - |
| AMG 416 | 20120229-22966167001 | ACINETOBACTER BACTEREMIA [アシネトバクター性菌血症] | 20[redacted]-02-16 | 391 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN, OTHER | NOT RELATED | 20[redacted]-02-17 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966167005 | WORSENING OF ELEVATED INTERNATIONAL NORMALIZED RATIO (INR) [国際標準比増加] | 20[redacted]-08-06T17:08 | 169 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-08-10T04:15 | - |
| AMG 416 | 20120229-22966171004 | LEFT SIDED WEAKNESS, CAUSE UNCERTAIN [不全片麻痺] | 20[redacted]-04-01 * | 41 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-02 * | - |
| AMG 416 | 20120229-22966171004 | MINI STROKE [一過性脳虚血発作] | 20[redacted]-02-12 | 358 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-03-06 | - |
| AMG 416 | 20120229-22966193002 | ALTERED MENTAL STATUS [精神状態変化] | 20[redacted]-09-11T15:37 | 183 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-17T12:55 | - |
| AMG 416 | 20120229-22966193002 | ASPIRATION PNEUMONIA [誤嚥性肺炎] | 20[redacted]-09-11T15:37 | 183 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-17T12:55 | - |
| AMG 416 | 20120229-22966193002 | GASTROENTERITIS [胃腸炎] | 20[redacted]-09-11T15:37 | 183 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-17T12:55 | - |
| AMG 416 | 20120229-22966193002 | NAUSEA [悪心] | 20[redacted]-09-11T15:37 | 183 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-17T12:55 | - |
| AMG 416 | 20120229-22966193002 | VOMITING [嘔吐] | 20[redacted]-09-11T15:37 | 183 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-17T12:55 | - |
| AMG 416 | 20120229-22966193002 | TUBULAR ADENOMACARCINOMA OF THE COLON [結腸腺癌] | 20[redacted]-09-29T07:00 * | 201 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | OTHER | NOT RELATED | 20[redacted]-10-09 * | - |
| AMG 416 | 20120229-22966193002 | ACUTE GASTROENTERITIS [胃腸炎] | 20[redacted]-01-10T08:00 | 304 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-14T08:00 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966193004 | C. DIFFICILE INFECTION [クロストリジウム・ディフィシレ感染] | 20[redacted]-12-26T08:00 | 288 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-04T08:00 * | - |
| AMG 416 | 20120229-22966193004 | LOWER GI BLEED [胃腸出血] | 20[redacted]-12-26T08:00 | 288 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-04T08:00 * | - |
| AMG 416 | 20120229-22966193004 | PRESUMPTIVE LIVER CIRRHOSIS [肝硬変] | 20[redacted]-12-26T08:00 * | 288 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-04T08:00 * | - |
| AMG 416 | 20120229-22966193004 | FRACTURED ANKLE [足関節部骨折] | 20[redacted]-01-18T07:00 * | 311 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-22T07:00 * | - |
| AMG 416 | 20120229-22966193004 | LOWER GI BLEED [胃腸出血] | 20[redacted]-03-09T07:00 | 361 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-12T07:00 | - |
| AMG 416 | 20120229-22966193009 | ALTERED MENTAL STATUS [精神状態変化] | 20[redacted]-05-31T07:00 | 19 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966193009 | VOMITTING [嘔吐] | 20[redacted]-05-31T07:00 | 19 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966215001 | FRACTURES, MULTIPLE [多発骨折] | 20[redacted]-01-27 | 274 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966215001 | INTRACRANIAL HEMORRHAGE [頭蓋内出血] | 20[redacted]-01-27 | 274 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120229-22966233001 | BRADYCARDIA [徐脈] | 20[redacted]-07-14 | 76 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-16 | - |
| AMG 416 | 20120229-22966233001 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-07-14 | 76 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-16 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120229-22966233001 | PRESYNCOPE LIKELY SECONDARY TO BRADYCARDIA [失神寸前の状態] | 20[redacted]-07-14 | 76 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-16 | - |
| AMG 416 | 20120230-23011006002 | RIGHT RECTUS SHEATH HAEMATOMA [腹壁血腫] | 20[redacted]-09-04 | 161 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-21 | - |
| AMG 416 | 20120230-23011006003 | HEADACHE [頭痛] | 20[redacted]-06-18 | 64 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-19 | - |
| AMG 416 | 20120230-23011006003 | UNCONSCIOUS COLLAPSE [失神] | 20[redacted]-06-18T14:45 | 64 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-18T14:54 | - |
| AMG 416 | 20120230-23011006003 | LOWER RESPIRATORY TRACT INFECTION [下気道感染] | 20[redacted]-06-23 | 69 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-26 | - |
| AMG 416 | 20120230-23011006003 | ACUTE PULMONARY OEDEMA [急性肺水腫] | 20[redacted]-06-23T10:09 | 69 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-23T20:45 | - |
| AMG 416 | 20120230-23011008002 | THROMBOSED RIGHT PTFE GRAFT (DIALYSIS ACCESS) [血管グラフト血栓症] | 20[redacted]-06-09T10:00 | 48 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-06-18T15:21 | - |
| AMG 416 | 20120230-23011008002 | MULTINODULAR GOITRE [甲状腺腫] | 20[redacted]-11-28T08:30 | 220 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-12-02T15:00 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23011008002 | THYROID FOLLICULAR LESION [甲状腺新生物] | 20[redacted]-11-28T08:30 | 220 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-12-02T15:00 | - |
| AMG 416 | 20120230-23011008002 | LOW SERUM CALCIUM [血中カルシウム減少] | 20[redacted]-11-28T17:32 | 220 | MODERATE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, OTHER | NOT RELATED | 20[redacted]-11-29T07:53 | - |
| AMG 416 | 20120230-23011008007 | BRITTLE TEETH AND BONE DUE TO TEETH DECAY [齲歯] | 20[redacted]-02-13T10:46 | 311 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-02-15T10:29 | - |
| AMG 416 | 20120230-23011010001 | WORSENING BILATERAL HIP PAIN [関節痛] | 20[redacted]-04-14 | 20 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | RELATED | 20[redacted]-05-14 | - |
| AMG 416 | 20120230-23011010001 | WORSENING HYPOPHOSPHATAEMIA [低リン酸血症] | 20[redacted]-04-14 | 20 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | RELATED | 20[redacted]-04-23 | - |
| AMG 416 | 20120230-23011010001 | FLUID OVERLOAD [水分過負荷] | 20[redacted]-04-28 | 34 | SEVERE | YES | - | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-04-29 | - |
| AMG 416 | 20120230-23011010001 | HYPERKALAEMIA [高カリウム血症] | 20[redacted]-04-28 | 34 | SEVERE | YES | - | DOSE NOT CHANGED | DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-04-29 | - |
| AMG 416 | 20120230-23011010001 | EXACERBATION OF CONGESTIVE CARDIAC FAILURE (CCF) [うっ血性心不全] | 20[redacted]-05-05 | 41 | SEVERE | YES | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-05 | - |
| AMG 416 | 20120230-23011010001 | INFECTED RIGHT INDEX FINGER [限局性感染] | 20[redacted]-10-25 | 214 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-10-27 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23011010001 | OBSTRUCTED LEFT RV AVF OUTFLOW [動静脈瘻閉塞] | 20[redacted]-12-01 | 251 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-04 | - |
| AMG 416 | 20120230-23011012003 | DIARRHOEA [下痢] | 20[redacted]-03-28T12:00 | 45 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-04-21T12:00 | - |
| AMG 416 | 20120230-23011012003 | CLOTTED FISTULA [動静脈瘻血栓症] | 20[redacted]-04-11T08:00 | 59 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-04-14 | - |
| AMG 416 | 20120230-23011012003 | LOWER RESPIRATORY TRACT INFECTION [下気道感染] | 20[redacted]-04-15T00:05 | 63 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-03T12:00 | - |
| AMG 416 | 20120230-23011012003 | POST OPERATIVE HAEMATOMA OF LEFT AVF [処置後血腫] | 20[redacted]-07-28T16:00 | 167 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-07-28T23:00 | - |
| AMG 416 | 20120230-23011012003 | HYPERKALEAMIA [高カリウム血症] | 20[redacted]-07-30T07:00 | 169 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-07-30T13:25** | - |
| AMG 416 | 20120230-23011012005 | SPLIT SKIN GRAFT TO ULCER ON LEFT LOWER LEG POSTERIA ASPECT [植皮感染] | 20[redacted]-10-21T12:00 | -200 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-08 | - |
| AMG 416 | 20120230-23011012005 | ATRIAL FIBRILATION [心房細動] | 20[redacted]-12-20T08:50* | -140 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-12-24T23:59** | - |
| AMG 416 | 20120230-23011012005 | NECROTIC ULCER IN THE LATERAL LOWER LEFT LEG [皮膚潰瘍] | 20[redacted]-08-28T12:00 | 112 | MODERATE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-04-29 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23011012005 | PERIPHERAL VASCULAR DISEASE- LEFT LEG ULCER [末梢血管障害] | 20[redacted]-08-28T12:00 * | 112 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-04-29 ** | - |
