## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| N | 21 | --- | --- | 21 | --- | --- |
| Any Adverse Events | 21 | 3 | 0 | 31 | 6 | 1 |
| 感染症および寄生虫症 | 1 | 0 | 0 | 0 | 1 | 1 |
| 上咽頭炎 | 1 | 0 | 0 | 0 | 0 | 0 |
| 胃腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 足部白癬 | 0 | 0 | 0 | 0 | 0 | 0 |
| 毛包炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯周炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膀胱炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９ | 0 | 0 | 0 | 0 | 0 | 0 |
| 蜂巣炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 気管支炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咽頭炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 菌血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 麦粒腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| シャント感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 爪の皮膚糸状菌症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯肉炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 外耳炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 白癬感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎嚢胞感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 憩室炎 | 0 | 0 | 0 | 0 | 0 | 1 |
| ウイルス性胃腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳下腺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上気道感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 尿路感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘリコバクター感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 医療機器関連感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔ヘルペス | 0 | 0 | 0 | 0 | 0 | 0 |
| 結膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 帯状疱疹 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮下組織膿瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 化膿 | 0 | 0 | 0 | 0 | 0 | 0 |
| 虫垂炎 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 1.0 ug/kg | | | MR13A9 1.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| N | 19 | --- | --- | 23 | --- | --- |
| Any Adverse Events | 18 | 3 | 0 | 47 | 11 | 0 |
| 感染症および寄生虫症 | 1 | 0 | 0 | 4 | 0 | 0 |
| 上咽頭炎 | 0 | 0 | 0 | 4 | 0 | 0 |
| 胃腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 足部白癬 | 0 | 0 | 0 | 0 | 0 | 0 |
| 毛包炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯周炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膀胱炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９ | 0 | 0 | 0 | 0 | 0 | 0 |
| 蜂巣炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 気管支炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咽頭炎 | 1 | 0 | 0 | 0 | 0 | 0 |
| 菌血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 麦粒腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| シャント感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 爪の皮膚糸状菌症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯肉炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 外耳炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 白癬感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎嚢胞感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 憩室炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| ウイルス性胃腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳下腺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上気道感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 尿路感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘリコバクター感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 医療機器関連感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔ヘルペス | 0 | 0 | 0 | 0 | 0 | 0 |
| 結膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 帯状疱疹 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮下組織膿瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 化膿 | 0 | 0 | 0 | 0 | 0 | 0 |
| 虫垂炎 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | MR13A9-4 | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.25 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| N | 21 | --- | --- | 61 | --- | --- |
| Any Adverse Events | 5 | 1 | 0 | 89 | 5 | 1 |
| 感染症および寄生虫症 | 0 | 0 | 0 | 13 | 1 | 0 |
| 上咽頭炎 | 0 | 0 | 0 | 8 | 0 | 0 |
| 胃腸炎 | 0 | 0 | 0 | 0 | 1 | 0 |
| 肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 足部白癬 | 0 | 0 | 0 | 1 | 0 | 0 |
| 毛包炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯周炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膀胱炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９ | 0 | 0 | 0 | 0 | 0 | 0 |
| 蜂巣炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 気管支炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 咽頭炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 菌血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 麦粒腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| シャント感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 爪の皮膚糸状菌症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯肉炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 外耳炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 白癬感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎嚢胞感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 憩室炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| ウイルス性胃腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳下腺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上気道感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 尿路感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘリコバクター感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 医療機器関連感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔ヘルペス | 0 | 0 | 0 | 0 | 0 | 0 |
| 結膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 帯状疱疹 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮下組織膿瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 化膿 | 0 | 0 | 0 | 0 | 0 | 0 |
| 虫垂炎 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 1.0 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| N | 61 | --- | --- | 62 | --- | --- |
| Any Adverse Events | 102 | 15 | 2 | 113 | 39 | 0 |
| 感染症および寄生虫症 | 17 | 2 | 1 | 8 | 3 | 0 |
| 上咽頭炎 | 7 | 1 | 0 | 2 | 1 | 0 |
| 胃腸炎 | 1 | 0 | 0 | 0 | 0 | 0 |
| 肺炎 | 0 | 0 | 0 | 0 | 1 | 0 |
| 足部白癬 | 0 | 0 | 0 | 0 | 0 | 0 |
| 毛包炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯周炎 | 1 | 0 | 0 | 0 | 0 | 0 |
| 膀胱炎 | 2 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９ | 0 | 0 | 0 | 0 | 0 | 0 |
| 蜂巣炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 気管支炎 | 1 | 0 | 0 | 0 | 0 | 0 |
| 咽頭炎 | 1 | 0 | 0 | 0 | 0 | 0 |
| 菌血症 | 0 | 1 | 0 | 0 | 0 | 0 |
| 麦粒腫 | 1 | 0 | 0 | 0 | 0 | 0 |
| シャント感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 爪の皮膚糸状菌症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯肉炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 外耳炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 白癬感染 | 0 | 0 | 0 | 1 | 0 | 0 |
| 鼻炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎嚢胞感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 憩室炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| ウイルス性胃腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳下腺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上気道感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 尿路感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘリコバクター感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 医療機器関連感染 | 0 | 0 | 1 | 0 | 0 | 0 |
| 口腔ヘルペス | 0 | 0 | 0 | 0 | 0 | 0 |
| 結膜炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 帯状疱疹 | 0 | 0 | 0 | 0 | 1 | 0 |
| 皮下組織膿瘍 | 0 | 0 | 0 | 1 | 0 | 0 |
| 化膿 | 0 | 0 | 0 | 0 | 0 | 0 |
| 虫垂炎 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
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(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | MR13A9-5 (DB) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| N | 63 | --- | --- | 89 | --- | --- |
| Any Adverse Events | 93 | 5 | 0 | 82 | 17 | 0 |
| 感染症および寄生虫症 | 15 | 2 | 0 | 8 | 0 | 0 |
| 上咽頭炎 | 8 | 0 | 0 | 4 | 0 | 0 |
| 胃腸炎 | 1 | 0 | 0 | 1 | 0 | 0 |
| 肺炎 | 0 | 1 | 0 | 0 | 0 | 0 |
| 足部白癬 | 0 | 0 | 0 | 1 | 0 | 0 |
| 毛包炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯周炎 | 2 | 0 | 0 | 0 | 0 | 0 |
| 膀胱炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９ | 0 | 0 | 0 | 0 | 0 | 0 |
| 蜂巣炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 気管支炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咽頭炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 菌血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 麦粒腫 | 1 | 0 | 0 | 0 | 0 | 0 |
| シャント感染 | 1 | 0 | 0 | 0 | 0 | 0 |
| 爪の皮膚糸状菌症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯肉炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 外耳炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 白癬感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻炎 | 1 | 0 | 0 | 0 | 0 | 0 |
| 腎嚢胞感染 | 1 | 0 | 0 | 0 | 0 | 0 |
| 憩室炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| ウイルス性胃腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳下腺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上気道感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 尿路感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘリコバクター感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 医療機器関連感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔ヘルペス | 0 | 0 | 0 | 0 | 0 | 0 |
| 結膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 帯状疱疹 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮下組織膿瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 化膿 | 0 | 0 | 0 | 0 | 0 | 0 |
| 虫垂炎 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (DB) | | | MR13A9-5 (Entire) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR-MR | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| N | 89 | --- | --- | 85 | --- | --- |
| Any Adverse Events | 81 | 11 | 3 | 553 | 76 | 9 |
| 感染症および寄生虫症 | 11 | 5 | 1 | 68 | 8 | 3 |
| 上咽頭炎 | 2 | 0 | 0 | 25 | 0 | 0 |
| 胃腸炎 | 1 | 0 | 0 | 6 | 1 | 0 |
| 肺炎 | 0 | 3 | 0 | 0 | 0 | 0 |
| 足部白癬 | 0 | 0 | 0 | 2 | 0 | 0 |
| 毛包炎 | 0 | 0 | 0 | 2 | 1 | 0 |
| 歯周炎 | 1 | 1 | 0 | 1 | 0 | 0 |
| 膀胱炎 | 0 | 0 | 0 | 2 | 0 | 0 |
| ＣＯＶＩＤ－１９ | 0 | 0 | 0 | 2 | 1 | 0 |
| 蜂巣炎 | 0 | 0 | 0 | 2 | 0 | 1 |
| 気管支炎 | 1 | 0 | 0 | 1 | 1 | 0 |
| 咽頭炎 | 1 | 0 | 0 | 3 | 0 | 0 |
| 菌血症 | 0 | 0 | 1 | 0 | 0 | 0 |
| 麦粒腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| シャント感染 | 0 | 0 | 0 | 1 | 0 | 1 |
| 爪の皮膚糸状菌症 | 0 | 0 | 0 | 2 | 0 | 0 |
| 歯肉炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 外耳炎 | 0 | 0 | 0 | 2 | 0 | 0 |
| 白癬感染 | 0 | 0 | 0 | 1 | 0 | 0 |
| 鼻炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 腎嚢胞感染 | 0 | 0 | 0 | 0 | 1 | 0 |
| 憩室炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| ウイルス性胃腸炎 | 0 | 0 | 0 | 2 | 0 | 0 |
| 耳下腺炎 | 0 | 0 | 0 | 2 | 0 | 0 |
| 上気道感染 | 0 | 0 | 0 | 2 | 0 | 0 |
| 尿路感染 | 0 | 0 | 0 | 1 | 0 | 0 |
| ヘリコバクター感染 | 0 | 0 | 0 | 1 | 0 | 0 |
| 医療機器関連感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔ヘルペス | 0 | 0 | 0 | 2 | 0 | 0 |
| 結膜炎 | 1 | 0 | 0 | 0 | 0 | 0 |
| 帯状疱疹 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮下組織膿瘍 | 0 | 0 | 0 | 1 | 0 | 0 |
| 化膿 | 2 | 0 | 0 | 0 | 0 | 0 |
| 虫垂炎 | 0 | 0 | 0 | 0 | 0 | 1 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
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(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (Entire) | | | MR13A9-5 (Long-term) | | |
|---|---|---|---|---|---|---|
| Group | P-MR | | | MR13A9 0.5 ug/kg (Long-term) | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| N | 83 | --- | --- | 172 | --- | --- |
| Any Adverse Events | 570 | 93 | 11 | 1057 | 161 | 19 |
| 感染症および寄生虫症 | 68 | 13 | 4 | 126 | 17 | 7 |
| 上咽頭炎 | 22 | 0 | 0 | 45 | 0 | 0 |
| 胃腸炎 | 3 | 0 | 0 | 8 | 1 | 0 |
| 肺炎 | 4 | 4 | 1 | 4 | 1 | 1 |
| 足部白癬 | 4 | 0 | 0 | 6 | 0 | 0 |
| 毛包炎 | 3 | 0 | 0 | 5 | 1 | 0 |
| 歯周炎 | 4 | 1 | 0 | 4 | 0 | 0 |
| 膀胱炎 | 1 | 0 | 0 | 3 | 0 | 0 |
| ＣＯＶＩＤ－１９ | 0 | 2 | 0 | 2 | 3 | 0 |
| 蜂巣炎 | 1 | 0 | 0 | 3 | 0 | 1 |
| 気管支炎 | 1 | 0 | 0 | 1 | 1 | 0 |
| 咽頭炎 | 1 | 0 | 0 | 3 | 0 | 0 |
| 菌血症 | 0 | 2 | 0 | 0 | 2 | 0 |
| 麦粒腫 | 2 | 0 | 0 | 2 | 0 | 0 |
| シャント感染 | 0 | 1 | 0 | 1 | 1 | 1 |
| 爪の皮膚糸状菌症 | 1 | 0 | 0 | 3 | 0 | 0 |
| 歯肉炎 | 1 | 0 | 0 | 2 | 0 | 0 |
| 外耳炎 | 0 | 0 | 0 | 2 | 0 | 0 |
| 白癬感染 | 1 | 0 | 0 | 2 | 0 | 0 |
| 鼻炎 | 1 | 0 | 0 | 2 | 0 | 0 |
| 腎嚢胞感染 | 0 | 1 | 0 | 0 | 2 | 0 |
| 憩室炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| ウイルス性胃腸炎 | 0 | 0 | 0 | 2 | 0 | 0 |
| 耳下腺炎 | 0 | 0 | 0 | 2 | 0 | 0 |
| 上気道感染 | 0 | 0 | 0 | 2 | 0 | 0 |
| 尿路感染 | 1 | 0 | 0 | 2 | 0 | 0 |
| ヘリコバクター感染 | 1 | 0 | 0 | 2 | 0 | 0 |
| 医療機器関連感染 | 1 | 0 | 0 | 1 | 0 | 0 |
| 口腔ヘルペス | 0 | 0 | 0 | 2 | 0 | 0 |
| 結膜炎 | 3 | 0 | 0 | 2 | 0 | 0 |
| 帯状疱疹 | 1 | 0 | 0 | 1 | 0 | 0 |
| 皮下組織膿瘍 | 0 | 0 | 0 | 1 | 0 | 0 |
| 化膿 | 3 | 0 | 0 | 1 | 0 | 0 |
| 虫垂炎 | 0 | 0 | 0 | 0 | 0 | 1 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 ALL | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| N | 254 | --- | --- | 440 | --- | --- |
| Any Adverse Events | 1190 | 182 | 22 | 1478 | 243 | 23 |
| 感染症および寄生虫症 | 143 | 20 | 9 | 170 | 24 | 9 |
| 上咽頭炎 | 52 | 1 | 0 | 67 | 2 | 0 |
| 胃腸炎 | 9 | 1 | 0 | 9 | 2 | 0 |
| 肺炎 | 4 | 1 | 1 | 4 | 2 | 1 |
| 足部白癬 | 6 | 0 | 0 | 7 | 0 | 0 |
| 毛包炎 | 5 | 1 | 0 | 5 | 1 | 0 |
| 歯周炎 | 5 | 0 | 0 | 5 | 0 | 0 |
| 膀胱炎 | 5 | 0 | 0 | 5 | 0 | 0 |
| ＣＯＶＩＤ－１９ | 2 | 3 | 0 | 2 | 3 | 0 |
| 蜂巣炎 | 3 | 0 | 1 | 4 | 0 | 1 |
| 気管支炎 | 2 | 1 | 0 | 3 | 1 | 0 |
| 咽頭炎 | 4 | 0 | 0 | 5 | 0 | 0 |
| 菌血症 | 0 | 3 | 0 | 0 | 3 | 0 |
| 麦粒腫 | 3 | 0 | 0 | 3 | 0 | 0 |
| シャント感染 | 1 | 1 | 1 | 1 | 1 | 1 |
| 爪の皮膚糸状菌症 | 3 | 0 | 0 | 3 | 0 | 0 |
| 歯肉炎 | 2 | 0 | 0 | 3 | 0 | 0 |
| 外耳炎 | 2 | 0 | 0 | 3 | 0 | 0 |
| 白癬感染 | 2 | 0 | 0 | 3 | 0 | 0 |
| 鼻炎 | 2 | 0 | 0 | 2 | 0 | 0 |
| 腎嚢胞感染 | 0 | 2 | 0 | 0 | 2 | 0 |
| 憩室炎 | 1 | 0 | 1 | 1 | 0 | 1 |
| ウイルス性胃腸炎 | 2 | 0 | 0 | 2 | 0 | 0 |
| 耳下腺炎 | 2 | 0 | 0 | 2 | 0 | 0 |
| 上気道感染 | 2 | 0 | 0 | 2 | 0 | 0 |
| 尿路感染 | 2 | 0 | 0 | 2 | 0 | 0 |
| ヘリコバクター感染 | 2 | 0 | 0 | 2 | 0 | 0 |
| 医療機器関連感染 | 1 | 0 | 1 | 1 | 0 | 1 |
| 口腔ヘルペス | 2 | 0 | 0 | 2 | 0 | 0 |
| 結膜炎 | 2 | 0 | 0 | 3 | 0 | 0 |
| 帯状疱疹 | 1 | 0 | 0 | 1 | 1 | 0 |
| 皮下組織膿瘍 | 1 | 0 | 0 | 2 | 0 | 0 |
| 化膿 | 1 | 0 | 0 | 1 | 0 | 0 |
| 虫垂炎 | 0 | 0 | 1 | 0 | 0 | 1 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | |
|---|---|---|---|
| Group | Placebo | | |
| Primary SOC, PT | Mild | Moderate | Severe |
| N | 173 | --- | --- |
| Any Adverse Events | 179 | 17 | 3 |
| 感染症および寄生虫症 | 26 | 7 | 1 |
| 上咽頭炎 | 10 | 0 | 0 |
| 胃腸炎 | 2 | 0 | 0 |
| 肺炎 | 0 | 4 | 0 |
| 足部白癬 | 0 | 0 | 0 |
| 毛包炎 | 0 | 0 | 0 |
| 歯周炎 | 3 | 1 | 0 |
| 膀胱炎 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９ | 0 | 0 | 0 |
| 蜂巣炎 | 0 | 0 | 0 |
| 気管支炎 | 1 | 0 | 0 |
| 咽頭炎 | 1 | 0 | 0 |
| 菌血症 | 0 | 0 | 1 |
| 麦粒腫 | 1 | 0 | 0 |
| シャント感染 | 1 | 0 | 0 |