| AMG 416 | 20120230-23011012005 | WORSENING OF NECROTIC ARTERIAL ULCER OF LEFT LOWER LEG [皮膚潰瘍] | 20[redacted]-12-04T12:00 | 210 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-08 | - |
| AMG 416 | 20120230-23013002001 | SYNCOPE [失神] | 20[redacted]-04-14T18:22 | 6 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-15T12:00 | - |
| AMG 416 | 20120230-23013002003 | PNEUMONIA [肺炎] | 20[redacted]-12-15T06:47 | 237 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-12-27 | - |
| AMG 416 | 20120230-23013004001 | ABDOMINAL ABCESS WALL [腹壁膿瘍] | 20[redacted]-06-04 | 87 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23013004004 | NODULE LEFT LUNG [肺腫瘤] | 20[redacted]-06-17 | 65 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-06-17 | - |
| AMG 416 | 20120230-23013004004 | AV FISTULA HEMORRAGY ON LEFT ARM [動静脈瘻部位出血] | 20[redacted]-07-31T18:00 | 109 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-07-31 | - |
| AMG 416 | 20120230-23013006002 | PULMONARY CONGESTION [肺うっ血] | 20[redacted]-02-06 | 28 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | ONGOING | - |

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| AMG 416 | 20120230-230130060 02 | WORSENING AORTIC VALVA INSUFFICIENCY [大動脈弁閉鎖不全症] | 20[redacted]-02-14 | 36 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-04-09 | - |
| AMG 416 | 20120230-230130060 02 | WORSENING CORONARY STENOSIS [冠動脈狭窄] | 20[redacted]-02-14 | 36 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-04-09 | - |
| AMG 416 | 20120230-230130060 02 | KLEBSIELLA SEPSIS ON DIALYSIS CATHETER [医療機器関連敗血症] | 20[redacted]-09-24 | 258 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-11 | - |
| AMG 416 | 20120230-230130080 02 | CHILL [悪寒] | 20[redacted]-03-17T10:00 | 1 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-03-17 | - |
| AMG 416 | 20120230-230130080 02 | PNEUMONIA [肺炎] | 20[redacted]-03-17T10:00 | 1 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-04-07 | - |
| AMG 416 | 20120230-230130080 02 | VOMITING [嘔吐] | 20[redacted]-03-17T10:00 | 1 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, OTHER | NOT RELATED | 20[redacted]-03-17 | - |
| AMG 416 | 20120230-230130080 03 | DISABLING PAIN IN RIGHT SIDE OF ABDOMEN (PARIETAL APPEARANCE) [腹痛] | 20[redacted]-10-26* | 196 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER | NOT RELATED | 20[redacted]-10-29 | - |
| AMG 416 | 20120230-230130080 03 | FEMORAL NECK FRACTURE (RIGHT SIDE) [大腿骨頚部骨折] | 20[redacted]-01-30T13:00 | 292 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-230130120 01 | ABSCESS IN THE AMPUTATION ZONE [術後膿瘍] | 20[redacted]-07-11 | -146 | SEVERE | YES | - | DOSE NOT CHANGED | CULTURE TAKEN, OTHER | NOT RELATED | 20[redacted]-12-19 | - |

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| AMG 416 | 20120230-23013012001 | HYPERVOLEMIA [血液量増加症] | 20[redacted]-02-09 * | 68 | SEVERE | YES | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-02-10 * | - |
| AMG 416 | 20120230-23013012001 | HYPERTHERMIA [高熱] | 20[redacted]-02-18 * | 77 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-28 * | - |
| AMG 416 | 20120230-23013012001 | ACUTE PANCREATITIS [急性膵炎] | 20[redacted]-03-08 * | 95 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-22 * | - |
| AMG 416 | 20120230-23013012001 | INFECTIOUS ENTERITIS [感染性腸炎] | 20[redacted]-08-22 | 262 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-30 | - |
| AMG 416 | 20120230-23013012003 | SQUAMOUS CELL CARCINOMA EYEBROW [皮膚有棘細胞癌] | 20[redacted]-02-05 | 56 | SEVERE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-02-05 | - |
| AMG 416 | 20120230-23016001004 | CORONARY DISEASE OF 3 VESSELS [冠動脈疾患] | 20[redacted]-02-17 | 308 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-02-26 | - |
| AMG 416 | 20120230-23016001004 | UPPER RESPIRATORY TRACT INFECTION [上気道感染] | 20[redacted]-03-30T11:07 | 349 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-03-31T11:48 | - |
| AMG 416 | 20120230-23016005003 | DIABETIC KETOACIDOSIS [糖尿病性ケトアシドーシス] | 20[redacted]-06-23 | 62 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23016005003 | DIABETIC KETOACIDOSIS [糖尿病性ケトアシドーシス] | 20[redacted]-10-27 | 188 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-29 | - |
| AMG 416 | 20120230-23016005003 | CONFUSION [錯乱状態] | 20[redacted]-11-22 | 214 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-28 | - |
| AMG 416 | 20120230-23016005003 | SYNCOPE [失神] | 20[redacted]-12-01 | 223 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23016005003 | FRACTURED BONE(RIGHT TALAR NECK)<br>[足骨折] | 20[redacted]-12-08 | 230 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23016005003 | TONIC-CLONIC SEIZURE<br>[全身性強直性間代性発作] | 20[redacted]-12-22 * | 244 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23016005003 | DELIRIUM<br>[譫妄] | 20[redacted]-03-25 | 337 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23021002001 | DUODENAL ULCUS FORREST IB, ENDOSCOPIC HEMOSTASIS<br>[十二指腸潰瘍] | 20[redacted]-11-30T11:41 | 4 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, TRANSFUSION PERFORMED, OTHER | NOT RELATED | 20[redacted]-12-06 | - |
| AMG 416 | 20120230-23021002001 | CONGESTIVE HEART FAILURE<br>[うっ血性心不全] | 20[redacted]-12-07T03:09 | 11 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-12-08T11:55 | - |
| AMG 416 | 20120230-23021002004 | DIABETES GANGRENE/NECROSIS OF 3RD,4TH,5TH TOE OF LEFT LEG<br>[糖尿病性壊疽] | 20[redacted]-05-14 | 125 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-06-05 | - |
| AMG 416 | 20120230-23021002005 | EPISTAXIS<br>[鼻出血] | 20[redacted]-07-13 * | 159 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-13 * | - |
| AMG 416 | 20120230-23021002005 | HEMODIALYSIS INDUCED HYPOTENSION<br>[処置による低血圧] | 20[redacted]-01-24 | 354 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-27 | - |
| AMG 416 | 20120230-23021010007 | WORSENING OF BENIGN PROSTATIC HYPERTROPHY.<br>[良性前立腺肥大症] | 20[redacted]-09-10T13:40 | 141 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-09-10T14:04 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-230210100 07 | WORSENING OF BENIGN PROSTATIC HYPERTROPHY [良性前立腺肥大症] | 20[redacted]-01-23T07 :54 * | 276 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-01-23T08: 24 | - |
| AMG 416 | 20120230-230210100 07 | UROSEPSIS [尿路性敗血症] | 20[redacted]-02-02T09 :30 | 286 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-230210120 01 | DILOCATION OF FRACTURE FRAGMENTS OF LEFT CLAVICULA BONE [鎖骨骨折] | 20[redacted]-06-11 | 134 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-06-14 | - |
| AMG 416 | 20120230-230210120 01 | STENOSIS OF AV PHISTULA [動静脈瘻部位合併症] | 20[redacted]-09-11 | 226 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-09-12 | - |
| AMG 416 | 20120230-230210120 03 | TROMBOSIS OF AV PHISTULA [動静脈瘻血栓症] | 20[redacted]-02-27T07 :00 | 8 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-28T12: 00 | - |
| AMG 416 | 20120230-230210120 03 | RETROMBOSIS OF AV PHISTULA [動静脈瘻血栓症] | 20[redacted]-03-04T07 :00 | 13 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-05T12: 00 | - |
| AMG 416 | 20120230-230210120 03 | ABSENCE OF AV PHISTULA [動静脈瘻部位合併症] | 20[redacted]-07-09 | 140 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-07-10 | - |
| AMG 416 | 20120230-230210120 03 | USELESS HEMODIALYSIS ACCESS [血管確保合併症] | 20[redacted]-09-10 | 203 | SEVERE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-09-11 | - |
| AMG 416 | 20120230-230210120 03 | TROMBOSIS OF AV PHISTULA [動静脈瘻血栓症] | 20[redacted]-09-18 | 211 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-09-20 | - |

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| AMG 416 | 20120230-23021012004 | ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞] | 20[redacted]-08-11 | 152 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-08-18 | - |
| AMG 416 | 20120230-23021012005 | STENOSIS OF AV PHISTULA [動静脈瘻部位合併症] | 20[redacted]-06-16 | 96 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-06-28 | - |
| AMG 416 | 20120230-23021012005 | TROMBOSIS OF AV PHISTULA [動静脈瘻血栓症] | 20[redacted]-08-07 | 148 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-08-12 | - |
| AMG 416 | 20120230-23021012005 | STENOSIS OF VENOUS PART OF AV PHISTULA [動静脈瘻部位合併症] | 20[redacted]-10-27 | 229 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, NON-IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-10-28 | - |
| AMG 416 | 20120230-23021012005 | TROMBOSIS OF AV PHISTULA [動静脈瘻血栓症] | 20[redacted]-11-15 | 248 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-11-16 | - |
| AMG 416 | 20120230-23021012006 | CARDIAC INSUFICENCE [心不全] | 20[redacted]-08-11 | 118 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-04T05:10 | - |
| AMG 416 | 20120230-23025004001 | ARTERIOVENOUS FISTULA STENOSIS [動静脈瘻部位合併症] | 20[redacted]-05-30T18:30 | 129 | SEVERE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-06-01 | - |
| AMG 416 | 20120230-23025004002 | FISTULA THROMBOSIS [動静脈瘻血栓症] | 20[redacted]-03-27T17:00 | 64 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-28T18:00 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23025004002 | FISTULA THROMBOSIS [動静脈瘻血栓症] | 20[redacted]-06-24T14:00 | 153 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-06-25T07:00 | - |
| AMG 416 | 20120230-23025004002 | ACUTE CORONARY SYNDROME [急性冠動脈症候群] | 20[redacted]-06-26T08:00 | 155 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-06-26T20:00 | - |
| AMG 416 | 20120230-23025004002 | HYPOGLYCEMIA [低血糖症] | 20[redacted]-09-04T13:00 | 225 | SEVERE | YES | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-15 | - |
| AMG 416 | 20120230-23025004004 | ARTERIOVENOUS FISTULA STENOSIS [動静脈瘻部位合併症] | 20[redacted]-02-12 | 323 | SEVERE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-02-12T20:00 | - |
| AMG 416 | 20120230-23025012002 | SEPSIS [敗血症] | 20[redacted]-08-25 | 132 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-01 | - |
| AMG 416 | 20120230-23025012005 | SIGMOITIDIS [大腸炎] | 20[redacted]-01-26 | 286 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, NON-IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-02-05 | - |
| AMG 416 | 20120230-23029004001 | CARDIATIC FAILURE [心不全] | 20[redacted]-08-03 | 236 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-06 | - |
| AMG 416 | 20120230-23029004003 | OSTEOMYELITIS PEDIS LATERIS SINISTRI [骨髄炎] | 20[redacted]-07-08 | 216 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, IV ANTIBIOTICS TAKEN, OTHER | NOT RELATED | 20[redacted]-08-15 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-230290040 03 | SEPSIS [敗血症] | 20[redacted]-08-23 | 262 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-09-05 | - |
| AMG 416 | 20120230-230290040 03 | DECUBITUS OF LEFT LEG [褥瘡性潰瘍] | 20[redacted]-09-05 | 275 | MILD | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-15 | - |
| AMG 416 | 20120230-230290040 03 | SEPSIS [敗血症] | 20[redacted]-10-15 | 315 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-18 | - |
| AMG 416 | 20120230-230290060 04 | LEG NUMBNESS [感覚鈍麻] | 20[redacted]-04-14T11:30 | 370 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-21 | - |
| AMG 416 | 20120230-230290080 02 | INCREASING OF AORTAL ANEURYSM [大動脈瘤] | 20[redacted]-04-28 | 131 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-10 | - |
| AMG 416 | 20120230-230290080 05 | HEARTH FAILURE [心不全] | 20[redacted]-11-19 | 332 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-25 | - |
| AMG 416 | 20120230-230290080 11 | SPONDYLARTHROSIS [変形性脊椎症] | 20[redacted]-03-20T14:29 | 30 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-31 | - |
| AMG 416 | 20120230-230290080 13 | PNEUMONIA [肺炎] | 20[redacted]-02-16 | 321 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-02 | - |
| AMG 416 | 20120230-230290100 02 | RIGHT KIDNEY CLEAR CELL CARCINOMA [腎明細胞癌] | 20[redacted]-06-16T11:00 | 152 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-23T17:04 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23032002006 | LT BRACHIO-AXILLAR ARTERIO-VENOUS FISTULOGRAPHY AND THROMBECTOMY ATEMPT OF PREVIOUSLY TROMBOSED AV GRAFT -FAILURE OF THROMBECTOMY (SITE REFUSED TO SPLIT) [処置後合併症] | 20[redacted]-05-27T10:34 | 27 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-05-28T12:29 | - |
| AMG 416 | 20120230-23032002006 | ELECTIVE HOSPITALIZATION FOR CONSTRUCTION OF ARTERIO-VENOUS GRAFT FOR HEMODIALYSIS [動静脈グラフト] | 20[redacted]-06-30T10:32 | 61 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-01T10:00 | - |
| AMG 416 | 20120230-23032002006 | UREMIC SYNDROME [高窒素血症] | 20[redacted]-12-07T13:00 | 221 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-12-16T14:47 | - |
| AMG 416 | 20120230-23032002009 | ACUTE MYOCARDIAL INFRACTION [急性心筋梗塞] | 20[redacted]-02-02T12:30 | 279 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-06T12:07 | - |
| AMG 416 | 20120230-23032004002 | RIGHT CAROTID STENOSIS [頚動脈狭窄] | 20[redacted]-03-31 | 335 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-04-03 | - |
| AMG 416 | 20120230-23033002003 | COMPLICATION OF FISTULA(ARTERIOVENOUS GRAFT FISTULA) [動静脈瘻部位合併症] | 20[redacted]-06-13 | 65 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-06-20 | - |
| AMG 416 | 20120230-23033002003 | COMPLICATION OF FISTULA ( STENOSIS OF FISTULA) [動静脈瘻部位合併症] | 20[redacted]-07-03 | 85 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-07-05 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23033002003 | STENOSIS OF FISTULA [動静脈瘻部位合併症] | 20[redacted]-09-09 | 153 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-09-13 | - |
| AMG 416 | 20120230-23033008004 | CHOLECISTITIS ALITIASICA [胆嚢炎] | 20[redacted]-08-28 | 234 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-09-07 | - |
| AMG 416 | 20120230-23033008004 | SEPSIS [敗血症] | 20[redacted]-08-28 | 234 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-07 | - |
| AMG 416 | 20120230-23042004001 | SHUNT CLOSE BY THROMBUS [シャント血栓症] | 20[redacted]-03-20T08:00 | 17 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-23T08:00 | - |
| AMG 416 | 20120230-23042004001 | BLADDER WITH PUS [膀胱炎] | 20[redacted]-03-23T08:00 | 20 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-29T08:00 ** | - |
| AMG 416 | 20120230-23042004001 | PNEUMONIA [肺炎] | 20[redacted]-12-30T08:00 * | 302 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-01-06T08:00 * | - |
| AMG 416 | 20120230-23042004001 | RECURRENCE RESPIRATORY INFECTION [気道感染] | 20[redacted]-01-15T08:00 * | 318 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-23 * | - |
| AMG 416 | 20120230-23042004001 | RECCURRENCE RESPIRATOR INFECTION [気道感染] | 20[redacted]-01-31T08:00 | 334 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-04T08:00 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-230420040 01 | PERI-ANAL ABSCESS [直腸周囲膿瘍] | 20[redacted]-02-18T20 :00 | 352 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-02 | - |
| AMG 416 | 20120230-230420060 02 | ACUTE CORONARY SYNDROME [急性冠動脈症候群] | 20[redacted]-06-30T19 :02 | 127 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-07-04 | - |
| AMG 416 | 20120230-230420060 03 | HERNIA INGUINALIS [鼠径ヘルニア] | 20[redacted]-10-20T08 :00 | 182 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-10-21 | - |
| AMG 416 | 20120230-230420100 01 | HOSPITALISATION DUE TO SHUNT INFECTION [シャント感染] | 20[redacted]-12-30 | 288 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN, NON-IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-01-06 * | - |
| AMG 416 | 20120230-230480020 03 | CHRONIC CORONARY HEART DISEASE [冠動脈疾患] | 20[redacted]-05-28 | 45 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-05-30 | - |
| AMG 416 | 20120230-230480020 03 | AGGRAVATED ARTERIAL HYPERTENSION [高血圧] | 20[redacted]-07-03 | 81 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-24 | - |
| AMG 416 | 20120230-230480020 03 | SUBARACHNOID HEMORRHAGE [くも膜下出血] | 20[redacted]-07-03 | 81 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-24 | - |
| AMG 416 | 20120230-230480020 03 | ATRIO-VENTRICULAR BLOCK 3 DEGREE [完全房室ブロック] | 20[redacted]-08-19 | 128 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-09-22 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23048002003 | AGGRAVATED DIABETIC FOOT [糖尿病性足病変] | 20[redacted]-10-20 | 190 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23048002004 | AGGRAVATED ARTERIAL HYPERTENSION [高血圧] | 20[redacted]-07-14 | 78 | SEVERE | YES | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-07-18 | - |
| AMG 416 | 20120230-23048002004 | MYOCARDIAL INFARCTION [心筋梗塞] | 20[redacted]-07-15 | 79 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-07-18 | - |
| AMG 416 | 20120230-23048002004 | CORONARY HEART DISEASE [冠動脈疾患] | 20[redacted]-08-18 | 113 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23048002004 | URINARY TRACT INFECTION [尿路感染] | 20[redacted]-08-27 | 122 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-08-29 | - |
| AMG 416 | 20120230-23048002004 | HEMORRHAGE TO PELVIC [骨盤内出血] | 20[redacted]-08-29 | 124 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-09-12 | - |
| AMG 416 | 20120230-23048002004 | HEART FAILURE [心不全] | 20[redacted]-12-10 | 227 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-22* | - |