| 爪の皮膚糸状菌症 | 0 | 0 | 0 |
| 歯肉炎 | 0 | 0 | 0 |
| 外耳炎 | 0 | 0 | 0 |
| 白癬感染 | 0 | 0 | 0 |
| 鼻炎 | 1 | 0 | 0 |
| 腎嚢胞感染 | 1 | 0 | 0 |
| 憩室炎 | 0 | 0 | 0 |
| ウイルス性胃腸炎 | 0 | 0 | 0 |
| 耳下腺炎 | 0 | 0 | 0 |
| 上気道感染 | 0 | 0 | 0 |
| 尿路感染 | 0 | 0 | 0 |
| ヘリコバクター感染 | 0 | 0 | 0 |
| 医療機器関連感染 | 0 | 0 | 0 |
| 口腔ヘルペス | 0 | 0 | 0 |
| 結膜炎 | 1 | 0 | 0 |
| 帯状疱疹 | 0 | 0 | 0 |
| 皮下組織膿瘍 | 0 | 0 | 0 |
| 化膿 | 2 | 0 | 0 |
| 虫垂炎 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 丹毒 | 0 | 0 | 0 | 0 | 0 | 0 |
| 単純ヘルペス | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘルペスウイルス感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| インフルエンザ | 0 | 0 | 0 | 0 | 1 | 0 |
| 爪囲炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 誤嚥性肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膿疱 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎盂腎炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性腎盂腎炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膿皮症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 敗血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 結核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門膿瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 移植片感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胆道感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 穿刺部位感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染性皮膚嚢腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 仮性動脈瘤感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| せつ | 0 | 0 | 0 | 0 | 0 | 0 |
| 咽頭扁桃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手白癬 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 骨髄炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 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） | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚乳頭腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 十二指腸の良性新生物 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃癌 | 0 | 0 | 0 | 0 | 0 | 0 |
| 新生物 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎癌 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脂漏性角化症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎明細胞癌 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 1.0 ug/kg | | | MR13A9 1.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 丹毒 | 0 | 0 | 0 | 0 | 0 | 0 |
| 単純ヘルペス | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘルペスウイルス感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| インフルエンザ | 0 | 0 | 0 | 0 | 0 | 0 |
| 爪囲炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 誤嚥性肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膿疱 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎盂腎炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性腎盂腎炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膿皮症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 敗血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 結核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門膿瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 移植片感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胆道感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 穿刺部位感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染性皮膚嚢腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 仮性動脈瘤感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| せつ | 0 | 0 | 0 | 0 | 0 | 0 |
| 咽頭扁桃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手白癬 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 骨髄炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 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） | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚乳頭腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 十二指腸の良性新生物 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃癌 | 0 | 0 | 0 | 0 | 0 | 0 |
| 新生物 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎癌 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脂漏性角化症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎明細胞癌 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | MR13A9-4 | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.25 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 丹毒 | 0 | 0 | 0 | 0 | 0 | 0 |
| 単純ヘルペス | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘルペスウイルス感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| インフルエンザ | 0 | 0 | 0 | 0 | 0 | 0 |
| 爪囲炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 誤嚥性肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膿疱 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎盂腎炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性腎盂腎炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膿皮症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 敗血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 結核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門膿瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 移植片感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胆道感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 穿刺部位感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染性皮膚嚢腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 仮性動脈瘤感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| せつ | 0 | 0 | 0 | 0 | 0 | 0 |
| 咽頭扁桃炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 手白癬 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 骨髄炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 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） | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚乳頭腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 十二指腸の良性新生物 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃癌 | 0 | 0 | 0 | 0 | 0 | 0 |
| 新生物 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎癌 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脂漏性角化症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎明細胞癌 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 1.0 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 丹毒 | 1 | 0 | 0 | 0 | 0 | 0 |
| 単純ヘルペス | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘルペスウイルス感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| インフルエンザ | 0 | 0 | 0 | 0 | 0 | 0 |
| 爪囲炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 誤嚥性肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膿疱 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎盂腎炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性腎盂腎炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膿皮症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 敗血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 結核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門膿瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 移植片感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔真菌感染 | 1 | 0 | 0 | 0 | 0 | 0 |
| 胆道感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 穿刺部位感染 | 1 | 0 | 0 | 0 | 0 | 0 |
| 感染性皮膚嚢腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 仮性動脈瘤感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| せつ | 0 | 0 | 0 | 1 | 0 | 0 |
| 咽頭扁桃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手白癬 | 0 | 0 | 0 | 1 | 0 | 0 |
| 皮膚真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 骨髄炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 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） | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚乳頭腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 十二指腸の良性新生物 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃癌 | 0 | 0 | 0 | 0 | 0 | 0 |
| 新生物 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎癌 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脂漏性角化症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎明細胞癌 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | MR13A9-5 (DB) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 丹毒 | 0 | 0 | 0 | 0 | 0 | 0 |
| 単純ヘルペス | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘルペスウイルス感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| インフルエンザ | 0 | 0 | 0 | 0 | 0 | 0 |
| 爪囲炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 誤嚥性肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膿疱 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎盂腎炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性腎盂腎炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膿皮症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 敗血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 結核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門膿瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 移植片感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胆道感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 穿刺部位感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染性皮膚嚢腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 仮性動脈瘤感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| せつ | 0 | 0 | 0 | 0 | 0 | 0 |
| 咽頭扁桃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手白癬 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 骨髄炎 | 0 | 1 | 0 | 0 | 0 | 0 |
| 皮膚感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 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） | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚乳頭腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 十二指腸の良性新生物 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃癌 | 0 | 0 | 0 | 0 | 0 | 0 |
| 新生物 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎癌 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脂漏性角化症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎明細胞癌 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (DB) | | | MR13A9-5 (Entire) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR-MR | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 丹毒 | 0 | 0 | 0 | 0 | 0 | 0 |
| 単純ヘルペス | 0 | 0 | 0 | 1 | 0 | 0 |
| ヘルペスウイルス感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| インフルエンザ | 0 | 0 | 0 | 0 | 0 | 0 |
| 爪囲炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 誤嚥性肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 膿疱 | 0 | 0 | 0 | 0 | 1 | 0 |
| 腎盂腎炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性腎盂腎炎 | 0 | 0 | 0 | 0 | 1 | 0 |
| 膿皮症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 敗血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 結核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門膿瘍 | 0 | 0 | 0 | 0 | 1 | 0 |
| 移植片感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胆道感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 穿刺部位感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染性皮膚嚢腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 仮性動脈瘤感染 | 0 | 0 | 0 | 1 | 0 | 0 |
| せつ | 0 | 0 | 0 | 0 | 0 | 0 |
| 咽頭扁桃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手白癬 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚真菌感染 | 1 | 0 | 0 | 0 | 0 | 0 |
| 骨髄炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚感染 | 1 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 1 | 0 | 0 | 0 | 0 |
| 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） | 0 | 1 | 0 | 4 | 1 | 0 |
| 皮膚乳頭腫 | 0 | 0 | 0 | 1 | 0 | 0 |
| 十二指腸の良性新生物 | 0 | 0 | 0 | 1 | 0 | 0 |
| 胃癌 | 0 | 0 | 0 | 0 | 0 | 0 |
| 新生物 | 0 | 0 | 0 | 1 | 0 | 0 |
| 腎癌 | 0 | 0 | 0 | 0 | 1 | 0 |
| 脂漏性角化症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 腎明細胞癌 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (Entire) | | | MR13A9-5 (Long-term) | | |
|---|---|---|---|---|---|---|
| Group | P-MR | | | MR13A9 0.5 ug/kg (Long-term) | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 丹毒 | 0 | 0 | 0 | 0 | 0 | 0 |
| 単純ヘルペス | 0 | 0 | 0 | 1 | 0 | 0 |
| ヘルペスウイルス感染 | 1 | 0 | 0 | 1 | 0 | 0 |
| 感染 | 1 | 0 | 0 | 1 | 0 | 0 |
| インフルエンザ | 0 | 0 | 0 | 0 | 0 | 0 |
| 爪囲炎 | 1 | 0 | 0 | 1 | 0 | 0 |
| 誤嚥性肺炎 | 0 | 0 | 1 | 0 | 0 | 1 |
| 膿疱 | 0 | 0 | 0 | 0 | 1 | 0 |
| 腎盂腎炎 | 1 | 0 | 0 | 1 | 0 | 0 |
| 急性腎盂腎炎 | 0 | 0 | 0 | 0 | 1 | 0 |
| 膿皮症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 敗血症 | 0 | 1 | 1 | 0 | 1 | 1 |
| 結核 | 0 | 0 | 1 | 0 | 0 | 1 |
| 肛門膿瘍 | 0 | 0 | 0 | 0 | 1 | 0 |
| 移植片感染 | 0 | 1 | 0 | 0 | 1 | 0 |
| 口腔真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胆道感染 | 1 | 0 | 0 | 1 | 0 | 0 |
| 穿刺部位感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 感染性皮膚嚢腫 | 1 | 0 | 0 | 1 | 0 | 0 |
| 仮性動脈瘤感染 | 0 | 0 | 0 | 1 | 0 | 0 |
| せつ | 0 | 0 | 0 | 0 | 0 | 0 |
| 咽頭扁桃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手白癬 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 骨髄炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚感染 | 1 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 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 | 3 | 0 | 5 | 3 | 0 |
| 皮膚乳頭腫 | 1 | 0 | 0 | 2 | 0 | 0 |
| 十二指腸の良性新生物 | 0 | 0 | 0 | 1 | 0 | 0 |
| 胃癌 | 0 | 1 | 0 | 0 | 1 | 0 |
| 新生物 | 0 | 0 | 0 | 1 | 0 | 0 |
| 腎癌 | 0 | 0 | 0 | 0 | 1 | 0 |
| 脂漏性角化症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 腎明細胞癌 | 0 | 1 | 0 | 0 | 1 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 ALL | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 丹毒 | 1 | 0 | 0 | 1 | 0 | 0 |
| 単純ヘルペス | 1 | 0 | 0 | 1 | 0 | 0 |
| ヘルペスウイルス感染 | 1 | 0 | 0 | 1 | 0 | 0 |
| 感染 | 1 | 0 | 0 | 1 | 0 | 0 |
| インフルエンザ | 0 | 1 | 0 | 0 | 1 | 0 |
| 爪囲炎 | 1 | 0 | 0 | 1 | 0 | 0 |
| 誤嚥性肺炎 | 0 | 0 | 1 | 0 | 0 | 1 |
| 膿疱 | 0 | 1 | 0 | 0 | 1 | 0 |
| 腎盂腎炎 | 1 | 0 | 0 | 1 | 0 | 0 |
| 急性腎盂腎炎 | 0 | 1 | 0 | 0 | 1 | 0 |
| 膿皮症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 敗血症 | 0 | 1 | 1 | 0 | 1 | 1 |
| 結核 | 0 | 0 | 1 | 0 | 0 | 1 |
| 肛門膿瘍 | 0 | 1 | 0 | 0 | 1 | 0 |
| 移植片感染 | 0 | 1 | 0 | 0 | 1 | 0 |
| 口腔真菌感染 | 1 | 0 | 0 | 1 | 0 | 0 |
| 胆道感染 | 1 | 0 | 0 | 1 | 0 | 0 |
| 穿刺部位感染 | 1 | 0 | 0 | 1 | 0 | 0 |
| 感染性皮膚嚢腫 | 1 | 0 | 0 | 1 | 0 | 0 |
| 仮性動脈瘤感染 | 1 | 0 | 0 | 1 | 0 | 0 |
| せつ | 0 | 0 | 0 | 1 | 0 | 0 |
| 咽頭扁桃炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 手白癬 | 0 | 0 | 0 | 1 | 0 | 0 |
| 皮膚真菌感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| 骨髄炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 皮膚感染 | 0 | 0 | 0 | 0 | 0 | 0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 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） | 5 | 3 | 0 | 5 | 3 | 0 |
| 皮膚乳頭腫 | 2 | 0 | 0 | 2 | 0 | 0 |
| 十二指腸の良性新生物 | 1 | 0 | 0 | 1 | 0 | 0 |
| 胃癌 | 0 | 1 | 0 | 0 | 1 | 0 |
| 新生物 | 1 | 0 | 0 | 1 | 0 | 0 |
| 腎癌 | 0 | 1 | 0 | 0 | 1 | 0 |
| 脂漏性角化症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 腎明細胞癌 | 0 | 1 | 0 | 0 | 1 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | |
|---|---|---|---|
| Group | Placebo | | |
| Primary SOC, PT | Mild | Moderate | Severe |
| 丹毒 | 0 | 0 | 0 |
| 単純ヘルペス | 0 | 0 | 0 |
| ヘルペスウイルス感染 | 0 | 0 | 0 |
| 感染 | 0 | 0 | 0 |