| AMG 416 | 20120230-23048002004 | PNEUMONIA [肺炎] | 20[redacted]-12-31* | 248 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-01-15 | - |
| AMG 416 | 20120230-23048002004 | AGGRAVATED ARTERIAL HYPERTENSION [高血圧] | 20[redacted]-01-26* | 274 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING* | - |
| AMG 416 | 20120230-23048002004 | MYOCARDIAL INFARCTION [心筋梗塞] | 20[redacted]-05-11 | 379 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-15 | - |
| AMG 416 | 20120230-23048002005 | HAEMORRHAGIC STROKE [出血性卒中] | 20[redacted]-02-27 | 411 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-02-27 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23048002009 | MECHANICAL SUBILEUS [亜イレウス] | 20[redacted]-05-24 | 33 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-10 | - |
| AMG 416 | 20120230-23048002009 | PARAPARESIS BECOUSE OF METASTASES TO THE SPINE [脊椎転移] | 20[redacted]-08-28 | 129 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-17 | - |
| AMG 416 | 20120230-23048002009 | BREAST CANCER [乳癌] | 20[redacted]-09-12 | 144 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-17T21:25 | - |
| AMG 416 | 20120230-23048004009 | PNEUMONIA [肺炎] | 20[redacted]-09-25 | 295 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-10-14 | - |
| AMG 416 | 20120230-23048004016 | POSITIVE HCV ANTIBODIES TEST [C型肝炎抗体陽性] | 20[redacted]-04-30 | 122 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23048004020 | SUDDEN DEATH [突然死] | 20[redacted]-11-24 | 266 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-11-24 | - |
| AMG 416 | 20120230-23048008001 | PARONYCHIA AND LEFT HAND SUBCUTANEOUS TISSUE INFLAMMATION. [皮膚感染] | 20[redacted]-05-17 | 38 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-07-01 | - |
| AMG 416 | 20120230-23048008001 | ALLERGY (PURPURA ALLERGICA) [ヘノッホ・シェーンライン紫斑病] | 20[redacted]-05-19 | 40 | SEVERE | YES | - | DRUG WITHDRAWN | MEDICATION TAKEN, OTHER | RELATED | 20[redacted]-07-01 | - |
| AMG 416 | 20120230-23048010001 | BLEEDING FROM GI TRACT [胃腸出血] | 20[redacted]-05-17T09:30 | 68 | SEVERE | YES | - | DOSE NOT CHANGED | TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-06-10 | - |
| AMG 416 | 20120230-23048010003 | MYOCARDIAL INFARCTION [心筋梗塞] | 20[redacted]-01-07T17:00 | 296 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-12T15:00 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23048010006 | BLEEDING ANORECTAL VARICES [肛門直腸静脈瘤出血] | 20[redacted]-04-13T14:53 | 34 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-16T11:00 | - |
| AMG 416 | 20120230-23048014001 | VENTRICULAR FIBRILLATION [心室細動] | 20[redacted]-04-08 | 21 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-04-09T22:00 | - |
| AMG 416 | 20120230-23048014002 | PROSTATE ADENOCARCINOMA [前立腺癌] | 20[redacted]-12-23* | 322 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23048014002 | VOMITING [嘔吐] | 20[redacted]-01-21* | 351 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23048014002 | ALTERED MENTAL STATUS [精神状態変化] | 20[redacted]-01-30* | 360 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23051004002 | HOSPITALISATION WITH SICK SINUS SYNDROME [洞結節機能不全] | 20[redacted]-03-23 | 365 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | RELATED | ONGOING | - |
| AMG 416 | 20120230-23051006006 | CHRONIC PANCREATITIS.ACUTE PHASE [急性膵炎] | 20[redacted]-03-20 | 52 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-03-26 | - |
| AMG 416 | 20120230-23051006006 | DIABETES MELLITUS, DECOMPENSATION [糖尿病] | 20[redacted]-03-20 | 52 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-31 | - |
| AMG 416 | 20120230-23051006008 | ARTERIOVENOUS FISTULA TROMBOSIS [動静脈瘻血栓症] | 20[redacted]-03-07 | 40 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-19 | - |
| AMG 416 | 20120230-23051006008 | ARTERIOVENOUS FISTULA TROMBOSIS [動静脈瘻血栓症] | 20[redacted]-08-18 | 204 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-22 | - |
| AMG 416 | 20120230-23051006009 | MYOCARDIAL INFARCTION [心筋梗塞] | 20[redacted]-02-08 | 5 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-11 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23051006009 | PAROXYSM OF ATRIAL FIBRILLATION [心房細動] | 20[redacted]-02-08 | 5 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-18 | - |
| AMG 416 | 20120230-23051006009 | PULMONARY ARTERY THROMBOEMBOLIA [肺塞栓症] | 20[redacted]-02-13 | 10 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-17 | - |
| AMG 416 | 20120230-23051006009 | PULMONARY INFARCTION S 4,5 [肺梗塞] | 20[redacted]-02-18 | 15 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-05 | - |
| AMG 416 | 20120230-23051006012 | RESIDUAL CHOLEDOCHOLITIASIS (PREVIOUSLY OBSTRUCTIVE JAUNDICE) [胆管結石] | 20[redacted]-05-06 | 98 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-19 | - |
| AMG 416 | 20120230-23058002004 | HEMORRHOID [痔核] | 20[redacted]-05-30 | 129 | SEVERE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-06-01 | - |
| AMG 416 | 20120230-23058002005 | HYPERHIDRATATION [水分過負荷] | 20[redacted]-03-07T11:59 | 45 | MODERATE | YES | - | DOSE NOT CHANGED | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-03-08T23:03 | - |
| AMG 416 | 20120230-23058002005 | ARTERIO-VENOUS FISTULA DYSFUNCTION [動静脈瘻部位合併症] | 20[redacted]-05-04 | 103 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-05-13 | - |
| AMG 416 | 20120230-23058002005 | PHERIPHERAL VERTIGO [回転性めまい] | 20[redacted]-05-04 | 103 | MODERATE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23058002006 | BLADDER ADENOCARCINOMA [膀胱腺癌、病期不明] | 20[redacted]-01-24 | 3 | SEVERE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-01-27 | - |
| AMG 416 | 20120230-23058004007 | SEPSIC SHOCK [敗血症性ショック] | 20[redacted]-09-12 | 164 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-12 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-230580040 14 | RENAL CYST INFECTION [腎嚢胞感染] | 20[redacted]-08-16 | 117 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-02 | - |
| AMG 416 | 20120230-230580080 02 | STROKE [脳血管発作] | 20[redacted]-01-17 | 54 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-22 | - |
| AMG 416 | 20120230-230580080 02 | DEHYDRATION [脱水] | 20[redacted]-06-20 | 208 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-22 | - |
| AMG 416 | 20120230-230580080 02 | CARDIAC ARREST [心停止] | 20[redacted]-11-22 | 363 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-11-22 | - |
| AMG 416 | 20120230-230580080 07 | AVF THROMBOSIS [動静脈瘻血栓症] | 20[redacted]-12-24 | 6 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, OTHER | NOT RELATED | 20[redacted]-12-28 | - |
| AMG 416 | 20120230-230580080 10 | AVF THROMBOSIS [動静脈瘻血栓症] | 20[redacted]-03-03 | 83 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-04 | - |
| AMG 416 | 20120230-230580080 10 | ABDOMINAL PAIN [腹痛] | 20[redacted]-11-14 | 339 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-21 | - |
| AMG 416 | 20120230-230580080 11 | DIABETIC ULCER IN RIGHT FOOT [糖尿病性足病変] | 20[redacted]-05-08 | 16 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-13 | - |
| AMG 416 | 20120230-230580100 04 | CAMPYLOBACTER JEJUNI ACUTE GASTROENTERITIS. DIARRHEA [カンピロバクター胃腸炎] | 20[redacted]-08-03T08:00 | 216 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-11 | - |
| AMG 416 | 20120230-230580100 04 | CAMPYLOBACTER JEJUNI ACUTE GASTROENTERITIS. FEVER [カンピロバクター胃腸炎] | 20[redacted]-08-03T08:00 | 216 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-11 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23059002001 | DIPLOPIA [複視] | 20[redacted]-08-27T02:39 | 113 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-28T17:30 | - |
| AMG 416 | 20120230-23059002001 | HEADACHE [頭痛] | 20[redacted]-08-27T02:39 | 113 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-28T17:30 | - |
| AMG 416 | 20120230-23059002001 | VERTIGO [回転性めまい] | 20[redacted]-08-27T02:39 | 113 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-28T17:30 | - |
| AMG 416 | 20120230-23059006001 | NON-STEMI [急性心筋梗塞] | 20[redacted]-05-04T07:30 | 11 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-05-04 | - |
| AMG 416 | 20120230-23059006001 | FEVER [発熱] | 20[redacted]-05-08 * | 15 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-12 * | - |
| AMG 416 | 20120230-23059006001 | FRACTURE OS NASALE [顔面骨骨折] | 20[redacted]-01-11 * | 263 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-01-12 * | - |
| AMG 416 | 20120230-23059006001 | SYNCOPE [失神] | 20[redacted]-01-11 | 263 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-12 | - |
| AMG 416 | 20120230-23066004003 | UNSTABLE ANGINA [不安定狭心症] | 20[redacted]-02-24 | 120 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-05 | - |
| AMG 416 | 20120230-23066004003 | STUMP BURSITIS [滑液包炎] | 20[redacted]-07-07 | 253 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-07-10 | - |
| AMG 416 | 20120230-23066004003 | ACUTE HEPATITIS [急性肝炎] | 20[redacted]-07-12 | 258 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-17 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066004003 | ENCEPHALOPATHY [脳症] | 20[redacted]-07-12 | 258 | SEVERE | YES | Requires or Prolongs Hospitalization | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-17 | - |
| AMG 416 | 20120230-23066004003 | ENCEPHALOPATHY [脳症] | 20[redacted]-07-24 | 270 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-30 | - |
| AMG 416 | 20120230-23066004007 | HYPOGLYCEMIA [低血糖症] | 20[redacted]-09-06 | 335 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-09-07 | - |
| AMG 416 | 20120230-23066004013 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-12-10 | 58 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-11 | - |
| AMG 416 | 20120230-23066004017 | INFLUENZA [インフルエンザ] | 20[redacted]-01-05 | 69 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-01-08 | - |
| AMG 416 | 20120230-23066004017 | SMALL BOWEL OBSTRUCTION [小腸閉塞] | 20[redacted]-01-05 | 69 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-01-08 | - |
| AMG 416 | 20120230-23066004017 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-01-27 | 91 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-01-28 | - |
| AMG 416 | 20120230-23066004017 | HYPOGLYCEMIA [低血糖症] | 20[redacted]-01-27 | 91 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-28 | - |
| AMG 416 | 20120230-23066004017 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-11-04 | 372 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-05 | - |
| AMG 416 | 20120230-23066004017 | UREMIA [高窒素血症] | 20[redacted]-11-11 | 379 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-11-13 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-230660040 22 | ISCHEMIC BOWEL [腸管虚血] | 20[redacted]-12-24 | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-12-31 | - |
| AMG 416 | 20120230-230660040 22 | SEPSIS [敗血症] | 20[redacted]-12-24 | 92 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-31 | - |
| AMG 416 | 20120230-230660040 24 | OSTEOMYELITIS LEFT FIFTH DIGIT [骨髄炎] | 20[redacted]-12-12* | 31 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | SURGICAL INTERVENTION, CULTURE TAKEN | NOT RELATED | 20[redacted]-12-16* | - |
| AMG 416 | 20120230-230660040 24 | OSTEOMYELITIS 4TH FINGER [骨髄炎] | 20[redacted]-01-03* | 53 | SEVERE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-01-08* | - |
| AMG 416 | 20120230-230660040 24 | ABSCESS LEFT HAND [四肢膿瘍] | 20[redacted]-02-04* | 85 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-02-12* | - |
| AMG 416 | 20120230-230660040 24 | SEPSIS [敗血症] | 20[redacted]-02-04* | 85 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN | NOT RELATED | 20[redacted]-02-12* | - |
| AMG 416 | 20120230-230660040 24 | ABDOMINAL WOUND [創傷] | 20[redacted]-06-27* | 228 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-07-03* | - |
| AMG 416 | 20120230-230660040 24 | CELLULITUS - WORSENED [蜂巣炎] | 20[redacted]-06-27* | 228 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-03* | - |
| AMG 416 | 20120230-230660040 24 | PERFORATED CECUM [大腸穿孔] | 20[redacted]-08-18* | 280 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-09-09* | - |
| AMG 416 | 20120230-230660040 24 | PERITONITIS [腹膜炎] | 20[redacted]-08-18 | 280 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-09 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066004024 | SEPSIS [敗血症] | 20[redacted]-08-24 * | 286 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-09 * | - |
| AMG 416 | 20120230-23066004024 | ABDOMINAL WOUND BLEEDING [創傷出血] | 20[redacted]-11-25 * | 379 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-26 * | - |
| AMG 416 | 20120230-23066004024 | ABDOMINAL WOUND INFECTION [創傷感染] | 20[redacted]-11-25 | 379 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-12-17 | - |
| AMG 416 | 20120230-23066004028 | VIRAL GASTROENTERITIS [ウイルス性胃腸炎] | 20[redacted]-06-17 | 191 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-23 | - |
| AMG 416 | 20120230-23066006001 | EXACERBATION OF CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-03-31 | 154 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-01 | - |
| AMG 416 | 20120230-23066006005 | CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-02-24 | 127 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-26 | - |
| AMG 416 | 20120230-23066006005 | WORSENING OF HYPERTENSION [高血圧] | 20[redacted]-02-24 | 127 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-26 | - |
| AMG 416 | 20120230-23066006006 | SENSORINEURAL HEARING LOSS [感音性難聴] | 20[redacted]-12-17 | 388 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23066006006 | SINUS NODE DISFUNCTION [洞結節機能不全] | 20[redacted]-12-17 | 388 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER | NOT RELATED | 20[redacted]-12-24 | - |
| AMG 416 | 20120230-23066006008 | CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-05-19 | 196 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-20 | - |
| AMG 416 | 20120230-23066006010 | HYPOTENSION [低血圧] | 20[redacted]-04-09 | 163 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-04-18 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-230660060 18 | GASTROINTESTINAL BLEEDING [胃腸出血] | 20[redacted]-03-03 | 15 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-05 | - |
| AMG 416 | 20120230-230660060 18 | ASTHMA EXACERBATION [喘息] | 20[redacted]-05-12 | 85 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-18 | - |
| AMG 416 | 20120230-230660060 18 | CHRONIC OBSTRUCTIVE PULMONARY DISEASE [慢性閉塞性肺疾患] | 20[redacted]-05-12 | 85 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-18 | - |
| AMG 416 | 20120230-230660060 18 | CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-05-12 | 85 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-18 | - |
| AMG 416 | 20120230-230660060 18 | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-08-05 | 170 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-10 | - |
| AMG 416 | 20120230-230660060 18 | ACUTE GASTROINTESTINAL BLEED [胃腸出血] | 20[redacted]-08-12 | 177 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-08-14 | - |
| AMG 416 | 20120230-230660060 18 | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-08-12 | 177 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-16 | - |
| AMG 416 | 20120230-230660060 18 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-08-12 | 177 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-16 | - |
| AMG 416 | 20120230-230660060 18 | KNEE OSTEOARTHRITIS [変形性関節症] | 20[redacted]-10-30* | 256 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-11-04* | - |
| AMG 416 | 20120230-230660060 18 | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-02-05 | 354 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-06 | - |
| AMG 416 | 20120230-230660060 21 | CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-05-05 | 43 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-07 | - |
| AMG 416 | 20120230-230660060 21 | CONSTIPATION [便秘] | 20[redacted]-05-05 | 43 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-05-07 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066006021 | HYPERTENSION [高血圧] | 20[redacted]-05-05 | 43 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-07 | - |
| AMG 416 | 20120230-23066006021 | EXACERBATION OF CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-09-07 | 168 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-09 | - |
| AMG 416 | 20120230-23066006021 | SMALL BOWEL OBSTRUCTION [小腸閉塞] | 20[redacted]-10-13 * | 204 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-10-31 * | - |
| AMG 416 | 20120230-23066006021 | EXACERBATION OF CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-03-09 | 351 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-13 | - |
| AMG 416 | 20120230-23066006026 | FLUID OVERLOAD [水分過負荷] | 20[redacted]-07-09 * | 94 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-14 * | - |
| AMG 416 | 20120230-23066006026 | BACTERIEMIA [菌血症] | 20[redacted]-01-05 * | 274 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-09 * | - |