| インフルエンザ | 0 | 0 | 0 |
| 爪囲炎 | 0 | 0 | 0 |
| 誤嚥性肺炎 | 0 | 0 | 0 |
| 膿疱 | 0 | 0 | 0 |
| 腎盂腎炎 | 0 | 0 | 0 |
| 急性腎盂腎炎 | 0 | 0 | 0 |
| 膿皮症 | 0 | 0 | 0 |
| 敗血症 | 0 | 0 | 0 |
| 結核 | 0 | 0 | 0 |
| 肛門膿瘍 | 0 | 0 | 0 |
| 移植片感染 | 0 | 0 | 0 |
| 口腔真菌感染 | 0 | 0 | 0 |
| 胆道感染 | 0 | 0 | 0 |
| 穿刺部位感染 | 0 | 0 | 0 |
| 感染性皮膚嚢腫 | 0 | 0 | 0 |
| 仮性動脈瘤感染 | 0 | 0 | 0 |
| せつ | 0 | 0 | 0 |
| 咽頭扁桃炎 | 0 | 0 | 0 |
| 手白癬 | 0 | 0 | 0 |
| 皮膚真菌感染 | 1 | 0 | 0 |
| 骨髄炎 | 0 | 1 | 0 |
| 皮膚感染 | 1 | 0 | 0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 1 | 0 |
| 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） | 0 | 1 | 0 |
| 皮膚乳頭腫 | 0 | 0 | 0 |
| 十二指腸の良性新生物 | 0 | 0 | 0 |
| 胃癌 | 0 | 0 | 0 |
| 新生物 | 0 | 0 | 0 |
| 腎癌 | 0 | 0 | 0 |
| 脂漏性角化症 | 0 | 0 | 0 |
| 腎明細胞癌 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 慢性骨髄性白血病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液およびリンパ系障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鉄欠乏性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 大球性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 免疫性血小板減少症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 播種性血管内凝固 | 0 | 0 | 0 | 0 | 0 | 0 |
| 免疫系障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 季節性アレルギー | 0 | 0 | 0 | 0 | 0 | 0 |
| 造影剤アレルギー | 0 | 0 | 0 | 0 | 0 | 0 |
| アナフィラキシーショック | 0 | 0 | 0 | 0 | 0 | 0 |
| 造影剤反応 | 0 | 0 | 0 | 0 | 0 | 0 |
| 内分泌障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 続発性副甲状腺機能亢進症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 甲状腺機能低下症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 副腎機能不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高プロラクチン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 甲状腺機能亢進症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 代謝および栄養障害 | 0 | 0 | 0 | 0 | 1 | 0 |
| 糖尿病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高リン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 食欲減退 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低血糖 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高カリウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高血糖 | 0 | 0 | 0 | 0 | 1 | 0 |
| 痛風 | 0 | 0 | 0 | 0 | 0 | 0 |
| 亜鉛欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高コレステロール血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脂質異常症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低カルニチン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高尿酸血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低カリウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低リン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低蛋白血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液量減少症 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 1.0 ug/kg | | | MR13A9 1.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 慢性骨髄性白血病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液およびリンパ系障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腎性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鉄欠乏性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 大球性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 免疫性血小板減少症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 播種性血管内凝固 | 0 | 0 | 0 | 0 | 0 | 0 |
| 免疫系障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 季節性アレルギー | 0 | 0 | 0 | 0 | 0 | 0 |
| 造影剤アレルギー | 0 | 0 | 0 | 0 | 0 | 0 |
| アナフィラキシーショック | 0 | 0 | 0 | 0 | 0 | 0 |
| 造影剤反応 | 0 | 0 | 0 | 0 | 0 | 0 |
| 内分泌障害 | 0 | 0 | 0 | 1 | 0 | 0 |
| 続発性副甲状腺機能亢進症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 甲状腺機能低下症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 副腎機能不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高プロラクチン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 甲状腺機能亢進症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 代謝および栄養障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 糖尿病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高リン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 食欲減退 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低血糖 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高カリウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高血糖 | 0 | 0 | 0 | 0 | 0 | 0 |
| 痛風 | 0 | 0 | 0 | 0 | 0 | 0 |
| 亜鉛欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高コレステロール血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脂質異常症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低カルニチン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高尿酸血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低カリウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低リン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低蛋白血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液量減少症 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | MR13A9-4 | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.25 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 慢性骨髄性白血病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液およびリンパ系障害 | 0 | 0 | 0 | 1 | 0 | 0 |
| 腎性貧血 | 0 | 0 | 0 | 1 | 0 | 0 |
| 鉄欠乏性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 大球性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 免疫性血小板減少症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 播種性血管内凝固 | 0 | 0 | 0 | 0 | 0 | 0 |
| 免疫系障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 季節性アレルギー | 0 | 0 | 0 | 0 | 0 | 0 |
| 造影剤アレルギー | 0 | 0 | 0 | 0 | 0 | 0 |
| アナフィラキシーショック | 0 | 0 | 0 | 0 | 0 | 0 |
| 造影剤反応 | 0 | 0 | 0 | 0 | 0 | 0 |
| 内分泌障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 続発性副甲状腺機能亢進症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 甲状腺機能低下症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 副腎機能不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高プロラクチン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 甲状腺機能亢進症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 代謝および栄養障害 | 0 | 0 | 0 | 6 | 0 | 0 |
| 糖尿病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高リン血症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 食欲減退 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低血糖 | 0 | 0 | 0 | 3 | 0 | 0 |
| 高カリウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高血糖 | 0 | 0 | 0 | 1 | 0 | 0 |
| 痛風 | 0 | 0 | 0 | 0 | 0 | 0 |
| 亜鉛欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高コレステロール血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脂質異常症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低カルニチン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高尿酸血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低カリウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低リン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低蛋白血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液量減少症 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 1.0 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 慢性骨髄性白血病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液およびリンパ系障害 | 1 | 0 | 0 | 0 | 2 | 0 |
| 腎性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鉄欠乏性貧血 | 0 | 0 | 0 | 0 | 1 | 0 |
| 貧血 | 1 | 0 | 0 | 0 | 1 | 0 |
| 大球性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 免疫性血小板減少症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 播種性血管内凝固 | 0 | 0 | 0 | 0 | 0 | 0 |
| 免疫系障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 季節性アレルギー | 0 | 0 | 0 | 0 | 0 | 0 |
| 造影剤アレルギー | 0 | 0 | 0 | 0 | 0 | 0 |
| アナフィラキシーショック | 0 | 0 | 0 | 0 | 0 | 0 |
| 造影剤反応 | 0 | 0 | 0 | 0 | 0 | 0 |
| 内分泌障害 | 0 | 0 | 0 | 3 | 0 | 0 |
| 続発性副甲状腺機能亢進症 | 0 | 0 | 0 | 2 | 0 | 0 |
| 甲状腺機能低下症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 副腎機能不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高プロラクチン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 甲状腺機能亢進症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 代謝および栄養障害 | 4 | 0 | 0 | 2 | 2 | 0 |
| 糖尿病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高リン血症 | 2 | 0 | 0 | 1 | 0 | 0 |
| 食欲減退 | 0 | 0 | 0 | 1 | 1 | 0 |
| 低血糖 | 1 | 0 | 0 | 0 | 0 | 0 |
| 高カリウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高血糖 | 1 | 0 | 0 | 0 | 1 | 0 |
| 痛風 | 0 | 0 | 0 | 0 | 0 | 0 |
| 亜鉛欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高コレステロール血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脂質異常症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低カルニチン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高尿酸血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低カリウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低リン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低蛋白血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液量減少症 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | MR13A9-5 (DB) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 慢性骨髄性白血病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液およびリンパ系障害 | 3 | 0 | 0 | 0 | 0 | 0 |
| 腎性貧血 | 2 | 0 | 0 | 0 | 0 | 0 |
| 鉄欠乏性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 貧血 | 1 | 0 | 0 | 0 | 0 | 0 |
| 大球性貧血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 免疫性血小板減少症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 播種性血管内凝固 | 0 | 0 | 0 | 0 | 0 | 0 |
| 免疫系障害 | 1 | 0 | 0 | 0 | 0 | 0 |
| 季節性アレルギー | 0 | 0 | 0 | 0 | 0 | 0 |
| 造影剤アレルギー | 1 | 0 | 0 | 0 | 0 | 0 |
| アナフィラキシーショック | 0 | 0 | 0 | 0 | 0 | 0 |
| 造影剤反応 | 0 | 0 | 0 | 0 | 0 | 0 |
| 内分泌障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 続発性副甲状腺機能亢進症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 甲状腺機能低下症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 副腎機能不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高プロラクチン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 甲状腺機能亢進症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 代謝および栄養障害 | 4 | 0 | 0 | 1 | 1 | 0 |
| 糖尿病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高リン血症 | 1 | 0 | 0 | 0 | 0 | 0 |
| 食欲減退 | 0 | 0 | 0 | 1 | 0 | 0 |
| 低血糖 | 2 | 0 | 0 | 0 | 1 | 0 |
| 高カリウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高血糖 | 0 | 0 | 0 | 0 | 0 | 0 |
| 痛風 | 0 | 0 | 0 | 0 | 0 | 0 |
| 亜鉛欠乏 | 1 | 0 | 0 | 0 | 0 | 0 |
| 高コレステロール血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脂質異常症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低カルニチン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高尿酸血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低カリウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低リン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低蛋白血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液量減少症 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (DB) | | | MR13A9-5 (Entire) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR-MR | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 慢性骨髄性白血病 | 0 | 1 | 0 | 0 | 0 | 0 |
| 血液およびリンパ系障害 | 0 | 1 | 0 | 3 | 1 | 0 |
| 腎性貧血 | 0 | 0 | 0 | 1 | 0 | 0 |
| 鉄欠乏性貧血 | 0 | 0 | 0 | 1 | 0 | 0 |
| 貧血 | 0 | 0 | 0 | 1 | 0 | 0 |
| 大球性貧血 | 0 | 0 | 0 | 0 | 1 | 0 |
| 免疫性血小板減少症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 播種性血管内凝固 | 0 | 1 | 0 | 0 | 0 | 0 |
| 免疫系障害 | 0 | 0 | 0 | 2 | 1 | 1 |
| 季節性アレルギー | 0 | 0 | 0 | 1 | 0 | 0 |
| 造影剤アレルギー | 0 | 0 | 0 | 0 | 1 | 0 |
| アナフィラキシーショック | 0 | 0 | 0 | 0 | 0 | 1 |
| 造影剤反応 | 0 | 0 | 0 | 1 | 0 | 0 |
| 内分泌障害 | 1 | 0 | 0 | 5 | 0 | 0 |
| 続発性副甲状腺機能亢進症 | 1 | 0 | 0 | 2 | 0 | 0 |
| 甲状腺機能低下症 | 0 | 0 | 0 | 2 | 0 | 0 |
| 副腎機能不全 | 0 | 0 | 0 | 1 | 0 | 0 |
| 高プロラクチン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 甲状腺機能亢進症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 代謝および栄養障害 | 3 | 0 | 0 | 26 | 6 | 0 |
| 糖尿病 | 0 | 0 | 0 | 2 | 3 | 0 |
| 高リン血症 | 1 | 0 | 0 | 3 | 0 | 0 |
| 食欲減退 | 0 | 0 | 0 | 3 | 1 | 0 |
| 低血糖 | 1 | 0 | 0 | 3 | 2 | 0 |
| 高カリウム血症 | 0 | 0 | 0 | 5 | 0 | 0 |
| 高血糖 | 0 | 0 | 0 | 1 | 0 | 0 |
| 痛風 | 0 | 0 | 0 | 2 | 0 | 0 |
| 亜鉛欠乏 | 0 | 0 | 0 | 2 | 0 | 0 |
| 高コレステロール血症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 脂質異常症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 低カルニチン血症 | 0 | 0 | 0 | 2 | 0 | 0 |
| 高尿酸血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低カリウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低リン血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 低蛋白血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液量減少症 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (Entire) | | | MR13A9-5 (Long-term) | | |
|---|---|---|---|---|---|---|
| Group | P-MR | | | MR13A9 0.5 ug/kg (Long-term) | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 慢性骨髄性白血病 | 0 | 1 | 0 | 0 | 0 | 0 |
| 血液およびリンパ系障害 | 8 | 3 | 0 | 11 | 3 | 0 |
| 腎性貧血 | 4 | 0 | 0 | 5 | 0 | 0 |
| 鉄欠乏性貧血 | 4 | 1 | 0 | 5 | 1 | 0 |
| 貧血 | 0 | 0 | 0 | 1 | 0 | 0 |
| 大球性貧血 | 0 | 0 | 0 | 0 | 1 | 0 |
| 免疫性血小板減少症 | 0 | 1 | 0 | 0 | 1 | 0 |
| 播種性血管内凝固 | 0 | 1 | 0 | 0 | 0 | 0 |
| 免疫系障害 | 3 | 0 | 0 | 5 | 1 | 1 |
| 季節性アレルギー | 2 | 0 | 0 | 3 | 0 | 0 |
| 造影剤アレルギー | 1 | 0 | 0 | 1 | 1 | 0 |
| アナフィラキシーショック | 0 | 0 | 0 | 0 | 0 | 1 |
| 造影剤反応 | 0 | 0 | 0 | 1 | 0 | 0 |
| 内分泌障害 | 2 | 0 | 0 | 6 | 0 | 0 |
| 続発性副甲状腺機能亢進症 | 1 | 0 | 0 | 2 | 0 | 0 |
| 甲状腺機能低下症 | 0 | 0 | 0 | 2 | 0 | 0 |
| 副腎機能不全 | 0 | 0 | 0 | 1 | 0 | 0 |
| 高プロラクチン血症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 甲状腺機能亢進症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 代謝および栄養障害 | 25 | 2 | 0 | 48 | 8 | 0 |
| 糖尿病 | 5 | 1 | 0 | 7 | 4 | 0 |
| 高リン血症 | 2 | 0 | 0 | 4 | 0 | 0 |
| 食欲減退 | 2 | 1 | 0 | 5 | 2 | 0 |
| 低血糖 | 2 | 0 | 0 | 4 | 2 | 0 |
| 高カリウム血症 | 1 | 0 | 0 | 6 | 0 | 0 |
| 高血糖 | 0 | 0 | 0 | 1 | 0 | 0 |
| 痛風 | 1 | 0 | 0 | 3 | 0 | 0 |
| 亜鉛欠乏 | 1 | 0 | 0 | 3 | 0 | 0 |
| 高コレステロール血症 | 1 | 0 | 0 | 2 | 0 | 0 |
| 脂質異常症 | 1 | 0 | 0 | 2 | 0 | 0 |
| 低カルニチン血症 | 0 | 0 | 0 | 2 | 0 | 0 |
| 高尿酸血症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 低カリウム血症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 低リン血症 | 2 | 0 | 0 | 2 | 0 | 0 |
| 低蛋白血症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 血液量減少症 | 1 | 0 | 0 | 1 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 ALL | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 慢性骨髄性白血病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血液およびリンパ系障害 | 12 | 3 | 0 | 13 | 5 | 0 |
| 腎性貧血 | 5 | 0 | 0 | 6 | 0 | 0 |
| 鉄欠乏性貧血 | 5 | 1 | 0 | 5 | 2 | 0 |
| 貧血 | 2 | 0 | 0 | 2 | 1 | 0 |
| 大球性貧血 | 0 | 1 | 0 | 0 | 1 | 0 |
| 免疫性血小板減少症 | 0 | 1 | 0 | 0 | 1 | 0 |
| 播種性血管内凝固 | 0 | 0 | 0 | 0 | 0 | 0 |
| 免疫系障害 | 5 | 1 | 1 | 5 | 1 | 1 |
| 季節性アレルギー | 3 | 0 | 0 | 3 | 0 | 0 |
| 造影剤アレルギー | 1 | 1 | 0 | 1 | 1 | 0 |
| アナフィラキシーショック | 0 | 0 | 1 | 0 | 0 | 1 |
| 造影剤反応 | 1 | 0 | 0 | 1 | 0 | 0 |
| 内分泌障害 | 6 | 0 | 0 | 10 | 0 | 0 |
| 続発性副甲状腺機能亢進症 | 2 | 0 | 0 | 4 | 0 | 0 |
| 甲状腺機能低下症 | 2 | 0 | 0 | 3 | 0 | 0 |
| 副腎機能不全 | 1 | 0 | 0 | 1 | 0 | 0 |
| 高プロラクチン血症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 甲状腺機能亢進症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 代謝および栄養障害 | 52 | 9 | 0 | 60 | 11 | 0 |
| 糖尿病 | 7 | 4 | 0 | 7 | 4 | 0 |