| AMG 416 | 20120230-23066006026 | ENCEPHALOPATHIA [脳症] | 20[redacted]-01-05 | 274 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-09 | - |
| AMG 416 | 20120230-23066006028 | CLOTTED LEFT UPPER ARM GRAFT [血管グラフト血栓症] | 20[redacted]-02-05 | 318 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-09 | - |
| AMG 416 | 20120230-23066006029 | UNSPECIFIED CHEST PAIN [胸痛] | 20[redacted]-12-25 | 276 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-27 | - |
| AMG 416 | 20120230-23066008001 | CHEST PAIN [胸痛] | 20[redacted]-03-03 | 125 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-05 | - |
| AMG 416 | 20120230-23066010007 | GASTROINTESTINAL BLEED [胃腸出血] | 20[redacted]-09-30 | 167 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-10-02 | - |

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| AMG 416 | 20120230-23066010007 | HEMORRHAGIC SHOCK [出血性ショック] | 20[redacted]-09-30 | 167 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-10-02 | - |
| AMG 416 | 20120230-23066010011 | CARDIOGENIC SHOCK [心原性ショック] | 20[redacted]-05-09 | 10 | MODERATE | YES | - | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN | NOT RELATED | 20[redacted]-06-18 | - |
| AMG 416 | 20120230-23066010011 | MYOCARDIAL INFARCTION [心筋梗塞] | 20[redacted]-05-09 | 10 | SEVERE | YES | - | DOSE NOT CHANGED | MEDICATION TAKEN, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-05-09 | - |
| AMG 416 | 20120230-23066012006 | ACUTE CORONARY SYNDROME [急性冠動脈症候群] | 20[redacted]-08-28* | 162 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-08-30* | - |
| AMG 416 | 20120230-23066012006 | INFLUENZA A [インフルエンザ] | 20[redacted]-01-16* | 303 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-19* | - |
| AMG 416 | 20120230-23066012006 | FRACTURED TIBIA AND FIBULA RIGHT LEG [下肢骨折] | 20[redacted]-02-28* | 346 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-02* | - |
| AMG 416 | 20120230-23066012006 | HYPOGLYCEMIA [低血糖症] | 20[redacted]-03-07* | 353 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-07* | - |
| AMG 416 | 20120230-23066012006 | PERIPHERAL VASCULAR DISEASE [末梢血管障害] | 20[redacted]-03-13 | 359 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-27 | - |
| AMG 416 | 20120230-23066014018 | RESPIRATORY FAILURE [呼吸不全] | 20[redacted]-01-31 | 293 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-18 | - |
| AMG 416 | 20120230-23066014018 | SEPSIS [敗血症] | 20[redacted]-01-31 | 293 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-18 | - |
| AMG 416 | 20120230-23066014018 | VOLUME OVERLOAD [水分過負荷] | 20[redacted]-01-31 | 293 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-18 | - |

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| AMG 416 | 20120230-23066016005 | MYOCARDIAL INFARTION [心筋梗塞] | 20[redacted]-11-20 | 240 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-11-22 | - |
| AMG 416 | 20120230-23066016007 | HEMORRHAGIC RENAL CYST IN LEFT KIDNEY [腎嚢胞出血] | 20[redacted]-06-27 | 171 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-09-25 | - |
| AMG 416 | 20120230-23066016014 | DISKITIS [椎間板炎] | 20[redacted]-06-12 | 44 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-07-01 | - |
| AMG 416 | 20120230-23066016014 | CELLULITIS RIGHT LEG [蜂巣炎] | 20[redacted]-07-07 | 69 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-10 | - |
| AMG 416 | 20120230-23066016014 | HEMATOMA RIGHT LEG [血腫] | 20[redacted]-07-07 | 69 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-07-10 | - |
| AMG 416 | 20120230-23066020001 | CONGESTIVE HEART FAILURE [うっ血性心不全] | 20[redacted]-04-28 | 55 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-30 | - |
| AMG 416 | 20120230-23066020001 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-04-28 | 55 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23066020001 | RESPIRATORY ARREST [呼吸停止] | 20[redacted]-04-28 | 55 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-29 | - |
| AMG 416 | 20120230-23066020001 | BLEEDING FROM AV FISTULA [動静脈瘻部位出血] | 20[redacted]-10-09 | 219 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-09 | - |

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| AMG 416 | 20120230-23066020001 | BLEEDING FROM AV FISTULA [動静脈瘻部位出血] | 20[redacted]-11-06 | 247 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-07 | - |
| AMG 416 | 20120230-23066020001 | BLEEDING FROM AV FISTULA [動静脈瘻部位出血] | 20[redacted]-11-08 | 249 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-21 | - |
| AMG 416 | 20120230-23066020003 | UREMIA [高窒素血症] | 20[redacted]-11-07 | 220 | MILD | YES | - | DOSE ALTERED OR WITHHELD | OTHER | NOT RELATED | 20[redacted]-11-13 | - |
| AMG 416 | 20120230-23066020003 | ABDOMINAL PAIN [腹痛] | 20[redacted]-11-09 | 222 | MILD | YES | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-11-13 | - |
| AMG 416 | 20120230-23066020003 | CHEST PAIN (UNKNOWN) [胸痛] | 20[redacted]-11-09 | 222 | MILD | YES | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-11-13 | - |
| AMG 416 | 20120230-23066020003 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-11-09 | 222 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-13 | - |
| AMG 416 | 20120230-23066022014 | SEPTIC SHOCK [敗血症性ショック] | 20[redacted]-04-09 | 382 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-12 | - |
| AMG 416 | 20120230-23066022014 | SEPTICEMIA [敗血症] | 20[redacted]-04-09 | 382 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-12 | - |
| AMG 416 | 20120230-23066022014 | SIGMOID PERFORATION DIVERTICULOSIS [憩室穿孔] | 20[redacted]-04-11 | 384 | MODERATE | YES | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-04-15 | - |
| AMG 416 | 20120230-23066022014 | ACUTE MULTIFACTORIAL ENCEPHALOPATHY [脳症] | 20[redacted]-04-23 | 396 | MODERATE | YES | - | DOSE NOT CHANGED | OTHER | NOT RELATED | 20[redacted]-04-23 | - |
| AMG 416 | 20120230-23066022014 | POSTOPERATIVE PANCREATITIS [膵炎] | 20[redacted]-04-23 | 396 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-12 | - |
| AMG 416 | 20120230-23066022019 | CLOTTED AV GRAFT [血管グラフト血栓症] | 20[redacted]-03-28 | 38 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-04-07 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066024005 | CHEST PAIN OF NON-CARDIAC ORIGIN [非心臓性胸痛] | 20[redacted]-02-09 | 349 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-10 | - |
| AMG 416 | 20120230-23066024005 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-02-09 | 349 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-10 | - |
| AMG 416 | 20120230-23066028005 | CORONARY ARTERY DISEASE [冠動脈疾患] | 20[redacted]-05-23T12:00 | 31 | SEVERE | YES | - | DOSE NOT CHANGED | SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-26T12:00 | - |
| AMG 416 | 20120230-23066028006 | ACUTE RESPIRATORY FAILURE [急性呼吸不全] | 20[redacted]-12-15T12:00 | 237 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-29T12:00 | - |
| AMG 416 | 20120230-23066032001 | ACUTE FRACTURE RIGHT INFERIOR CALCANEOUS [足骨折] | 20[redacted]-02-25 | 100 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, OTHER | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23066032001 | WORSENING AORTIC VALVULAR DISEASE [大動脈弁疾患] | 20[redacted]-08-19 | 275 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-08-21 | - |
| AMG 416 | 20120230-23066032001 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-11-19 | 367 | SEVERE | YES | - | DOSE NOT CHANGED | DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-11-20 | - |
| AMG 416 | 20120230-23066032001 | SUPRAVENTRICULAR TACHYCARDIA [上室性頻脈] | 20[redacted]-11-19 | 367 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-19 | - |
| AMG 416 | 20120230-23066032004 | WORSENED ENDSTAGE RENAL DISEASE [慢性腎臓病] | 20[redacted]-05-28 | 164 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER | NOT RELATED | 20[redacted]-06-13 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066032004 | LARGE PERIRENAL HEMATOMA [腎周囲血腫] | 20[redacted]-05-29T11:57 | 165 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-30T00:20 | - |
| AMG 416 | 20120230-23066032005 | CARDIOPULMONARY ARREST [心肺停止] | 20[redacted]-03-18 | 79 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-18 | - |
| AMG 416 | 20120230-23066032005 | HYPERKALEMIA [高カリウム血症] | 20[redacted]-03-18 | 79 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-18 | - |
| AMG 416 | 20120230-23066032005 | CARDIAC ARREST [心停止] | 20[redacted]-03-22 | 83 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | MEDICATION TAKEN | NOT RELATED | 20[redacted]-03-22 | - |
| AMG 416 | 20120230-23066032006 | CEREBROVASCULAR ACCIDENT [脳血管発作] | 20[redacted]-12-04* | -40 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING* | - |