| 高リン血症 | 6 | 0 | 0 | 8 | 0 | 0 |
| 食欲減退 | 5 | 2 | 0 | 6 | 3 | 0 |
| 低血糖 | 5 | 2 | 0 | 8 | 2 | 0 |
| 高カリウム血症 | 6 | 0 | 0 | 6 | 0 | 0 |
| 高血糖 | 2 | 1 | 0 | 3 | 2 | 0 |
| 痛風 | 3 | 0 | 0 | 3 | 0 | 0 |
| 亜鉛欠乏 | 3 | 0 | 0 | 3 | 0 | 0 |
| 高コレステロール血症 | 2 | 0 | 0 | 2 | 0 | 0 |
| 脂質異常症 | 2 | 0 | 0 | 2 | 0 | 0 |
| 低カルニチン血症 | 2 | 0 | 0 | 2 | 0 | 0 |
| 高尿酸血症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 低カリウム血症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 低リン血症 | 2 | 0 | 0 | 2 | 0 | 0 |
| 低蛋白血症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 血液量減少症 | 1 | 0 | 0 | 1 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | |
|---|---|---|---|
| Group | Placebo | | |
| Primary SOC, PT | Mild | Moderate | Severe |
| 慢性骨髄性白血病 | 0 | 1 | 0 |
| 血液およびリンパ系障害 | 3 | 1 | 0 |
| 腎性貧血 | 2 | 0 | 0 |
| 鉄欠乏性貧血 | 0 | 0 | 0 |
| 貧血 | 1 | 0 | 0 |
| 大球性貧血 | 0 | 0 | 0 |
| 免疫性血小板減少症 | 0 | 0 | 0 |
| 播種性血管内凝固 | 0 | 1 | 0 |
| 免疫系障害 | 1 | 0 | 0 |
| 季節性アレルギー | 0 | 0 | 0 |
| 造影剤アレルギー | 1 | 0 | 0 |
| アナフィラキシーショック | 0 | 0 | 0 |
| 造影剤反応 | 0 | 0 | 0 |
| 内分泌障害 | 1 | 0 | 0 |
| 続発性副甲状腺機能亢進症 | 1 | 0 | 0 |
| 甲状腺機能低下症 | 0 | 0 | 0 |
| 副腎機能不全 | 0 | 0 | 0 |
| 高プロラクチン血症 | 0 | 0 | 0 |
| 甲状腺機能亢進症 | 0 | 0 | 0 |
| 代謝および栄養障害 | 7 | 0 | 0 |
| 糖尿病 | 0 | 0 | 0 |
| 高リン血症 | 2 | 0 | 0 |
| 食欲減退 | 0 | 0 | 0 |
| 低血糖 | 3 | 0 | 0 |
| 高カリウム血症 | 0 | 0 | 0 |
| 高血糖 | 0 | 0 | 0 |
| 痛風 | 0 | 0 | 0 |
| 亜鉛欠乏 | 1 | 0 | 0 |
| 高コレステロール血症 | 0 | 0 | 0 |
| 脂質異常症 | 0 | 0 | 0 |
| 低カルニチン血症 | 0 | 0 | 0 |
| 高尿酸血症 | 0 | 0 | 0 |
| 低カリウム血症 | 0 | 0 | 0 |
| 低リン血症 | 0 | 0 | 0 |
| 低蛋白血症 | 0 | 0 | 0 |
| 血液量減少症 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 低亜鉛血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| ビタミンK欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高脂血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鉄欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高カルシウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 精神障害 | 1 | 0 | 0 | 7 | 0 | 0 |
| 不眠症 | 1 | 0 | 0 | 2 | 0 | 0 |
| 不安 | 0 | 0 | 0 | 0 | 0 | 0 |
| 譫妄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 多幸気分 | 0 | 0 | 0 | 5 | 0 | 0 |
| 幻覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| 初期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 易刺激性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 中期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 無為 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経系障害 | 5 | 1 | 0 | 6 | 1 | 0 |
| 浮動性めまい | 1 | 0 | 0 | 3 | 1 | 0 |
| 頭痛 | 0 | 1 | 0 | 0 | 0 | 0 |
| 傾眠 | 4 | 0 | 0 | 3 | 0 | 0 |
| 感覚鈍麻 | 0 | 0 | 0 | 0 | 0 | 0 |
| 下肢静止不能症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 意識消失 | 0 | 0 | 0 | 0 | 0 | 0 |
| 失神 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脳梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 片頭痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| ラクナ梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 起立不耐性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頭部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 意識変容状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手根管症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚腕症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| ジスキネジア | 0 | 0 | 0 | 0 | 0 | 0 |
| てんかん | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 1.0 ug/kg | | | MR13A9 1.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 低亜鉛血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| ビタミンK欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高脂血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鉄欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高カルシウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 精神障害 | 1 | 0 | 0 | 2 | 0 | 0 |
| 不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 不安 | 0 | 0 | 0 | 1 | 0 | 0 |
| 譫妄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 多幸気分 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| 初期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 易刺激性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 中期不眠症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 神経症 | 1 | 0 | 0 | 0 | 0 | 0 |
| 無為 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経系障害 | 2 | 0 | 0 | 11 | 5 | 0 |
| 浮動性めまい | 2 | 0 | 0 | 3 | 1 | 0 |
| 頭痛 | 0 | 0 | 0 | 1 | 1 | 0 |
| 傾眠 | 0 | 0 | 0 | 6 | 2 | 0 |
| 感覚鈍麻 | 0 | 0 | 0 | 0 | 0 | 0 |
| 下肢静止不能症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経痛 | 0 | 0 | 0 | 1 | 0 | 0 |
| 意識消失 | 0 | 0 | 0 | 0 | 0 | 0 |
| 失神 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脳梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 片頭痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| ラクナ梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 起立不耐性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頭部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 意識変容状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手根管症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚腕症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| ジスキネジア | 0 | 0 | 0 | 0 | 0 | 0 |
| てんかん | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | MR13A9-4 | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.25 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 低亜鉛血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| ビタミンK欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高脂血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鉄欠乏 | 0 | 0 | 0 | 1 | 0 | 0 |
| 高カルシウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 精神障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 不安 | 0 | 0 | 0 | 0 | 0 | 0 |
| 譫妄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 多幸気分 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| 初期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 易刺激性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 中期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 無為 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経系障害 | 0 | 0 | 0 | 7 | 0 | 0 |
| 浮動性めまい | 0 | 0 | 0 | 3 | 0 | 0 |
| 頭痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 傾眠 | 0 | 0 | 0 | 2 | 0 | 0 |
| 感覚鈍麻 | 0 | 0 | 0 | 0 | 0 | 0 |
| 下肢静止不能症候群 | 0 | 0 | 0 | 1 | 0 | 0 |
| 神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 意識消失 | 0 | 0 | 0 | 0 | 0 | 0 |
| 失神 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脳梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 片頭痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| ラクナ梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 起立不耐性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頭部不快感 | 0 | 0 | 0 | 1 | 0 | 0 |
| 意識変容状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手根管症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚腕症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| ジスキネジア | 0 | 0 | 0 | 0 | 0 | 0 |
| てんかん | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 1.0 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 低亜鉛血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| ビタミンK欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高脂血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鉄欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高カルシウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 精神障害 | 0 | 0 | 0 | 2 | 0 | 0 |
| 不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 不安 | 0 | 0 | 0 | 1 | 0 | 0 |
| 譫妄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 多幸気分 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| 初期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 易刺激性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 中期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 無為 | 0 | 0 | 0 | 1 | 0 | 0 |
| 神経系障害 | 10 | 1 | 1 | 14 | 2 | 0 |
| 浮動性めまい | 3 | 0 | 0 | 5 | 0 | 0 |
| 頭痛 | 2 | 0 | 0 | 0 | 0 | 0 |
| 傾眠 | 3 | 0 | 0 | 6 | 0 | 0 |
| 感覚鈍麻 | 0 | 0 | 0 | 0 | 0 | 0 |
| 下肢静止不能症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 意識消失 | 0 | 0 | 0 | 0 | 0 | 0 |
| 失神 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脳梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 片頭痛 | 1 | 0 | 0 | 0 | 0 | 0 |
| ラクナ梗塞 | 0 | 1 | 0 | 0 | 0 | 0 |
| 起立不耐性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頭部不快感 | 0 | 0 | 0 | 1 | 0 | 0 |
| 意識変容状態 | 0 | 0 | 1 | 0 | 0 | 0 |
| 頚動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手根管症候群 | 1 | 0 | 0 | 0 | 0 | 0 |
| 頚腕症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| ジスキネジア | 0 | 0 | 0 | 0 | 0 | 0 |
| てんかん | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | MR13A9-5 (DB) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 低亜鉛血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| ビタミンK欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高脂血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鉄欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高カルシウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 精神障害 | 0 | 0 | 0 | 0 | 1 | 0 |
| 不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 不安 | 0 | 0 | 0 | 0 | 1 | 0 |
| 譫妄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 多幸気分 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| 初期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 易刺激性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 中期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 無為 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経系障害 | 9 | 0 | 0 | 9 | 1 | 0 |
| 浮動性めまい | 4 | 0 | 0 | 0 | 0 | 0 |
| 頭痛 | 1 | 0 | 0 | 3 | 0 | 0 |
| 傾眠 | 3 | 0 | 0 | 1 | 0 | 0 |
| 感覚鈍麻 | 0 | 0 | 0 | 1 | 0 | 0 |
| 下肢静止不能症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 意識消失 | 0 | 0 | 0 | 0 | 1 | 0 |
| 失神 | 0 | 0 | 0 | 2 | 0 | 0 |
| 脳梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 片頭痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| ラクナ梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 起立不耐性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頭部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 意識変容状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手根管症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚腕症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| ジスキネジア | 0 | 0 | 0 | 0 | 0 | 0 |
| てんかん | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (DB) | | | MR13A9-5 (Entire) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR-MR | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 低亜鉛血症 | 0 | 0 | 0 | 1 | 0 | 0 |
| ビタミンK欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高脂血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鉄欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高カルシウム血症 | 1 | 0 | 0 | 0 | 0 | 0 |
| 精神障害 | 0 | 0 | 0 | 9 | 1 | 0 |
| 不眠症 | 0 | 0 | 0 | 6 | 0 | 0 |
| 不安 | 0 | 0 | 0 | 0 | 1 | 0 |
| 譫妄 | 0 | 0 | 0 | 2 | 0 | 0 |
| 多幸気分 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| 初期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 易刺激性 | 0 | 0 | 0 | 1 | 0 | 0 |
| 中期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 無為 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経系障害 | 7 | 0 | 0 | 32 | 3 | 0 |
| 浮動性めまい | 4 | 0 | 0 | 7 | 0 | 0 |
| 頭痛 | 0 | 0 | 0 | 8 | 0 | 0 |
| 傾眠 | 1 | 0 | 0 | 4 | 0 | 0 |
| 感覚鈍麻 | 0 | 0 | 0 | 2 | 0 | 0 |
| 下肢静止不能症候群 | 0 | 0 | 0 | 2 | 0 | 0 |
| 神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 意識消失 | 0 | 0 | 0 | 0 | 1 | 0 |
| 失神 | 0 | 0 | 0 | 3 | 0 | 0 |
| 脳梗塞 | 0 | 0 | 0 | 0 | 1 | 0 |
| 片頭痛 | 0 | 0 | 0 | 1 | 0 | 0 |
| ラクナ梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 起立不耐性 | 0 | 0 | 0 | 0 | 1 | 0 |
| 頭部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 意識変容状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 手根管症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚腕症候群 | 0 | 0 | 0 | 1 | 0 | 0 |
| ジスキネジア | 0 | 0 | 0 | 1 | 0 | 0 |
| てんかん | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (Entire) | | | MR13A9-5 (Long-term) | | |
|---|---|---|---|---|---|---|
| Group | P-MR | | | MR13A9 0.5 ug/kg (Long-term) | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 低亜鉛血症 | 0 | 0 | 0 | 1 | 0 | 0 |
| ビタミンK欠乏 | 1 | 0 | 0 | 1 | 0 | 0 |
| 高脂血症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 鉄欠乏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高カルシウム血症 | 1 | 0 | 0 | 0 | 0 | 0 |
| 精神障害 | 8 | 1 | 0 | 17 | 2 | 0 |
| 不眠症 | 6 | 0 | 0 | 12 | 0 | 0 |
| 不安 | 0 | 0 | 0 | 0 | 1 | 0 |
| 譫妄 | 1 | 0 | 0 | 3 | 0 | 0 |
| 多幸気分 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻覚 | 0 | 1 | 0 | 0 | 1 | 0 |
| 初期不眠症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 易刺激性 | 0 | 0 | 0 | 1 | 0 | 0 |
| 中期不眠症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 無為 | 0 | 0 | 0 | 0 | 0 | 0 |
| 神経系障害 | 51 | 1 | 1 | 79 | 4 | 1 |
| 浮動性めまい | 11 | 0 | 0 | 16 | 0 | 0 |
| 頭痛 | 14 | 0 | 0 | 23 | 0 | 0 |
| 傾眠 | 4 | 0 | 0 | 7 | 0 | 0 |
| 感覚鈍麻 | 4 | 0 | 0 | 6 | 0 | 0 |
| 下肢静止不能症候群 | 2 | 0 | 0 | 4 | 0 | 0 |
| 神経痛 | 3 | 0 | 0 | 3 | 0 | 0 |
| 意識消失 | 4 | 0 | 0 | 4 | 1 | 0 |
| 失神 | 2 | 0 | 0 | 5 | 0 | 0 |
| 脳梗塞 | 1 | 0 | 0 | 1 | 1 | 0 |
| 片頭痛 | 0 | 0 | 0 | 1 | 0 | 0 |
| ラクナ梗塞 | 1 | 0 | 0 | 1 | 0 | 0 |
| 起立不耐性 | 1 | 0 | 0 | 1 | 1 | 0 |
| 頭部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 意識変容状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚動脈狭窄 | 1 | 0 | 0 | 1 | 0 | 0 |
| 手根管症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頚腕症候群 | 0 | 0 | 0 | 1 | 0 | 0 |
| ジスキネジア | 0 | 0 | 0 | 1 | 0 | 0 |
| てんかん | 0 | 1 | 0 | 0 | 1 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 ALL | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 低亜鉛血症 | 1 | 0 | 0 | 1 | 0 | 0 |
| ビタミンK欠乏 | 1 | 0 | 0 | 1 | 0 | 0 |
| 高脂血症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 鉄欠乏 | 0 | 0 | 0 | 1 | 0 | 0 |
| 高カルシウム血症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 精神障害 | 24 | 2 | 0 | 30 | 2 | 0 |
| 不眠症 | 14 | 0 | 0 | 15 | 0 | 0 |
| 不安 | 0 | 1 | 0 | 2 | 1 | 0 |
| 譫妄 | 3 | 0 | 0 | 3 | 0 | 0 |
| 多幸気分 | 5 | 0 | 0 | 5 | 0 | 0 |
| 幻覚 | 0 | 1 | 0 | 0 | 1 | 0 |
| 初期不眠症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 易刺激性 | 1 | 0 | 0 | 1 | 0 | 0 |
| 中期不眠症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 神経症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 無為 | 0 | 0 | 0 | 1 | 0 | 0 |
| 神経系障害 | 95 | 6 | 2 | 134 | 14 | 2 |
| 浮動性めまい | 22 | 1 | 0 | 36 | 2 | 0 |
| 頭痛 | 25 | 0 | 0 | 26 | 2 | 0 |
| 傾眠 | 13 | 0 | 0 | 31 | 2 | 0 |
| 感覚鈍麻 | 6 | 0 | 0 | 6 | 0 | 0 |
| 下肢静止不能症候群 | 4 | 0 | 0 | 5 | 0 | 0 |
| 神経痛 | 3 | 0 | 0 | 4 | 0 | 0 |
| 意識消失 | 4 | 1 | 0 | 4 | 1 | 0 |
| 失神 | 5 | 0 | 0 | 5 | 0 | 0 |
| 脳梗塞 | 1 | 1 | 0 | 1 | 1 | 0 |
| 片頭痛 | 2 | 0 | 0 | 2 | 0 | 0 |
| ラクナ梗塞 | 1 | 1 | 0 | 1 | 1 | 0 |
| 起立不耐性 | 1 | 1 | 0 | 1 | 1 | 0 |
| 頭部不快感 | 0 | 0 | 0 | 2 | 0 | 0 |
| 意識変容状態 | 0 | 0 | 1 | 0 | 0 | 1 |
| 頚動脈狭窄 | 1 | 0 | 0 | 1 | 0 | 0 |
| 手根管症候群 | 1 | 0 | 0 | 1 | 0 | 0 |
| 頚腕症候群 | 1 | 0 | 0 | 1 | 0 | 0 |
| ジスキネジア | 1 | 0 | 0 | 1 | 0 | 0 |
| てんかん | 0 | 1 | 0 | 0 | 1 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | |
|---|---|---|---|
| Group | Placebo | | |
| Primary SOC, PT | Mild | Moderate | Severe |
| 低亜鉛血症 | 0 | 0 | 0 |
| ビタミンK欠乏 | 0 | 0 | 0 |
| 高脂血症 | 0 | 0 | 0 |
| 鉄欠乏 | 0 | 0 | 0 |
| 高カルシウム血症 | 1 | 0 | 0 |
| 精神障害 | 0 | 0 | 0 |
| 不眠症 | 0 | 0 | 0 |
| 不安 | 0 | 0 | 0 |
| 譫妄 | 0 | 0 | 0 |
| 多幸気分 | 0 | 0 | 0 |
| 幻覚 | 0 | 0 | 0 |
| 初期不眠症 | 0 | 0 | 0 |
| 易刺激性 | 0 | 0 | 0 |
| 中期不眠症 | 0 | 0 | 0 |
| 神経症 | 0 | 0 | 0 |
| 無為 | 0 | 0 | 0 |
| 神経系障害 | 16 | 0 | 0 |
| 浮動性めまい | 8 | 0 | 0 |
| 頭痛 | 1 | 0 | 0 |
| 傾眠 | 4 | 0 | 0 |
| 感覚鈍麻 | 0 | 0 | 0 |
| 下肢静止不能症候群 | 0 | 0 | 0 |
| 神経痛 | 0 | 0 | 0 |
| 意識消失 | 0 | 0 | 0 |
| 失神 | 0 | 0 | 0 |
| 脳梗塞 | 0 | 0 | 0 |
| 片頭痛 | 0 | 0 | 0 |
| ラクナ梗塞 | 0 | 0 | 0 |
| 起立不耐性 | 0 | 0 | 0 |
| 頭部不快感 | 0 | 0 | 0 |
| 意識変容状態 | 0 | 0 | 0 |
| 頚動脈狭窄 | 0 | 0 | 0 |
| 手根管症候群 | 0 | 0 | 0 |
| 頚腕症候群 | 0 | 0 | 0 |
| ジスキネジア | 0 | 0 | 0 |
| てんかん | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 末梢性ニューロパチー | 0 | 0 | 0 | 0 | 0 | 0 |
| 錯感覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘルペス後神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| てんかん重積状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| ミオクロニーてんかん | 0 | 0 | 0 | 0 | 0 | 0 |
| 糖尿病性ニューロパチー | 0 | 0 | 0 | 0 | 0 | 0 |
| 感覚障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 振戦 | 0 | 0 | 0 | 0 | 0 | 0 |
| 三叉神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻肢症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脳幹梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 一過性脳虚血発作 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肋間神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼障害 | 1 | 0 | 0 | 0 | 0 | 0 |
| 白内障 | 0 | 0 | 0 | 0 | 0 | 0 |
| アレルギー性結膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| ドライアイ | 0 | 0 | 0 | 0 | 0 | 0 |
| 結膜出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜上膜 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 霰粒腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 糖尿病網膜症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 複視 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涙増加 | 0 | 0 | 0 | 0 | 0 | 0 |
| 黄斑浮腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜裂孔 | 0 | 0 | 0 | 0 | 0 | 0 |
| 加齢黄斑変性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 霧視 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高眼圧症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硝子体混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼そう痒症 | 1 | 0 | 0 | 0 | 0 | 0 |
| 後嚢部混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳および迷路障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 回転性めまい | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳鳴 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頭位性回転性めまい | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 1.0 ug/kg | | | MR13A9 1.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 末梢性ニューロパチー | 0 | 0 | 0 | 0 | 0 | 0 |
| 錯感覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘルペス後神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| てんかん重積状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| ミオクロニーてんかん | 0 | 0 | 0 | 0 | 0 | 0 |
| 糖尿病性ニューロパチー | 0 | 0 | 0 | 0 | 0 | 0 |
| 感覚障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 振戦 | 0 | 0 | 0 | 0 | 0 | 0 |
| 三叉神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻肢症候群 | 0 | 0 | 0 | 0 | 1 | 0 |
| 脳幹梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 一過性脳虚血発作 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肋間神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 白内障 | 0 | 0 | 0 | 0 | 0 | 0 |
| アレルギー性結膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| ドライアイ | 0 | 0 | 0 | 0 | 0 | 0 |
| 結膜出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜上膜 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 霰粒腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 糖尿病網膜症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 複視 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涙増加 | 0 | 0 | 0 | 0 | 0 | 0 |
| 黄斑浮腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜裂孔 | 0 | 0 | 0 | 0 | 0 | 0 |
| 加齢黄斑変性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 霧視 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高眼圧症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硝子体混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼そう痒症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 後嚢部混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳および迷路障害 | 0 | 0 | 0 | 0 | 1 | 0 |
| 回転性めまい | 0 | 0 | 0 | 0 | 1 | 0 |
| 耳鳴 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頭位性回転性めまい | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | MR13A9-4 | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.25 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 末梢性ニューロパチー | 0 | 0 | 0 | 0 | 0 | 0 |
| 錯感覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘルペス後神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| てんかん重積状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| ミオクロニーてんかん | 0 | 0 | 0 | 0 | 0 | 0 |
| 糖尿病性ニューロパチー | 0 | 0 | 0 | 0 | 0 | 0 |
| 感覚障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 振戦 | 0 | 0 | 0 | 0 | 0 | 0 |
| 三叉神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻肢症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脳幹梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 一過性脳虚血発作 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肋間神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 白内障 | 0 | 0 | 0 | 0 | 0 | 0 |
| アレルギー性結膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| ドライアイ | 0 | 0 | 0 | 0 | 0 | 0 |
| 結膜出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜上膜 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 霰粒腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 糖尿病網膜症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 複視 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涙増加 | 0 | 0 | 0 | 0 | 0 | 0 |
| 黄斑浮腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜裂孔 | 0 | 0 | 0 | 0 | 0 | 0 |
| 加齢黄斑変性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 霧視 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高眼圧症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硝子体混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼そう痒症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 後嚢部混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳および迷路障害 | 0 | 0 | 0 | 2 | 0 | 0 |
| 回転性めまい | 0 | 0 | 0 | 1 | 0 | 0 |
| 耳鳴 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頭位性回転性めまい | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 1.0 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 末梢性ニューロパチー | 0 | 0 | 0 | 0 | 0 | 0 |
| 錯感覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘルペス後神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| てんかん重積状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| ミオクロニーてんかん | 0 | 0 | 0 | 0 | 0 | 0 |
| 糖尿病性ニューロパチー | 0 | 0 | 0 | 1 | 0 | 0 |
| 感覚障害 | 0 | 0 | 0 | 1 | 0 | 0 |
| 振戦 | 0 | 0 | 0 | 0 | 1 | 0 |
| 三叉神経痛 | 0 | 0 | 0 | 0 | 1 | 0 |
| 幻肢症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脳幹梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 一過性脳虚血発作 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肋間神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼障害 | 0 | 0 | 0 | 5 | 1 | 0 |
| 白内障 | 0 | 0 | 0 | 0 | 0 | 0 |
| アレルギー性結膜炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| ドライアイ | 0 | 0 | 0 | 1 | 0 | 0 |
| 結膜出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜上膜 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜出血 | 0 | 0 | 0 | 1 | 0 | 0 |
| 霰粒腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 糖尿病網膜症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 複視 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涙増加 | 0 | 0 | 0 | 0 | 0 | 0 |
| 黄斑浮腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜裂孔 | 0 | 0 | 0 | 0 | 0 | 0 |
| 加齢黄斑変性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 霧視 | 0 | 0 | 0 | 1 | 0 | 0 |
| 高眼圧症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 硝子体混濁 | 0 | 0 | 0 | 0 | 1 | 0 |
| 眼そう痒症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 後嚢部混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳および迷路障害 | 2 | 0 | 0 | 2 | 0 | 0 |
| 回転性めまい | 1 | 0 | 0 | 0 | 0 | 0 |
| 耳鳴 | 0 | 0 | 0 | 1 | 0 | 0 |
| 頭位性回転性めまい | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | MR13A9-5 (DB) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 末梢性ニューロパチー | 0 | 0 | 0 | 0 | 0 | 0 |
| 錯感覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘルペス後神経痛 | 0 | 0 | 0 | 1 | 0 | 0 |
| てんかん重積状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| ミオクロニーてんかん | 0 | 0 | 0 | 1 | 0 | 0 |
| 糖尿病性ニューロパチー | 0 | 0 | 0 | 0 | 0 | 0 |
| 感覚障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 振戦 | 0 | 0 | 0 | 0 | 0 | 0 |
| 三叉神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻肢症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脳幹梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 一過性脳虚血発作 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肋間神経痛 | 1 | 0 | 0 | 0 | 0 | 0 |
| 眼障害 | 1 | 1 | 0 | 0 | 0 | 0 |
| 白内障 | 0 | 0 | 0 | 0 | 0 | 0 |
| アレルギー性結膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| ドライアイ | 0 | 0 | 0 | 0 | 0 | 0 |
| 結膜出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜上膜 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 霰粒腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 糖尿病網膜症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 複視 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涙増加 | 0 | 0 | 0 | 0 | 0 | 0 |
| 黄斑浮腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜裂孔 | 0 | 0 | 0 | 0 | 0 | 0 |
| 加齢黄斑変性 | 0 | 0 | 0 | 0 | 0 | 0 |
| 霧視 | 1 | 0 | 0 | 0 | 0 | 0 |
| 高眼圧症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硝子体混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼そう痒症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 後嚢部混濁 | 0 | 1 | 0 | 0 | 0 | 0 |
| 耳および迷路障害 | 0 | 0 | 0 | 1 | 0 | 0 |
| 回転性めまい | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳鳴 | 0 | 0 | 0 | 1 | 0 | 0 |
| 頭位性回転性めまい | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (DB) | | | MR13A9-5 (Entire) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR-MR | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 末梢性ニューロパチー | 0 | 0 | 0 | 1 | 0 | 0 |
| 錯感覚 | 0 | 0 | 0 | 0 | 0 | 0 |
| ヘルペス後神経痛 | 0 | 0 | 0 | 1 | 0 | 0 |
| てんかん重積状態 | 0 | 0 | 0 | 0 | 0 | 0 |
| ミオクロニーてんかん | 0 | 0 | 0 | 1 | 0 | 0 |
| 糖尿病性ニューロパチー | 0 | 0 | 0 | 0 | 0 | 0 |
| 感覚障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 振戦 | 0 | 0 | 0 | 0 | 0 | 0 |
| 三叉神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻肢症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脳幹梗塞 | 1 | 0 | 0 | 0 | 0 | 0 |
| 一過性脳虚血発作 | 1 | 0 | 0 | 0 | 0 | 0 |
| 肋間神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼障害 | 0 | 0 | 0 | 10 | 2 | 0 |
| 白内障 | 0 | 0 | 0 | 1 | 1 | 0 |
| アレルギー性結膜炎 | 0 | 0 | 0 | 2 | 0 | 0 |
| ドライアイ | 0 | 0 | 0 | 1 | 0 | 0 |
| 結膜出血 | 0 | 0 | 0 | 2 | 0 | 0 |
| 網膜上膜 | 0 | 0 | 0 | 1 | 1 | 0 |
| 網膜出血 | 0 | 0 | 0 | 1 | 0 | 0 |
| 霰粒腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 糖尿病網膜症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 複視 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涙増加 | 0 | 0 | 0 | 1 | 0 | 0 |
| 黄斑浮腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 網膜裂孔 | 0 | 0 | 0 | 0 | 0 | 0 |
| 加齢黄斑変性 | 0 | 0 | 0 | 1 | 0 | 0 |
| 霧視 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高眼圧症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硝子体混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼そう痒症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 後嚢部混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳および迷路障害 | 0 | 0 | 0 | 6 | 2 | 0 |
| 回転性めまい | 0 | 0 | 0 | 3 | 1 | 0 |
| 耳鳴 | 0 | 0 | 0 | 1 | 0 | 0 |
| 頭位性回転性めまい | 0 | 0 | 0 | 1 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (Entire) | | | MR13A9-5 (Long-term) | | |
|---|---|---|---|---|---|---|
| Group | P-MR | | | MR13A9 0.5 ug/kg (Long-term) | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 末梢性ニューロパチー | 0 | 0 | 0 | 1 | 0 | 0 |
| 錯感覚 | 1 | 0 | 0 | 1 | 0 | 0 |
| ヘルペス後神経痛 | 0 | 0 | 0 | 1 | 0 | 0 |
| てんかん重積状態 | 0 | 0 | 1 | 0 | 0 | 1 |
| ミオクロニーてんかん | 0 | 0 | 0 | 1 | 0 | 0 |
| 糖尿病性ニューロパチー | 0 | 0 | 0 | 0 | 0 | 0 |
| 感覚障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 振戦 | 0 | 0 | 0 | 0 | 0 | 0 |
| 三叉神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 幻肢症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 脳幹梗塞 | 1 | 0 | 0 | 0 | 0 | 0 |
| 一過性脳虚血発作 | 1 | 0 | 0 | 0 | 0 | 0 |
| 肋間神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼障害 | 11 | 2 | 0 | 21 | 4 | 0 |
| 白内障 | 2 | 1 | 0 | 3 | 2 | 0 |
| アレルギー性結膜炎 | 2 | 0 | 0 | 4 | 0 | 0 |
| ドライアイ | 2 | 0 | 0 | 3 | 0 | 0 |
| 結膜出血 | 1 | 0 | 0 | 3 | 0 | 0 |
| 網膜上膜 | 0 | 0 | 0 | 1 | 1 | 0 |
| 網膜出血 | 0 | 0 | 0 | 1 | 0 | 0 |
| 霰粒腫 | 1 | 0 | 0 | 1 | 0 | 0 |
| 糖尿病網膜症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 複視 | 1 | 0 | 0 | 1 | 0 | 0 |
| 流涙増加 | 0 | 0 | 0 | 1 | 0 | 0 |
| 黄斑浮腫 | 0 | 1 | 0 | 0 | 1 | 0 |
| 網膜裂孔 | 1 | 0 | 0 | 1 | 0 | 0 |
| 加齢黄斑変性 | 0 | 0 | 0 | 1 | 0 | 0 |
| 霧視 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高眼圧症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硝子体混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼そう痒症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 後嚢部混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳および迷路障害 | 0 | 0 | 0 | 6 | 2 | 0 |
| 回転性めまい | 0 | 0 | 0 | 3 | 1 | 0 |
| 耳鳴 | 0 | 0 | 0 | 1 | 0 | 0 |
| 頭位性回転性めまい | 0 | 0 | 0 | 1 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
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(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 ALL | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 末梢性ニューロパチー | 1 | 0 | 0 | 1 | 0 | 0 |
| 錯感覚 | 1 | 0 | 0 | 1 | 0 | 0 |
| ヘルペス後神経痛 | 1 | 0 | 0 | 1 | 0 | 0 |
| てんかん重積状態 | 0 | 0 | 1 | 0 | 0 | 1 |
| ミオクロニーてんかん | 1 | 0 | 0 | 1 | 0 | 0 |
| 糖尿病性ニューロパチー | 0 | 0 | 0 | 1 | 0 | 0 |
| 感覚障害 | 0 | 0 | 0 | 1 | 0 | 0 |
| 振戦 | 0 | 0 | 0 | 0 | 1 | 0 |
| 三叉神経痛 | 0 | 0 | 0 | 0 | 1 | 0 |
| 幻肢症候群 | 0 | 0 | 0 | 0 | 1 | 0 |
| 脳幹梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 一過性脳虚血発作 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肋間神経痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 眼障害 | 21 | 4 | 0 | 27 | 5 | 0 |