| AMG 416 | 20120230-23066032006 | PNEUMONIA [肺炎] | 20[redacted]-02-12* | 31 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-14* | - |
| AMG 416 | 20120230-23066032006 | UPPER RESPIRATORY INFECTION [上気道感染] | 20[redacted]-12-08 | 330 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-15 | - |
| AMG 416 | 20120230-23066034002 | TIA [一過性脳虚血発作] | 20[redacted]-11-06T08:00 | 198 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-12T12:00 | - |
| AMG 416 | 20120230-23066034009 | HYPOTENSION [低血圧] | 20[redacted]-11-01T14:00 | 188 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-06T12:00 | - |
| AMG 416 | 20120230-23066034009 | TRANSIENT ALTERATION IN CONSCIOUSNESS [意識変容状態] | 20[redacted]-11-01T14:00 | 188 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-06T12:00 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066034010 | CARDIAC ARREST [心停止] | 20[redacted]-11-03T13:06 | 190 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-11-03T14:30 | - |
| AMG 416 | 20120230-23066036002 | PSEUDOANEURYSOM OF THE A-V GRAFT [移植血管合併症] | 20[redacted]-11-15* | 9 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, OTHER | NOT RELATED | 20[redacted]-11-17* | - |
| AMG 416 | 20120230-23066036002 | INFECTION OF THE LEFT A-V GRAFT [動静脈グラフト部位感染] | 20[redacted]-04-03* | 148 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-04-14* | - |
| AMG 416 | 20120230-23066036002 | LEFT A-V GRAFT INFECTION S/P REVISION [動静脈グラフト部位感染] | 20[redacted]-05-01* | 176 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-14* | - |
| AMG 416 | 20120230-23066036002 | LEFT ARM A-V GRAFT INFECTION (WOUND EXPLORATION & EXCISION OF THE REMNANTS OF TEH A-V GRAFT) [動静脈グラフト部位感染] | 20[redacted]-07-08 | 244 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-07-11 | - |
| AMG 416 | 20120230-23066036004 | TRACHEITIS [気管炎] | 20[redacted]-03-31 | 106 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-04 | - |
| AMG 416 | 20120230-23066036004 | TRACHEOSTOMY SITE PAIN [ストーマ部疼痛] | 20[redacted]-05-07 | 143 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-17 | - |
| AMG 416 | 20120230-23066036004 | PNEUMONIA TRACHEITIS [細菌性気管炎] | 20[redacted]-07-30 | 227 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-07 | - |
| AMG 416 | 20120230-23066036004 | HERPES ZOSTER [帯状疱疹] | 20[redacted]-08-15 | 243 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-18 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066036016 | MEDICATION REACTION [医薬品副作用] | 20[redacted]-03-08 | 87 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-03-09 | - |
| AMG 416 | 20120230-23066036019 | DIVERTICULITIS [憩室炎] | 20[redacted]-09-22 | 230 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-28 | - |
| AMG 416 | 20120230-23066042001 | ACUTE TRACHEOBRONCHITIS [気管気管支炎] | 20[redacted]-01-12 | 336 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-17 | - |
| AMG 416 | 20120230-23066042001 | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-01-12 | 336 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-17 | - |
| AMG 416 | 20120230-23066042001 | THROMBOCYTOPENIA [血小板減少症] | 20[redacted]-01-12 | 336 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-17 | - |
| AMG 416 | 20120230-23066042002 | HYPOGLYCEMIA [低血糖症] | 20[redacted]-01-28 | 37 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-02-02 | - |
| AMG 416 | 20120230-23066042002 | HYPOGLYCEMIA [低血糖症] | 20[redacted]-02-09 | 49 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-14 | - |
| AMG 416 | 20120230-23066042002 | HEMATEMESIS [吐血] | 20[redacted]-03-31 | 99 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-02* | - |
| AMG 416 | 20120230-23066042002 | NSTEMI [急性心筋梗塞] | 20[redacted]-12-29 | 372 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-02* | - |
| AMG 416 | 20120230-23066042002 | URINARY TRACT INFECTION [尿路感染] | 20[redacted]-12-29 | 372 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-02* | - |
| AMG 416 | 20120230-23066042006 | GI HEMORRHAGE [胃腸出血] | 20[redacted]-04-18 | 81 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-04-20 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066042006 | GI HEMORRHAGE [胃腸出血] | 20[redacted]-09-12 | 228 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-14 | - |
| AMG 416 | 20120230-23066046007 | GASTRITIS [胃炎] | 20[redacted]-06-21 | 176 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-06-23 | - |
| AMG 416 | 20120230-23066046008 | SUSPECTED METASTATIC LUNG CANCER [遠隔転移を伴う肺癌] | 20[redacted]-01-16 | 20 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-01-29 | - |
| AMG 416 | 20120230-23066046008 | WORSENING ABDOMINAL PAIN [腹痛] | 20[redacted]-01-16 | 20 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-01-29 | - |
| AMG 416 | 20120230-23066052003 | CARDIOMYOPATHY [心筋症] | 20[redacted]-01-10 | 18 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-12 | - |
| AMG 416 | 20120230-23066052008 | CORONARY ARTERY STENOSIS [冠動脈狭窄] | 20[redacted]-11-11* | 308 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-22* | - |
| AMG 416 | 20120230-23066052008 | GASTROENTERITIS [胃腸炎] | 20[redacted]-01-19 | 377 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-21 | - |
| AMG 416 | 20120230-23066056001 | FEVER OF UNKNOWN ORIGIN [発熱] | 20[redacted]-07-06 | 147 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-10 | - |
| AMG 416 | 20120230-23066056002 | RESPIRATORY FAILURE [呼吸不全] | 20[redacted]-08-03 | 175 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-08-10 | - |
| AMG 416 | 20120230-23066056003 | ATYPICAL CHEST PAIN [胸痛] | 20[redacted]-12-20 | 320 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-12-21 | - |

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| AMG 416 | 20120230-23066056003 | CHEST PAIN [胸痛] | 20[redacted]-12-22 | 322 | MILD | YES | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-12-23 | - |
| AMG 416 | 20120230-23066056003 | PSUEDOANEURYSM OFF THE LEFT FEMORAL ARTERY [血管偽動脈瘤] | 20[redacted]-12-30 * | 330 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-01 * | - |
| AMG 416 | 20120230-23066056003 | CHOLELITHIASIS [胆石症] | 20[redacted]-01-19 | 350 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-22 * | - |
| AMG 416 | 20120230-23066056005 | WORSENING HYPERKALEMIA [高カリウム血症] | 20[redacted]-02-10 | 7 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-02-25 | - |
| AMG 416 | 20120230-23066056005 | HYPOTESION [低血圧] | 20[redacted]-04-01 | 57 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-11 | - |
| AMG 416 | 20120230-23066056005 | BRADYCARDIC [徐脈] | 20[redacted]-04-01T15:15 | 57 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-11 | - |
| AMG 416 | 20120230-23066056005 | CLOTTED FEMORAL GRAFT [移植片血栓症] | 20[redacted]-04-12 | 68 | LIFE THREATENING | YES | Requires or Prolongs Hospitalization, Is Life Threatening | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-16 | - |
| AMG 416 | 20120230-23066056005 | RESPIRATORY FAILURE [呼吸不全] | 20[redacted]-04-16 | 72 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-25 | - |
| AMG 416 | 20120230-23066056008 | ALTERED LEVEL OF CONSCIOUSNESS [意識変容状態] | 20[redacted]-03-13 | 59 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-16 | - |
| AMG 416 | 20120230-23066056008 | METABOLIC ENCEPHALOPATHY [代謝性脳症] | 20[redacted]-05-19 | 126 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-22 | - |

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| AMG 416 | 20120230-23066056011 | VERTIGO [回転性めまい] | 20[redacted]-09-16 * | 212 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-21 * | - |
| AMG 416 | 20120230-23066056011 | WORSENING HIP ARTHRITIS [関節炎] | 20[redacted]-02-11 | 360 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-12 | - |
| AMG 416 | 20120230-23066056015 | PARTIAL SMALL BOWEL OBSTRUCTION [小腸閉塞] | 20[redacted]-03-21 * | 26 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-27 * | - |
| AMG 416 | 20120230-23066056015 | RIGHT CHRONIC TIBIAL PLATEAU FRACTURE [脛骨骨折] | 20[redacted]-02-16 | 358 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-24 | - |
| AMG 416 | 20120230-23066078001 | GASTROENTERITIS [胃腸炎] | 20[redacted]-04-02T07:46 | 36 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-04-03T14:35 | - |
| AMG 416 | 20120230-23066078001 | FEVER OF UNKNOWN ORIGIN [発熱] | 20[redacted]-09-12 | 199 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIBIOTICS TAKEN, CULTURE TAKEN | NOT RELATED | 20[redacted]-09-15 | - |
| AMG 416 | 20120230-23066078001 | LARGE LEFT PLEURAL EFFUSION [胸水] | 20[redacted]-11-18 * | 266 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT | NOT RELATED | ONGOING * | - |