| 白内障 | 3 | 2 | 0 | 3 | 2 | 0 |
| アレルギー性結膜炎 | 4 | 0 | 0 | 5 | 0 | 0 |
| ドライアイ | 3 | 0 | 0 | 4 | 0 | 0 |
| 結膜出血 | 3 | 0 | 0 | 3 | 0 | 0 |
| 網膜上膜 | 1 | 1 | 0 | 1 | 1 | 0 |
| 網膜出血 | 1 | 0 | 0 | 2 | 0 | 0 |
| 霰粒腫 | 1 | 0 | 0 | 1 | 0 | 0 |
| 糖尿病網膜症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 複視 | 1 | 0 | 0 | 1 | 0 | 0 |
| 流涙増加 | 1 | 0 | 0 | 1 | 0 | 0 |
| 黄斑浮腫 | 0 | 1 | 0 | 0 | 1 | 0 |
| 網膜裂孔 | 1 | 0 | 0 | 1 | 0 | 0 |
| 加齢黄斑変性 | 1 | 0 | 0 | 1 | 0 | 0 |
| 霧視 | 0 | 0 | 0 | 1 | 0 | 0 |
| 高眼圧症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 硝子体混濁 | 0 | 0 | 0 | 0 | 1 | 0 |
| 眼そう痒症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 後嚢部混濁 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳および迷路障害 | 8 | 2 | 0 | 12 | 3 | 0 |
| 回転性めまい | 4 | 1 | 0 | 5 | 2 | 0 |
| 耳鳴 | 1 | 0 | 0 | 2 | 0 | 0 |
| 頭位性回転性めまい | 1 | 0 | 0 | 1 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | |
|---|---|---|---|
| Group | Placebo | | |
| Primary SOC, PT | Mild | Moderate | Severe |
| 末梢性ニューロパチー | 0 | 0 | 0 |
| 錯感覚 | 0 | 0 | 0 |
| ヘルペス後神経痛 | 0 | 0 | 0 |
| てんかん重積状態 | 0 | 0 | 0 |
| ミオクロニーてんかん | 0 | 0 | 0 |
| 糖尿病性ニューロパチー | 0 | 0 | 0 |
| 感覚障害 | 0 | 0 | 0 |
| 振戦 | 0 | 0 | 0 |
| 三叉神経痛 | 0 | 0 | 0 |
| 幻肢症候群 | 0 | 0 | 0 |
| 脳幹梗塞 | 1 | 0 | 0 |
| 一過性脳虚血発作 | 1 | 0 | 0 |
| 肋間神経痛 | 1 | 0 | 0 |
| 眼障害 | 1 | 1 | 0 |
| 白内障 | 0 | 0 | 0 |
| アレルギー性結膜炎 | 0 | 0 | 0 |
| ドライアイ | 0 | 0 | 0 |
| 結膜出血 | 0 | 0 | 0 |
| 網膜上膜 | 0 | 0 | 0 |
| 網膜出血 | 0 | 0 | 0 |
| 霰粒腫 | 0 | 0 | 0 |
| 糖尿病網膜症 | 0 | 0 | 0 |
| 複視 | 0 | 0 | 0 |
| 流涙増加 | 0 | 0 | 0 |
| 黄斑浮腫 | 0 | 0 | 0 |
| 網膜裂孔 | 0 | 0 | 0 |
| 加齢黄斑変性 | 0 | 0 | 0 |
| 霧視 | 1 | 0 | 0 |
| 高眼圧症 | 0 | 0 | 0 |
| 硝子体混濁 | 0 | 0 | 0 |
| 眼そう痒症 | 0 | 0 | 0 |
| 後嚢部混濁 | 0 | 1 | 0 |
| 耳および迷路障害 | 0 | 0 | 0 |
| 回転性めまい | 0 | 0 | 0 |
| 耳鳴 | 0 | 0 | 0 |
| 頭位性回転性めまい | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 耳不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 突発性難聴 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳管狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 外耳道びらん | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳垢栓塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心臓障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 動悸 | 0 | 0 | 0 | 0 | 0 | 0 |
| 狭心症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 不安定狭心症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性心筋梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 冠動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心房細動 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心室性期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 徐脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心筋虚血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 洞性頻脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上室性期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 発作性房室ブロック | 0 | 0 | 0 | 0 | 0 | 0 |
| 心機能障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 大動脈弁狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頻脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| うっ血性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 慢性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血管障害 | 1 | 0 | 0 | 2 | 1 | 0 |
| 透析低血圧 | 0 | 0 | 0 | 1 | 0 | 0 |
| 低血圧 | 0 | 0 | 0 | 0 | 1 | 0 |
| 末梢動脈閉塞性疾患 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高血圧 | 0 | 0 | 0 | 0 | 0 | 0 |
| ほてり | 1 | 0 | 0 | 1 | 0 | 0 |
| 内出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血管痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 起立性低血圧 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 1.0 ug/kg | | | MR13A9 1.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 耳不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 突発性難聴 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳管狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 外耳道びらん | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳垢栓塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心臓障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 動悸 | 0 | 0 | 0 | 0 | 0 | 0 |
| 狭心症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 不安定狭心症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性心筋梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 冠動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心房細動 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心室性期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 徐脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心筋虚血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 洞性頻脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上室性期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 発作性房室ブロック | 0 | 0 | 0 | 0 | 0 | 0 |
| 心機能障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 大動脈弁狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頻脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| うっ血性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 慢性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血管障害 | 0 | 2 | 0 | 2 | 1 | 0 |
| 透析低血圧 | 0 | 1 | 0 | 1 | 0 | 0 |
| 低血圧 | 0 | 1 | 0 | 0 | 0 | 0 |
| 末梢動脈閉塞性疾患 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高血圧 | 0 | 0 | 0 | 0 | 1 | 0 |
| ほてり | 0 | 0 | 0 | 1 | 0 | 0 |
| 内出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血管痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 起立性低血圧 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | MR13A9-4 | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.25 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 耳不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 突発性難聴 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳管狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 外耳道びらん | 0 | 0 | 0 | 1 | 0 | 0 |
| 耳垢栓塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心臓障害 | 0 | 0 | 0 | 4 | 0 | 1 |
| 動悸 | 0 | 0 | 0 | 3 | 0 | 0 |
| 狭心症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 不安定狭心症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性心筋梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 冠動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心房細動 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心室性期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 徐脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心筋虚血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 洞性頻脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上室性期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 発作性房室ブロック | 0 | 0 | 0 | 0 | 0 | 0 |
| 心機能障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 大動脈弁狭窄 | 0 | 0 | 0 | 0 | 0 | 1 |
| 頻脈 | 0 | 0 | 0 | 1 | 0 | 0 |
| うっ血性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 慢性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血管障害 | 1 | 1 | 0 | 11 | 0 | 0 |
| 透析低血圧 | 0 | 0 | 0 | 7 | 0 | 0 |
| 低血圧 | 0 | 0 | 0 | 1 | 0 | 0 |
| 末梢動脈閉塞性疾患 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高血圧 | 0 | 1 | 0 | 1 | 0 | 0 |
| ほてり | 0 | 0 | 0 | 0 | 0 | 0 |
| 内出血 | 0 | 0 | 0 | 2 | 0 | 0 |
| 血管痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 起立性低血圧 | 1 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 1.0 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 耳不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 突発性難聴 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳管狭窄 | 1 | 0 | 0 | 0 | 0 | 0 |
| 外耳道びらん | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳垢栓塞 | 0 | 0 | 0 | 1 | 0 | 0 |
| 心臓障害 | 0 | 1 | 0 | 1 | 2 | 0 |
| 動悸 | 0 | 0 | 0 | 1 | 0 | 0 |
| 狭心症 | 0 | 1 | 0 | 0 | 1 | 0 |
| 不安定狭心症 | 0 | 0 | 0 | 0 | 1 | 0 |
| 急性心筋梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 冠動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心房細動 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心室性期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 徐脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心筋虚血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 洞性頻脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上室性期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 発作性房室ブロック | 0 | 0 | 0 | 0 | 0 | 0 |
| 心機能障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 大動脈弁狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頻脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| うっ血性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 慢性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血管障害 | 1 | 3 | 0 | 6 | 3 | 0 |
| 透析低血圧 | 1 | 2 | 0 | 3 | 0 | 0 |
| 低血圧 | 0 | 0 | 0 | 2 | 2 | 0 |
| 末梢動脈閉塞性疾患 | 0 | 0 | 0 | 0 | 1 | 0 |
| 高血圧 | 0 | 1 | 0 | 0 | 0 | 0 |
| ほてり | 0 | 0 | 0 | 1 | 0 | 0 |
| 内出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血管痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 起立性低血圧 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | MR13A9-5 (DB) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 耳不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 突発性難聴 | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳管狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 外耳道びらん | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳垢栓塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心臓障害 | 4 | 0 | 0 | 0 | 1 | 0 |
| 動悸 | 2 | 0 | 0 | 0 | 1 | 0 |
| 狭心症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 不安定狭心症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性心筋梗塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 冠動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心房細動 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心室性期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心不全 | 1 | 0 | 0 | 0 | 0 | 0 |
| 徐脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心筋虚血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 洞性頻脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上室性期外収縮 | 0 | 0 | 0 | 0 | 0 | 0 |
| 発作性房室ブロック | 0 | 0 | 0 | 0 | 0 | 0 |
| 心機能障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 大動脈弁狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頻脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| うっ血性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 慢性心不全 | 1 | 0 | 0 | 0 | 0 | 0 |
| 血管障害 | 9 | 0 | 0 | 1 | 1 | 0 |
| 透析低血圧 | 4 | 0 | 0 | 0 | 0 | 0 |
| 低血圧 | 3 | 0 | 0 | 0 | 0 | 0 |
| 末梢動脈閉塞性疾患 | 0 | 0 | 0 | 0 | 0 | 0 |
| 高血圧 | 1 | 0 | 0 | 0 | 0 | 0 |
| ほてり | 0 | 0 | 0 | 1 | 0 | 0 |
| 内出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血管痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血腫 | 1 | 0 | 0 | 0 | 0 | 0 |
| 起立性低血圧 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (DB) | | | MR13A9-5 (Entire) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR-MR | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 耳不快感 | 0 | 0 | 0 | 1 | 0 | 0 |
| 突発性難聴 | 0 | 0 | 0 | 0 | 1 | 0 |
| 耳管狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 外耳道びらん | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳垢栓塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心臓障害 | 1 | 1 | 1 | 11 | 4 | 3 |
| 動悸 | 0 | 0 | 0 | 2 | 1 | 0 |
| 狭心症 | 0 | 0 | 0 | 0 | 1 | 0 |
| 不安定狭心症 | 0 | 0 | 0 | 2 | 0 | 0 |
| 急性心筋梗塞 | 0 | 0 | 0 | 0 | 0 | 2 |
| 冠動脈狭窄 | 0 | 1 | 0 | 1 | 0 | 0 |
| 心房細動 | 0 | 0 | 0 | 1 | 0 | 0 |
| 心室性期外収縮 | 0 | 0 | 0 | 2 | 0 | 0 |
| 心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 徐脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| 急性心不全 | 0 | 0 | 0 | 0 | 1 | 0 |
| 期外収縮 | 0 | 0 | 0 | 1 | 0 | 0 |
| 心筋虚血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 洞性頻脈 | 0 | 0 | 0 | 1 | 0 | 0 |
| 上室性期外収縮 | 0 | 0 | 0 | 1 | 0 | 0 |
| 発作性房室ブロック | 0 | 0 | 0 | 0 | 0 | 1 |
| 心機能障害 | 0 | 0 | 0 | 0 | 1 | 0 |
| 大動脈弁狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頻脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| うっ血性心不全 | 1 | 0 | 1 | 0 | 0 | 0 |
| 慢性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血管障害 | 2 | 0 | 0 | 21 | 5 | 0 |
| 透析低血圧 | 1 | 0 | 0 | 9 | 0 | 0 |
| 低血圧 | 0 | 0 | 0 | 1 | 0 | 0 |
| 末梢動脈閉塞性疾患 | 0 | 0 | 0 | 1 | 3 | 0 |
| 高血圧 | 0 | 0 | 0 | 1 | 1 | 0 |
| ほてり | 0 | 0 | 0 | 0 | 0 | 0 |
| 内出血 | 1 | 0 | 0 | 3 | 0 | 0 |
| 血管痛 | 0 | 0 | 0 | 2 | 0 | 0 |
| 血腫 | 0 | 0 | 0 | 1 | 0 | 0 |
| 起立性低血圧 | 0 | 0 | 0 | 1 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (Entire) | | | MR13A9-5 (Long-term) | | |
|---|---|---|---|---|---|---|
| Group | P-MR | | | MR13A9 0.5 ug/kg (Long-term) | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 耳不快感 | 0 | 0 | 0 | 1 | 0 | 0 |
| 突発性難聴 | 0 | 0 | 0 | 0 | 1 | 0 |
| 耳管狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 外耳道びらん | 0 | 0 | 0 | 0 | 0 | 0 |
| 耳垢栓塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心臓障害 | 4 | 6 | 1 | 14 | 9 | 4 |
| 動悸 | 1 | 0 | 0 | 3 | 1 | 0 |
| 狭心症 | 0 | 1 | 0 | 0 | 2 | 0 |
| 不安定狭心症 | 0 | 1 | 0 | 2 | 1 | 0 |
| 急性心筋梗塞 | 0 | 1 | 0 | 0 | 1 | 2 |
| 冠動脈狭窄 | 0 | 1 | 1 | 1 | 0 | 1 |
| 心房細動 | 1 | 0 | 0 | 2 | 0 | 0 |
| 心室性期外収縮 | 0 | 0 | 0 | 2 | 0 | 0 |
| 心不全 | 1 | 0 | 0 | 1 | 0 | 0 |
| 徐脈 | 0 | 1 | 0 | 0 | 1 | 0 |
| 急性心不全 | 0 | 0 | 0 | 0 | 1 | 0 |
| 期外収縮 | 0 | 0 | 0 | 1 | 0 | 0 |
| 心筋虚血 | 0 | 1 | 0 | 0 | 1 | 0 |
| 洞性頻脈 | 0 | 0 | 0 | 1 | 0 | 0 |
| 上室性期外収縮 | 0 | 0 | 0 | 1 | 0 | 0 |
| 発作性房室ブロック | 0 | 0 | 0 | 0 | 0 | 1 |
| 心機能障害 | 0 | 0 | 0 | 0 | 1 | 0 |
| 大動脈弁狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 頻脈 | 0 | 0 | 0 | 0 | 0 | 0 |
| うっ血性心不全 | 1 | 0 | 0 | 0 | 0 | 0 |
| 慢性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血管障害 | 18 | 4 | 1 | 38 | 9 | 1 |
| 透析低血圧 | 10 | 0 | 0 | 18 | 0 | 0 |
| 低血圧 | 2 | 1 | 0 | 3 | 1 | 0 |
| 末梢動脈閉塞性疾患 | 0 | 3 | 1 | 1 | 6 | 1 |
| 高血圧 | 1 | 0 | 0 | 2 | 1 | 0 |
| ほてり | 1 | 0 | 0 | 2 | 0 | 0 |
| 内出血 | 1 | 0 | 0 | 3 | 0 | 0 |
| 血管痛 | 1 | 0 | 0 | 3 | 0 | 0 |
| 血腫 | 1 | 0 | 0 | 2 | 0 | 0 |
| 起立性低血圧 | 1 | 0 | 0 | 2 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 ALL | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 耳不快感 | 1 | 0 | 0 | 1 | 0 | 0 |
| 突発性難聴 | 0 | 1 | 0 | 0 | 1 | 0 |
| 耳管狭窄 | 1 | 0 | 0 | 1 | 0 | 0 |
| 外耳道びらん | 0 | 0 | 0 | 1 | 0 | 0 |
| 耳垢栓塞 | 0 | 0 | 0 | 1 | 0 | 0 |
| 心臓障害 | 14 | 10 | 4 | 19 | 12 | 5 |
| 動悸 | 3 | 1 | 0 | 7 | 1 | 0 |
| 狭心症 | 0 | 3 | 0 | 0 | 4 | 0 |
| 不安定狭心症 | 2 | 1 | 0 | 2 | 2 | 0 |
| 急性心筋梗塞 | 0 | 1 | 2 | 0 | 1 | 2 |
| 冠動脈狭窄 | 1 | 0 | 1 | 1 | 0 | 1 |
| 心房細動 | 2 | 0 | 0 | 2 | 0 | 0 |
| 心室性期外収縮 | 2 | 0 | 0 | 2 | 0 | 0 |
| 心不全 | 1 | 0 | 0 | 1 | 0 | 0 |
| 徐脈 | 0 | 1 | 0 | 0 | 1 | 0 |
| 急性心不全 | 0 | 1 | 0 | 0 | 1 | 0 |
| 期外収縮 | 1 | 0 | 0 | 1 | 0 | 0 |
| 心筋虚血 | 0 | 1 | 0 | 0 | 1 | 0 |
| 洞性頻脈 | 1 | 0 | 0 | 1 | 0 | 0 |
| 上室性期外収縮 | 1 | 0 | 0 | 1 | 0 | 0 |
| 発作性房室ブロック | 0 | 0 | 1 | 0 | 0 | 1 |
| 心機能障害 | 0 | 1 | 0 | 0 | 1 | 0 |
| 大動脈弁狭窄 | 0 | 0 | 0 | 0 | 0 | 1 |
| 頻脈 | 0 | 0 | 0 | 1 | 0 | 0 |
| うっ血性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 慢性心不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血管障害 | 41 | 13 | 1 | 61 | 19 | 1 |
| 透析低血圧 | 20 | 2 | 0 | 31 | 3 | 0 |
| 低血圧 | 3 | 2 | 0 | 6 | 5 | 0 |
| 末梢動脈閉塞性疾患 | 1 | 6 | 1 | 1 | 7 | 1 |
| 高血圧 | 2 | 2 | 0 | 3 | 3 | 0 |
| ほてり | 3 | 0 | 0 | 6 | 0 | 0 |
| 内出血 | 3 | 0 | 0 | 5 | 0 | 0 |
| 血管痛 | 3 | 0 | 0 | 3 | 0 | 0 |
| 血腫 | 2 | 0 | 0 | 2 | 0 | 0 |
| 起立性低血圧 | 2 | 0 | 0 | 2 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | |
|---|---|---|---|
| Group | Placebo | | |
| Primary SOC, PT | Mild | Moderate | Severe |
| 耳不快感 | 0 | 0 | 0 |
| 突発性難聴 | 0 | 0 | 0 |
| 耳管狭窄 | 0 | 0 | 0 |
| 外耳道びらん | 0 | 0 | 0 |
| 耳垢栓塞 | 0 | 0 | 0 |
| 心臓障害 | 5 | 1 | 1 |
| 動悸 | 2 | 0 | 0 |
| 狭心症 | 0 | 0 | 0 |
| 不安定狭心症 | 0 | 0 | 0 |
| 急性心筋梗塞 | 0 | 0 | 0 |
| 冠動脈狭窄 | 0 | 1 | 0 |
| 心房細動 | 0 | 0 | 0 |
| 心室性期外収縮 | 0 | 0 | 0 |
| 心不全 | 1 | 0 | 0 |
| 徐脈 | 0 | 0 | 0 |
| 急性心不全 | 0 | 0 | 0 |
| 期外収縮 | 0 | 0 | 0 |
| 心筋虚血 | 0 | 0 | 0 |
| 洞性頻脈 | 0 | 0 | 0 |
| 上室性期外収縮 | 0 | 0 | 0 |
| 発作性房室ブロック | 0 | 0 | 0 |
| 心機能障害 | 0 | 0 | 0 |
| 大動脈弁狭窄 | 0 | 0 | 0 |
| 頻脈 | 0 | 0 | 0 |
| うっ血性心不全 | 1 | 0 | 1 |
| 慢性心不全 | 1 | 0 | 0 |
| 血管障害 | 12 | 1 | 0 |
| 透析低血圧 | 5 | 0 | 0 |
| 低血圧 | 3 | 0 | 0 |
| 末梢動脈閉塞性疾患 | 0 | 0 | 0 |
| 高血圧 | 1 | 1 | 0 |
| ほてり | 0 | 0 | 0 |
| 内出血 | 1 | 0 | 0 |
| 血管痛 | 0 | 0 | 0 |
| 血腫 | 1 | 0 | 0 |
| 起立性低血圧 | 1 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 末梢冷感 | 0 | 0 | 0 | 0 | 0 | 0 |
| アテローム塞栓症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸器、胸郭および縦隔障害 | 1 | 1 | 0 | 1 | 0 | 0 |
| 上気道の炎症 | 1 | 1 | 0 | 1 | 0 | 0 |
| 口腔咽頭痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻漏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 誤嚥 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喘息 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸困難 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咳嗽 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻閉 | 0 | 0 | 0 | 0 | 0 | 0 |
| 湿性咳嗽 | 0 | 0 | 0 | 0 | 0 | 0 |
| 発声障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胸水 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胸膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| アレルギー性鼻炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 睡眠時無呼吸症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀痰増加 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咳喘息 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔咽頭不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 過換気 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻の炎症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸窮迫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸障害 | 4 | 0 | 0 | 2 | 1 | 0 |
| 便秘 | 1 | 0 | 0 | 1 | 0 | 0 |
| 下痢 | 0 | 0 | 0 | 0 | 0 | 0 |
| 悪心 | 1 | 0 | 0 | 0 | 0 | 0 |
| 嘔吐 | 1 | 0 | 0 | 0 | 0 | 0 |
| 痔核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 齲歯 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃食道逆流性疾患 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上腹部痛 | 1 | 0 | 0 | 0 | 0 | 0 |
| 腹部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 1.0 ug/kg | | | MR13A9 1.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 末梢冷感 | 0 | 0 | 0 | 0 | 0 | 0 |
| アテローム塞栓症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸器、胸郭および縦隔障害 | 1 | 0 | 0 | 0 | 0 | 0 |
| 上気道の炎症 | 1 | 0 | 0 | 0 | 0 | 0 |
| 口腔咽頭痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻漏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 誤嚥 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喘息 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸困難 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咳嗽 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻閉 | 0 | 0 | 0 | 0 | 0 | 0 |
| 湿性咳嗽 | 0 | 0 | 0 | 0 | 0 | 0 |
| 発声障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胸水 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胸膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| アレルギー性鼻炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 睡眠時無呼吸症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀痰増加 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咳喘息 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔咽頭不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 過換気 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻の炎症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸窮迫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸障害 | 2 | 0 | 0 | 9 | 1 | 0 |
| 便秘 | 1 | 0 | 0 | 3 | 0 | 0 |
| 下痢 | 0 | 0 | 0 | 0 | 0 | 0 |
| 悪心 | 0 | 0 | 0 | 4 | 1 | 0 |
| 嘔吐 | 1 | 0 | 0 | 1 | 0 | 0 |
| 痔核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 齲歯 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃食道逆流性疾患 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上腹部痛 | 0 | 0 | 0 | 1 | 0 | 0 |
| 腹部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | MR13A9-4 | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.25 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 末梢冷感 | 0 | 0 | 0 | 0 | 0 | 0 |
| アテローム塞栓症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸器、胸郭および縦隔障害 | 0 | 0 | 0 | 3 | 0 | 0 |
| 上気道の炎症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔咽頭痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻漏 | 0 | 0 | 0 | 1 | 0 | 0 |
| 誤嚥 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喘息 | 0 | 0 | 0 | 1 | 0 | 0 |
| 呼吸困難 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咳嗽 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻閉 | 0 | 0 | 0 | 0 | 0 | 0 |
| 湿性咳嗽 | 0 | 0 | 0 | 0 | 0 | 0 |
| 発声障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胸水 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胸膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| アレルギー性鼻炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 睡眠時無呼吸症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀痰増加 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咳喘息 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔咽頭不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 過換気 | 0 | 0 | 0 | 1 | 0 | 0 |
| 鼻の炎症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸窮迫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸障害 | 2 | 0 | 0 | 9 | 2 | 0 |
| 便秘 | 0 | 0 | 0 | 4 | 1 | 0 |
| 下痢 | 1 | 0 | 0 | 2 | 0 | 0 |
| 悪心 | 1 | 0 | 0 | 0 | 0 | 0 |
| 嘔吐 | 0 | 0 | 0 | 0 | 1 | 0 |
| 痔核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 齲歯 | 0 | 0 | 0 | 2 | 0 | 0 |
| 胃食道逆流性疾患 | 0 | 0 | 0 | 0 | 0 | 0 |
| 上腹部痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腹部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 1.0 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大動脈狭窄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 末梢冷感 | 0 | 0 | 0 | 0 | 0 | 0 |
| アテローム塞栓症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸器、胸郭および縦隔障害 | 2 | 0 | 0 | 4 | 0 | 0 |
| 上気道の炎症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 口腔咽頭痛 | 0 | 0 | 0 | 1 | 0 | 0 |
| 鼻漏 | 0 | 0 | 0 | 0 | 0 | 0 |
| 誤嚥 | 1 | 0 | 0 | 0 | 0 | 0 |
| 喘息 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸困難 | 0 | 0 | 0 | 1 | 0 | 0 |
| 咳嗽 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻閉 | 0 | 0 | 0 | 0 | 0 | 0 |
| 湿性咳嗽 | 0 | 0 | 0 | 0 | 0 | 0 |
| 発声障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胸水 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胸膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| アレルギー性鼻炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 睡眠時無呼吸症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀痰増加 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咳喘息 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔咽頭不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 過換気 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻の炎症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 喀血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸窮迫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸障害 | 10 | 0 | 0 | 23 | 9 | 0 |
| 便秘 | 3 | 0 | 0 | 4 | 3 | 0 |
| 下痢 | 2 | 0 | 0 | 1 | 1 | 0 |
| 悪心 | 1 | 0 | 0 | 5 | 0 | 0 |
| 嘔吐 | 1 | 0 | 0 | 5 | 0 | 0 |
| 痔核 | 0 | 0 | 0 | 0 | 1 | 0 |
| 齲歯 | 1 | 0 | 0 | 1 | 0 | 0 |
| 胃食道逆流性疾患 | 0 | 0 | 0 | 1 | 0 | 0 |
| 上腹部痛 | 0 | 0 | 0 | 1 | 0 | 0 |
| 腹部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | MR13A9-5 (DB) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大動脈狭窄 | 0 | 0 | 0 | 0 | 1 | 0 |
| 末梢冷感 | 0 | 0 | 0 | 0 | 0 | 0 |
| アテローム塞栓症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸器、胸郭および縦隔障害 | 2 | 0 | 0 | 2 | 1 | 0 |
| 上気道の炎症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔咽頭痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻漏 | 1 | 0 | 0 | 0 | 0 | 0 |
| 誤嚥 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喘息 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸困難 | 0 | 0 | 0 | 1 | 0 | 0 |
| 咳嗽 | 0 | 0 | 0 | 1 | 0 | 0 |
| 鼻閉 | 1 | 0 | 0 | 0 | 0 | 0 |
| 湿性咳嗽 | 0 | 0 | 0 | 0 | 0 | 0 |
| 発声障害 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胸水 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胸膜炎 | 0 | 0 | 0 | 0 | 1 | 0 |
| 呼吸不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| アレルギー性鼻炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 睡眠時無呼吸症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀痰増加 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咳喘息 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔咽頭不快感 | 0 | 0 | 0 | 0 | 0 | 0 |
| 過換気 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻の炎症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸窮迫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸障害 | 15 | 0 | 0 | 20 | 2 | 0 |
| 便秘 | 0 | 0 | 0 | 4 | 0 | 0 |
| 下痢 | 3 | 0 | 0 | 2 | 0 | 0 |
| 悪心 | 1 | 0 | 0 | 2 | 0 | 0 |
| 嘔吐 | 3 | 0 | 0 | 3 | 0 | 0 |
| 痔核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 齲歯 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃食道逆流性疾患 | 1 | 0 | 0 | 2 | 0 | 0 |
| 上腹部痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腹部不快感 | 0 | 0 | 0 | 2 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
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(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (DB) | | | MR13A9-5 (Entire) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR-MR | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大動脈狭窄 | 0 | 0 | 0 | 0 | 1 | 0 |
| 末梢冷感 | 0 | 0 | 0 | 1 | 0 | 0 |
| アテローム塞栓症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 呼吸器、胸郭および縦隔障害 | 5 | 0 | 0 | 10 | 0 | 0 |
| 上気道の炎症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口腔咽頭痛 | 1 | 0 | 0 | 1 | 0 | 0 |
| 鼻漏 | 0 | 0 | 0 | 1 | 0 | 0 |
| 誤嚥 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喘息 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸困難 | 0 | 0 | 0 | 1 | 0 | 0 |
| 咳嗽 | 1 | 0 | 0 | 2 | 0 | 0 |
| 鼻閉 | 0 | 0 | 0 | 1 | 0 | 0 |
| 湿性咳嗽 | 1 | 0 | 0 | 0 | 0 | 0 |
| 発声障害 | 0 | 0 | 0 | 2 | 0 | 0 |
| 胸水 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胸膜炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸不全 | 0 | 0 | 0 | 0 | 0 | 0 |
| アレルギー性鼻炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 睡眠時無呼吸症候群 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀痰増加 | 0 | 0 | 0 | 0 | 0 | 0 |
| 咳喘息 | 0 | 0 | 0 | 1 | 0 | 0 |
| 口腔咽頭不快感 | 0 | 0 | 0 | 1 | 0 | 0 |
| 過換気 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻の炎症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀血 | 1 | 0 | 0 | 0 | 0 | 0 |
| 呼吸窮迫 | 1 | 0 | 0 | 0 | 0 | 0 |
| 胃腸障害 | 11 | 0 | 0 | 79 | 10 | 0 |
| 便秘 | 1 | 0 | 0 | 13 | 0 | 0 |
| 下痢 | 4 | 0 | 0 | 18 | 0 | 0 |
| 悪心 | 1 | 0 | 0 | 16 | 0 | 0 |
| 嘔吐 | 0 | 0 | 0 | 7 | 1 | 0 |
| 痔核 | 0 | 0 | 0 | 1 | 0 | 0 |
| 齲歯 | 0 | 0 | 0 | 0 | 1 | 0 |
| 胃食道逆流性疾患 | 0 | 0 | 0 | 3 | 0 | 0 |
| 上腹部痛 | 0 | 0 | 0 | 2 | 0 | 0 |
| 腹部不快感 | 0 | 0 | 0 | 3 | 1 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
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(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (Entire) | | | MR13A9-5 (Long-term) | | |
|---|---|---|---|---|---|---|
| Group | P-MR | | | MR13A9 0.5 ug/kg (Long-term) | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大動脈狭窄 | 0 | 0 | 0 | 0 | 1 | 0 |
| 末梢冷感 | 0 | 0 | 0 | 1 | 0 | 0 |
| アテローム塞栓症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 呼吸器、胸郭および縦隔障害 | 20 | 1 | 2 | 25 | 2 | 2 |
| 上気道の炎症 | 2 | 0 | 0 | 2 | 0 | 0 |
| 口腔咽頭痛 | 4 | 0 | 0 | 4 | 0 | 0 |
| 鼻漏 | 2 | 0 | 0 | 3 | 0 | 0 |
| 誤嚥 | 1 | 0 | 1 | 1 | 0 | 1 |
| 喘息 | 1 | 0 | 0 | 1 | 0 | 0 |
| 呼吸困難 | 0 | 0 | 0 | 1 | 0 | 0 |
| 咳嗽 | 1 | 0 | 0 | 2 | 0 | 0 |
| 鼻閉 | 0 | 0 | 0 | 1 | 0 | 0 |
| 湿性咳嗽 | 3 | 0 | 0 | 2 | 0 | 0 |
| 発声障害 | 0 | 0 | 0 | 2 | 0 | 0 |
| 胸水 | 2 | 0 | 0 | 2 | 0 | 0 |
| 胸膜炎 | 0 | 0 | 0 | 0 | 1 | 0 |
| 呼吸不全 | 0 | 0 | 1 | 0 | 0 | 1 |
| アレルギー性鼻炎 | 1 | 0 | 0 | 1 | 0 | 0 |
| 睡眠時無呼吸症候群 | 0 | 1 | 0 | 0 | 1 | 0 |
| 喀痰増加 | 1 | 0 | 0 | 1 | 0 | 0 |
| 咳喘息 | 0 | 0 | 0 | 1 | 0 | 0 |
| 口腔咽頭不快感 | 0 | 0 | 0 | 1 | 0 | 0 |
| 過換気 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼻の炎症 | 0 | 0 | 0 | 0 | 0 | 0 |
| 喀血 | 1 | 0 | 0 | 0 | 0 | 0 |
| 呼吸窮迫 | 1 | 0 | 0 | 0 | 0 | 0 |
| 胃腸障害 | 80 | 4 | 1 | 150 | 14 | 1 |
| 便秘 | 11 | 0 | 0 | 23 | 0 | 0 |
| 下痢 | 26 | 0 | 0 | 40 | 0 | 0 |
| 悪心 | 6 | 0 | 0 | 21 | 0 | 0 |
| 嘔吐 | 5 | 0 | 0 | 13 | 1 | 0 |
| 痔核 | 6 | 0 | 0 | 7 | 0 | 0 |
| 齲歯 | 2 | 0 | 0 | 2 | 1 | 0 |
| 胃食道逆流性疾患 | 2 | 0 | 0 | 5 | 0 | 0 |
| 上腹部痛 | 1 | 0 | 0 | 3 | 0 | 0 |
| 腹部不快感 | 2 | 0 | 0 | 5 | 1 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
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(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 ALL | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大動脈狭窄 | 0 | 1 | 0 | 0 | 1 | 0 |
| 末梢冷感 | 1 | 0 | 0 | 1 | 0 | 0 |
| アテローム塞栓症 | 1 | 0 | 0 | 1 | 0 | 0 |
| 呼吸器、胸郭および縦隔障害 | 28 | 2 | 2 | 37 | 3 | 2 |
| 上気道の炎症 | 4 | 0 | 0 | 7 | 1 | 0 |
| 口腔咽頭痛 | 4 | 0 | 0 | 5 | 0 | 0 |
| 鼻漏 | 3 | 0 | 0 | 4 | 0 | 0 |
| 誤嚥 | 2 | 0 | 1 | 2 | 0 | 1 |
| 喘息 | 1 | 0 | 0 | 2 | 0 | 0 |
| 呼吸困難 | 1 | 0 | 0 | 2 | 0 | 0 |
| 咳嗽 | 2 | 0 | 0 | 2 | 0 | 0 |
| 鼻閉 | 1 | 0 | 0 | 1 | 0 | 0 |
| 湿性咳嗽 | 2 | 0 | 0 | 2 | 0 | 0 |
| 発声障害 | 2 | 0 | 0 | 2 | 0 | 0 |
| 胸水 | 2 | 0 | 0 | 2 | 0 | 0 |
| 胸膜炎 | 0 | 1 | 0 | 0 | 1 | 0 |
| 呼吸不全 | 0 | 0 | 1 | 0 | 0 | 1 |
| アレルギー性鼻炎 | 1 | 0 | 0 | 1 | 0 | 0 |
| 睡眠時無呼吸症候群 | 0 | 1 | 0 | 0 | 1 | 0 |
| 喀痰増加 | 1 | 0 | 0 | 1 | 0 | 0 |
| 咳喘息 | 1 | 0 | 0 | 1 | 0 | 0 |
| 口腔咽頭不快感 | 1 | 0 | 0 | 1 | 0 | 0 |
| 過換気 | 0 | 0 | 0 | 1 | 0 | 0 |
| 鼻の炎症 | 0 | 0 | 0 | 1 | 0 | 0 |
| 喀血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 呼吸窮迫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸障害 | 162 | 15 | 1 | 209 | 27 | 1 |