| AMG 416 | 20120230-23066078001 | BRONCHITIS [気管支炎] | 20[redacted]-01-28 | 337 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, EMERGENCY ROOM VISIT, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-01-31 | - |
| AMG 416 | 20120230-23066078012 | UNCONTROLLED HYPERTENSION [高血圧] | 20[redacted]-04-23 | 17 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-26 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066078012 | CEREBRAL VASCULAR ACCIDENT [脳血管発作] | 20[redacted]-03-07 * | 335 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, DEVICE / PROCEDURE INTERVENTION, EMERGENCY ROOM VISIT | NOT RELATED | 20[redacted]-03-13 * | - |
| AMG 416 | 20120230-23066078012 | ACUTE MYOCARDIAL INFARCTION [急性心筋梗塞] | 20[redacted]-03-12 | 340 | LIFE THREATENING | YES | Results in Death, Requires or Prolongs Hospitalization, Is Life Threatening | DRUG WITHDRAWN | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-13 | - |
| AMG 416 | 20120230-23066078014 | ERYSIPELAS NOSE [丹毒] | 20[redacted]-04-26T15:51 * | 20 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION, IV ANTIMICROBIAL TAKEN | NOT RELATED | 20[redacted]-04-29T11:30 * | - |
| AMG 416 | 20120230-23066078014 | PULMONARY EDEMA [肺水腫] | 20[redacted]-03-01T21:43 | 329 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-03-03T14:35 | - |
| AMG 416 | 20120230-23066080003 | ABDOMINAL PAIN [腹痛] | 20[redacted]-09-05 | 169 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-10 | - |
| AMG 416 | 20120230-23066080003 | NON-CARDIAC CHEST PAIN [非心臓性胸痛] | 20[redacted]-09-05 | 169 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-09-10 | - |
| AMG 416 | 20120230-23066084004 | BILATERAL PLEURAL EFFUSION [胸水] | 20[redacted]-09-08 | 209 | SEVERE | YES | - | DOSE ALTERED OR WITHHELD | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | CONSTIPATION [便秘] | 20[redacted]-09-08 | 209 | MODERATE | YES | - | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066084004 | POORLY DIFFERENTIATED CARCINOMA; UNKNOWN PRIMARY [悪性新生物] | 20[redacted]-09-08 | 209 | LIFE THREATENING | YES | Results in Death, Is Life Threatening | DRUG WITHDRAWN | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066084004 | RIGHT LOWER LOBE PULMONARY EMBOLUS [肺塞栓症] | 20[redacted]-09-23 | 224 | LIFE THREATENING | YES | Is Life Threatening | DOSE NOT CHANGED | NO ACTION TAKEN | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066102005 | HYPOXIA [低酸素症] | 20[redacted]-05-10 | 25 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-13 | - |
| AMG 416 | 20120230-23066102005 | GENERALIZED WEAKNESS [無力症] | 20[redacted]-05-10T15:42 | 25 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-05-13 | - |
| AMG 416 | 20120230-23066102005 | ATRIAL FLUTTER [心房粗動] | 20[redacted]-05-28 | 43 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-31 | - |
| AMG 416 | 20120230-23066104004 | ARTERIAL VENOUS MALFORMATION DUODENUM [胃腸血管奇形] | 20[redacted]-04-16 | 59 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-04-20 | - |
| AMG 416 | 20120230-23066104004 | GASTRIC ANTRAL VASCULAR ECTASIA [胃前庭部毛細血管拡張症] | 20[redacted]-04-16 | 59 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-04-20 | - |
| AMG 416 | 20120230-23066104004 | WORSENED CHRONIC ANEMIA [貧血] | 20[redacted]-07-17 | 151 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-07-18 | - |
| AMG 416 | 20120230-23066104004 | BLEEDING GASTRIC ANTRAL VASCULAR ECTASIA [胃出血] | 20[redacted]-08-14 | 179 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-08-16 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066104004 | ANEMIA [貧血] | 20[redacted]-09-20 | 216 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066104004 | GASTRIC ANTRAL VASCULAR ECTASIA [胃前庭部毛細血管拡張症] | 20[redacted]-09-20 * | 216 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-09-23 | - |
| AMG 416 | 20120230-23066104004 | SYMPTOMATIC ANEMIA [貧血] | 20[redacted]-01-14 | 332 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED, DEVICE / PROCEDURE INTERVENTION | NOT RELATED | 20[redacted]-01-15 * | - |
| AMG 416 | 20120230-23066104006 | NON HEALING ULCER OF LEFT FOOT [治癒不良] | 20[redacted]-04-23 | 63 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-25 | - |
| AMG 416 | 20120230-23066104006 | UNHEALING ULCER OF LEFT FOOT [皮膚潰瘍] | 20[redacted]-04-23 | 63 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-04-25 | - |
| AMG 416 | 20120230-23066104006 | OSTEOMYELITIS OF LEFT LEG [骨髄炎] | 20[redacted]-05-15 | 85 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-05-20 | - |
| AMG 416 | 20120230-23066104011 | LEFT HALLUX ULCER [皮膚潰瘍] | 20[redacted]-10-22 | 177 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION, IV ANTIBIOTICS TAKEN | NOT RELATED | 20[redacted]-10-31 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-230661040 12 | CHOLELITHIASIS [胆石症] | 20[redacted]-02-24 | -77 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-03-03 | - |
| AMG 416 | 20120230-230661040 12 | COMPLICATIONS WITH WOUNDS OF BILATERAL FOOT BURNS [熱傷] | 20[redacted]-06-24 | 44 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-230661040 12 | COMPLICATIONS WITH FEET WOUNDS [創合併症] | 20[redacted]-09-19 | 131 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-230661040 12 | INFECTION OF RIGHT FOOT CHRONIC NON-HEALING ULCERATION [感染性皮膚潰瘍] | 20[redacted]-12-02 | 205 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-12-05 | - |
| AMG 416 | 20120230-230661040 12 | OSTEOMYELITIS OF RIGHT CALCANEOUS [骨髄炎] | 20[redacted]-12-02 | 205 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, SURGICAL INTERVENTION | NOT RELATED | 20[redacted]-12-05 | - |
| AMG 416 | 20120230-230661300 08 | HYPERTENSIVE EMERGENCY [高血圧緊急症] | 20[redacted]-08-26 | 134 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-08-29 | - |
| AMG 416 | 20120230-230661300 08 | PULMONARY EDEMA [肺水腫] | 20[redacted]-08-26 | 134 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-08-29 | - |
| AMG 416 | 20120230-230661300 08 | SHORTNESS OF BREATH [呼吸困難] | 20[redacted]-08-26 | 134 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-08-29 | - |
| AMG 416 | 20120230-230661320 02 | HYPERTENSION [高血圧] | 20[redacted]-07-07 | 106 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-07-10 | - |
| AMG 416 | 20120230-230661320 02 | DIZZINESS [浮動性めまい] | 20[redacted]-08-01 | 131 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION, OTHER | NOT RELATED | 20[redacted]-08-03 | - |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMG 416 | 20120230-23066132002 | ACINETOBACTER BAUMANNI [アシネトバクター感染] | 20[redacted]-02-08 * | 322 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-13 * | - |
| AMG 416 | 20120230-23066132002 | ACUTE ENCEPHALOPATHY [脳症] | 20[redacted]-02-08 * | 322 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-13 * | - |
| AMG 416 | 20120230-23066132002 | CHOLECYSTITIS [胆嚢炎] | 20[redacted]-02-08 | 322 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-02-13 | - |
| AMG 416 | 20120230-23066132003 | URINARY TRACT INFECTION [尿路感染] | 20[redacted]-01-21 | 288 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | MEDICATION TAKEN, HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-01-28 | - |
| AMG 416 | 20120230-23066132005 | GASTROPATHY [胃障害] | 20[redacted]-05-07 | 22 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION, TRANSFUSION PERFORMED | NOT RELATED | 20[redacted]-05-13 | - |
| AMG 416 | 20120230-23066132005 | ENDOCARDITIS [心内膜炎] | 20[redacted]-08-25 | 132 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-10-21 | - |
| AMG 416 | 20120230-23066132005 | ATRIAL FIBRILLATION [心房細動] | 20[redacted]-09-08 | 146 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-09 | - |
| AMG 416 | 20120230-23066132005 | DISKITIS [椎間板炎] | 20[redacted]-09-08 | 146 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-07 | - |
| AMG 416 | 20120230-23066132005 | TRICUSPID REGURGITATION [三尖弁閉鎖不全症] | 20[redacted]-09-08 | 146 | MODERATE | YES | Requires or Prolongs Hospitalization | DOSE NOT CHANGED | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |
| AMG 416 | 20120230-23066132005 | ATRIAL FLUTTER [心房粗動] | 20[redacted]-11-04 | 203 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | 20[redacted]-11-09 | - |
| AMG 416 | 20120230-23066150001 | ULCER RIGHT FOOT [皮膚潰瘍] | 20[redacted]-11-21 | -90 | SEVERE | YES | Requires or Prolongs Hospitalization | DOSE ALTERED OR WITHHELD | HOSPITALIZED / PROLONGED HOSPITALIZATION | NOT RELATED | ONGOING | - |

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