| 便秘 | 27 | 0 | 0 | 40 | 4 | 0 |
| 下痢 | 42 | 0 | 0 | 45 | 1 | 0 |
| 悪心 | 22 | 0 | 0 | 32 | 1 | 0 |
| 嘔吐 | 14 | 1 | 0 | 22 | 2 | 0 |
| 痔核 | 7 | 0 | 0 | 7 | 1 | 0 |
| 齲歯 | 3 | 1 | 0 | 6 | 1 | 0 |
| 胃食道逆流性疾患 | 5 | 0 | 0 | 6 | 0 | 0 |
| 上腹部痛 | 3 | 0 | 0 | 6 | 0 | 0 |
| 腹部不快感 | 5 | 1 | 0 | 5 | 1 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | |
|---|---|---|---|
| Group | Placebo | | |
| Primary SOC, PT | Mild | Moderate | Severe |
| 大動脈狭窄 | 0 | 0 | 0 |
| 末梢冷感 | 0 | 0 | 0 |
| アテローム塞栓症 | 0 | 0 | 0 |
| 呼吸器、胸郭および縦隔障害 | 7 | 0 | 0 |
| 上気道の炎症 | 0 | 0 | 0 |
| 口腔咽頭痛 | 1 | 0 | 0 |
| 鼻漏 | 1 | 0 | 0 |
| 誤嚥 | 0 | 0 | 0 |
| 喘息 | 0 | 0 | 0 |
| 呼吸困難 | 0 | 0 | 0 |
| 咳嗽 | 1 | 0 | 0 |
| 鼻閉 | 1 | 0 | 0 |
| 湿性咳嗽 | 1 | 0 | 0 |
| 発声障害 | 0 | 0 | 0 |
| 胸水 | 0 | 0 | 0 |
| 胸膜炎 | 0 | 0 | 0 |
| 呼吸不全 | 0 | 0 | 0 |
| アレルギー性鼻炎 | 0 | 0 | 0 |
| 睡眠時無呼吸症候群 | 0 | 0 | 0 |
| 喀痰増加 | 0 | 0 | 0 |
| 咳喘息 | 0 | 0 | 0 |
| 口腔咽頭不快感 | 0 | 0 | 0 |
| 過換気 | 0 | 0 | 0 |
| 鼻の炎症 | 0 | 0 | 0 |
| 喀血 | 1 | 0 | 0 |
| 呼吸窮迫 | 1 | 0 | 0 |
| 胃腸障害 | 28 | 0 | 0 |
| 便秘 | 1 | 0 | 0 |
| 下痢 | 8 | 0 | 0 |
| 悪心 | 3 | 0 | 0 |
| 嘔吐 | 3 | 0 | 0 |
| 痔核 | 0 | 0 | 0 |
| 齲歯 | 0 | 0 | 0 |
| 胃食道逆流性疾患 | 1 | 0 | 0 |
| 上腹部痛 | 0 | 0 | 0 |
| 腹部不快感 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大腸ポリープ | 0 | 0 | 0 | 0 | 0 | 0 |
| 腹痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 慢性胃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腹部膨満 | 0 | 0 | 0 | 0 | 1 | 0 |
| 腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 軟便 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門脱 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口内炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血便排泄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 消化不良 | 0 | 0 | 0 | 0 | 0 | 0 |
| 裂孔ヘルニア | 0 | 0 | 0 | 0 | 0 | 0 |
| 虚血性大腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性腸憩室 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃ポリープ | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯肉出血 | 0 | 0 | 0 | 1 | 0 | 0 |
| 吐血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血栓性痔核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃酸過多 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼠径ヘルニア | 0 | 0 | 0 | 0 | 0 | 0 |
| 膵炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯周病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門周囲痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 直腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涎過多 | 0 | 0 | 0 | 0 | 0 | 0 |
| 憩室穿孔 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口唇血腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口角口唇炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硬便 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼓腸 | 0 | 0 | 0 | 0 | 0 | 0 |
| 小腸閉塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心窩部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 1.0 ug/kg | | | MR13A9 1.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大腸ポリープ | 0 | 0 | 0 | 0 | 0 | 0 |
| 腹痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 慢性胃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腹部膨満 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 軟便 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門脱 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口内炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血便排泄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 消化不良 | 0 | 0 | 0 | 0 | 0 | 0 |
| 裂孔ヘルニア | 0 | 0 | 0 | 0 | 0 | 0 |
| 虚血性大腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性腸憩室 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃ポリープ | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯肉出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 吐血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血栓性痔核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃酸過多 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼠径ヘルニア | 0 | 0 | 0 | 0 | 0 | 0 |
| 膵炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯周病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門周囲痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 直腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涎過多 | 0 | 0 | 0 | 0 | 0 | 0 |
| 憩室穿孔 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口唇血腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口角口唇炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硬便 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼓腸 | 0 | 0 | 0 | 0 | 0 | 0 |
| 小腸閉塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心窩部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-3 | | | MR13A9-4 | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.25 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大腸ポリープ | 0 | 0 | 0 | 0 | 0 | 0 |
| 腹痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 慢性胃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 腹部膨満 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 軟便 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門脱 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口内炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血便排泄 | 0 | 0 | 0 | 0 | 0 | 0 |
| 消化不良 | 0 | 0 | 0 | 0 | 0 | 0 |
| 裂孔ヘルニア | 0 | 0 | 0 | 0 | 0 | 0 |
| 虚血性大腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性腸憩室 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃ポリープ | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯肉出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 吐血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血栓性痔核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃酸過多 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼠径ヘルニア | 0 | 0 | 0 | 0 | 0 | 0 |
| 膵炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯周病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門周囲痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 直腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涎過多 | 0 | 0 | 0 | 0 | 0 | 0 |
| 憩室穿孔 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口唇血腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口角口唇炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硬便 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼓腸 | 0 | 0 | 0 | 0 | 0 | 0 |
| 小腸閉塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心窩部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 1.0 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大腸ポリープ | 0 | 0 | 0 | 0 | 1 | 0 |
| 腹痛 | 0 | 0 | 0 | 0 | 1 | 0 |
| 歯痛 | 1 | 0 | 0 | 0 | 0 | 0 |
| 慢性胃炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 胃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腹部膨満 | 1 | 0 | 0 | 0 | 0 | 0 |
| 腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 軟便 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門脱 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口内炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 血便排泄 | 0 | 0 | 0 | 1 | 0 | 0 |
| 消化不良 | 0 | 0 | 0 | 0 | 0 | 0 |
| 裂孔ヘルニア | 0 | 0 | 0 | 0 | 0 | 0 |
| 虚血性大腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性腸憩室 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃ポリープ | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯肉出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 吐血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血栓性痔核 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃酸過多 | 0 | 0 | 0 | 0 | 0 | 0 |
| 単径ヘルニア | 0 | 0 | 0 | 0 | 0 | 0 |
| 膵炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯周病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門周囲痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 直腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涎過多 | 0 | 0 | 0 | 0 | 0 | 0 |
| 憩室穿孔 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口唇血腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口角口唇炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 硬便 | 0 | 0 | 0 | 0 | 1 | 0 |
| 鼓腸 | 0 | 0 | 0 | 1 | 0 | 0 |
| 小腸閉塞 | 0 | 0 | 0 | 0 | 1 | 0 |
| 心窩部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-4 | | | MR13A9-5 (DB) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR13A9 0.5 ug/kg | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大腸ポリープ | 0 | 0 | 0 | 0 | 1 | 0 |
| 腹痛 | 0 | 0 | 0 | 1 | 0 | 0 |
| 歯痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 慢性胃炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 胃炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腹部膨満 | 0 | 0 | 0 | 0 | 0 | 0 |
| 腸炎 | 1 | 0 | 0 | 0 | 0 | 0 |
| 軟便 | 1 | 0 | 0 | 0 | 0 | 0 |
| 肛門脱 | 0 | 0 | 0 | 0 | 1 | 0 |
| 口内炎 | 2 | 0 | 0 | 0 | 0 | 0 |
| 血便排泄 | 0 | 0 | 0 | 1 | 0 | 0 |
| 消化不良 | 0 | 0 | 0 | 0 | 0 | 0 |
| 裂孔ヘルニア | 0 | 0 | 0 | 0 | 0 | 0 |
| 虚血性大腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性腸憩室 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃ポリープ | 0 | 0 | 0 | 1 | 0 | 0 |
| 胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯肉出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 吐血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血栓性痔核 | 0 | 0 | 0 | 1 | 0 | 0 |
| 胃酸過多 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼠径ヘルニア | 0 | 0 | 0 | 0 | 0 | 0 |
| 膵炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯周病 | 0 | 0 | 0 | 0 | 0 | 0 |
| 肛門周囲痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 直腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涎過多 | 0 | 0 | 0 | 0 | 0 | 0 |
| 憩室穿孔 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口唇血腫 | 0 | 0 | 0 | 0 | 0 | 0 |
| 口角口唇炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硬便 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼓腸 | 0 | 0 | 0 | 0 | 0 | 0 |
| 小腸閉塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心窩部不快感 | 1 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (DB) | | | MR13A9-5 (Entire) | | |
|---|---|---|---|---|---|---|
| Group | Placebo | | | MR-MR | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大腸ポリープ | 1 | 0 | 0 | 1 | 2 | 0 |
| 腹痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯痛 | 1 | 0 | 0 | 2 | 0 | 0 |
| 慢性胃炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 胃炎 | 0 | 0 | 0 | 2 | 0 | 0 |
| 腹部膨満 | 1 | 0 | 0 | 0 | 0 | 0 |
| 腸炎 | 0 | 0 | 0 | 2 | 0 | 0 |
| 軟便 | 0 | 0 | 0 | 1 | 0 | 0 |
| 肛門脱 | 0 | 0 | 0 | 1 | 1 | 0 |
| 口内炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血便排泄 | 0 | 0 | 0 | 1 | 0 | 0 |
| 消化不良 | 1 | 0 | 0 | 0 | 0 | 0 |
| 裂孔ヘルニア | 1 | 0 | 0 | 0 | 0 | 0 |
| 虚血性大腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性腸憩室 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃ポリープ | 0 | 0 | 0 | 1 | 0 | 0 |
| 胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 出血性胃潰瘍 | 0 | 0 | 0 | 0 | 0 | 0 |
| 胃腸出血 | 0 | 0 | 0 | 0 | 1 | 0 |
| 歯肉出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 吐血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 血栓性痔核 | 0 | 0 | 0 | 1 | 0 | 0 |
| 胃酸過多 | 0 | 0 | 0 | 1 | 0 | 0 |
| 鼠径ヘルニア | 0 | 0 | 0 | 0 | 1 | 0 |
| 膵炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 歯周病 | 0 | 0 | 0 | 0 | 1 | 0 |
| 肛門周囲痛 | 0 | 0 | 0 | 0 | 0 | 0 |
| 直腸炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 流涎過多 | 0 | 0 | 0 | 1 | 0 | 0 |
| 憩室穿孔 | 0 | 0 | 0 | 0 | 1 | 0 |
| 口唇血腫 | 0 | 0 | 0 | 1 | 0 | 0 |
| 口角口唇炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硬便 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼓腸 | 0 | 0 | 0 | 0 | 0 | 0 |
| 小腸閉塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心窩部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
Run Date: 2023-01-11 16:41



(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | MR13A9-5 (Entire) | | | MR13A9-5 (Long-term) | | |
|---|---|---|---|---|---|---|
| Group | P-MR | | | MR13A9 0.5 ug/kg (Long-term) | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大腸ポリープ | 2 | 0 | 0 | 2 | 2 | 0 |
| 腹痛 | 3 | 0 | 0 | 4 | 0 | 0 |
| 歯痛 | 2 | 0 | 0 | 3 | 0 | 0 |
| 慢性胃炎 | 1 | 0 | 0 | 2 | 0 | 0 |
| 胃炎 | 0 | 0 | 0 | 2 | 0 | 0 |
| 腹部膨満 | 1 | 0 | 0 | 0 | 0 | 0 |
| 腸炎 | 0 | 1 | 0 | 2 | 1 | 0 |
| 軟便 | 1 | 0 | 0 | 2 | 0 | 0 |
| 肛門脱 | 0 | 0 | 0 | 1 | 1 | 0 |
| 口内炎 | 1 | 0 | 0 | 1 | 0 | 0 |
| 血便排泄 | 0 | 0 | 0 | 1 | 0 | 0 |
| 消化不良 | 2 | 0 | 0 | 1 | 0 | 0 |
| 裂孔ヘルニア | 2 | 0 | 0 | 1 | 0 | 0 |
| 虚血性大腸炎 | 0 | 1 | 0 | 0 | 1 | 0 |
| 出血性腸憩室 | 1 | 0 | 0 | 1 | 0 | 0 |
| 胃ポリープ | 0 | 0 | 0 | 1 | 0 | 0 |
| 胃潰瘍 | 1 | 0 | 0 | 1 | 0 | 0 |
| 出血性胃潰瘍 | 0 | 1 | 0 | 0 | 1 | 0 |
| 胃腸出血 | 0 | 0 | 0 | 0 | 1 | 0 |
| 歯肉出血 | 0 | 0 | 0 | 0 | 0 | 0 |
| 吐血 | 0 | 0 | 1 | 0 | 0 | 1 |
| 血栓性痔核 | 0 | 0 | 0 | 1 | 0 | 0 |
| 胃酸過多 | 0 | 0 | 0 | 1 | 0 | 0 |
| 単径ヘルニア | 0 | 0 | 0 | 0 | 1 | 0 |
| 膵炎 | 0 | 1 | 0 | 0 | 1 | 0 |
| 歯周病 | 0 | 0 | 0 | 0 | 1 | 0 |
| 肛門周囲痛 | 1 | 0 | 0 | 1 | 0 | 0 |
| 直腸炎 | 1 | 0 | 0 | 1 | 0 | 0 |
| 流涎過多 | 0 | 0 | 0 | 1 | 0 | 0 |
| 憩室穿孔 | 0 | 0 | 0 | 0 | 1 | 0 |
| 口唇血腫 | 0 | 0 | 0 | 1 | 0 | 0 |
| 口角口唇炎 | 0 | 0 | 0 | 0 | 0 | 0 |
| 硬便 | 0 | 0 | 0 | 0 | 0 | 0 |
| 鼓腸 | 0 | 0 | 0 | 0 | 0 | 0 |
| 小腸閉塞 | 0 | 0 | 0 | 0 | 0 | 0 |
| 心窩部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |

MR13A9 = ジフェリケファリン
SOCs and PTs were coded using MedDRA version 24.1.
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(Source: 5.3.5.3-1)

## Table 9.3.6-1 Occurrence of Adverse Events by Severity

Unit: Events

| Study | Overall | | | | | |
|---|---|---|---|---|---|---|
| Group | MR13A9 0.5 ug/kg | | | MR13A9 ALL | | |
| Primary SOC, PT | Mild | Moderate | Severe | Mild | Moderate | Severe |
| 大腸ポリープ | 2 | 2 | 0 | 2 | 3 | 0 |
| 腹痛 | 4 | 0 | 0 | 4 | 1 | 0 |
| 歯痛 | 4 | 0 | 0 | 4 | 0 | 0 |
| 慢性胃炎 | 2 | 0 | 0 | 3 | 0 | 0 |
| 胃炎 | 2 | 0 | 0 | 3 | 0 | 0 |
| 腹部膨満 | 1 | 1 | 0 | 1 | 1 | 0 |
| 腸炎 | 2 | 1 | 0 | 2 | 1 | 0 |
| 軟便 | 2 | 0 | 0 | 2 | 0 | 0 |
| 肛門脱 | 1 | 1 | 0 | 1 | 1 | 0 |
| 口内炎 | 1 | 0 | 0 | 2 | 0 | 0 |
| 血便排泄 | 1 | 0 | 0 | 2 | 0 | 0 |
| 消化不良 | 1 | 0 | 0 | 1 | 0 | 0 |
| 裂孔ヘルニア | 1 | 0 | 0 | 1 | 0 | 0 |
| 虚血性大腸炎 | 0 | 1 | 0 | 0 | 1 | 0 |
| 出血性腸憩室 | 1 | 0 | 0 | 1 | 0 | 0 |
| 胃ポリープ | 1 | 0 | 0 | 1 | 0 | 0 |
| 胃潰瘍 | 1 | 0 | 0 | 1 | 0 | 0 |
| 出血性胃潰瘍 | 0 | 1 | 0 | 0 | 1 | 0 |
| 胃腸出血 | 0 | 1 | 0 | 0 | 1 | 0 |
| 歯肉出血 | 1 | 0 | 0 | 1 | 0 | 0 |
| 吐血 | 0 | 0 | 1 | 0 | 0 | 1 |
| 血栓性痔核 | 1 | 0 | 0 | 1 | 0 | 0 |
| 胃酸過多 | 1 | 0 | 0 | 1 | 0 | 0 |
| 単径ヘルニア | 0 | 1 | 0 | 0 | 1 | 0 |
| 膵炎 | 0 | 1 | 0 | 0 | 1 | 0 |
| 歯周病 | 0 | 1 | 0 | 0 | 1 | 0 |
| 肛門周囲痛 | 1 | 0 | 0 | 1 | 0 | 0 |
| 直腸炎 | 1 | 0 | 0 | 1 | 0 | 0 |
| 流涎過多 | 1 | 0 | 0 | 1 | 0 | 0 |
| 憩室穿孔 | 0 | 1 | 0 | 0 | 1 | 0 |
| 口唇血腫 | 1 | 0 | 0 | 1 | 0 | 0 |
| 口角口唇炎 | 0 | 0 | 0 | 1 | 0 | 0 |
| 硬便 | 0 | 0 | 0 | 0 | 1 | 0 |
| 鼓腸 | 0 | 0 | 0 | 1 | 0 | 0 |
| 小腸閉塞 | 0 | 0 | 0 | 0 | 1 | 0 |
| 心窩部不快感 | 0 | 0 | 0 | 0 | 0 | 0 |

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(Source: 5.3.5.3-1)