Table 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| N | 21 | --- | 21 | --- | 19 | --- | 23 | --- |
| Any Adverse Drug Reactions | 7 | 33.3 | 13 | 61.9 | 9 | 47.4 | 18 | 78.3 |
| 感染症および寄生虫症 | 0 | 0.0 | 1 | 4.8 | 1 | 5.3 | 0 | 0.0 |
| 上咽頭炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足部白癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 毛包炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯周炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膀胱炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ＣＯＶＩＤ－１９ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 蜂巣炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 気管支炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咽頭炎 | 0 | 0.0 | 0 | 0.0 | 1 | 5.3 | 0 | 0.0 |
| 菌血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 麦粒腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪の皮膚糸状菌症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯肉炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外耳炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白癬感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎嚢胞感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 憩室炎 | 0 | 0.0 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 |
| ウイルス性胃腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳下腺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上気道感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尿路感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘリコバクター感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 医療機器関連感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔ヘルペス | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 帯状疱疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下組織膿瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 化膿 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| N | 21 | --- | 61 | --- | 61 | --- | 62 | --- |
| Any Adverse Drug Reactions | 4 | 19.0 | 9 | 14.8 | 9 | 14.8 | 17 | 27.4 |
| 感染症および寄生虫症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上咽頭炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足部白癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 毛包炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯周炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膀胱炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ＣＯＶＩＤ－１９ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 蜂巣炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 気管支炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咽頭炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 菌血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 麦粒腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪の皮膚糸状菌症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯肉炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外耳炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白癬感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎嚢胞感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 憩室炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ウイルス性胃腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳下腺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上気道感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尿路感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘリコバクター感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 医療機器関連感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔ヘルペス | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 帯状疱疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下組織膿瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 化膿 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| N | 63 | --- | 89 | --- | 89 | --- | 85 | --- |
| Any Adverse Drug Reactions | 7 | 11.1 | 13 | 14.6 | 3 | 3.4 | 16 | 18.8 |
| 感染症および寄生虫症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上咽頭炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足部白癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 毛包炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯周炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膀胱炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ＣＯＶＩＤ－１９ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 蜂巣炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 気管支炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咽頭炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 菌血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 麦粒腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪の皮膚糸状菌症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯肉炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外耳炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白癬感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎嚢胞感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 憩室炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ウイルス性胃腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳下腺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上気道感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尿路感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘリコバクター感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 医療機器関連感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔ヘルペス | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 帯状疱疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下組織膿瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 化膿 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| N | 83 | --- | 172 | --- | 254 | --- | 440 | --- |
| Any Adverse Drug Reactions | 11 | 13.3 | 28 | 16.3 | 50 | 19.7 | 110 | 25.0 |
| 感染症および寄生虫症 | 0 | 0.0 | 0 | 0.0 | 1 | 0.4 | 2 | 0.5 |
| 上咽頭炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足部白癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 毛包炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯周炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膀胱炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ＣＯＶＩＤ－１９ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 蜂巣炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 気管支炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咽頭炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 菌血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 麦粒腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪の皮膚糸状菌症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯肉炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外耳炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白癬感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎嚢胞感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 憩室炎 | 0 | 0.0 | 0 | 0.0 | 1 | 0.4 | 1 | 0.2 |
| ウイルス性胃腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳下腺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上気道感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尿路感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘリコバクター感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 医療機器関連感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔ヘルペス | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 帯状疱疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下組織膿瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 化膿 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| N | 173 | --- |
| Any Adverse Drug Reactions | 14 | 8.1 |
| 感染症および寄生虫症 | 0 | 0.0 |
| 上咽頭炎 | 0 | 0.0 |
| 胃腸炎 | 0 | 0.0 |
| 肺炎 | 0 | 0.0 |
| 足部白癬 | 0 | 0.0 |
| 毛包炎 | 0 | 0.0 |
| 歯周炎 | 0 | 0.0 |
| 膀胱炎 | 0 | 0.0 |
| ＣＯＶＩＤ－１９ | 0 | 0.0 |
| 蜂巣炎 | 0 | 0.0 |
| 気管支炎 | 0 | 0.0 |
| 咽頭炎 | 0 | 0.0 |
| 菌血症 | 0 | 0.0 |
| 麦粒腫 | 0 | 0.0 |
| シャント感染 | 0 | 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 | 0 | 0.0 |
| 腎嚢胞感染 | 0 | 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 | 0 | 0.0 |
| 帯状疱疹 | 0 | 0.0 |
| 皮下組織膿瘍 | 0 | 0.0 |
| 化膿 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 虫垂炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 丹毒 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 単純ヘルペス | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘルペスウイルス感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| インフルエンザ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪囲炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 誤嚥性肺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膿疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎盂腎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性腎盂腎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膿皮症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 敗血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門膿瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 移植片感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔真菌感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆道感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 穿刺部位感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感染性皮膚嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 仮性動脈瘤感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| せつ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咽頭扁桃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 手白癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚真菌感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨髄炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 0.0 | 0 | 0.0 | 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 | 0 | 0.0 | 0 | 0.0 |
| 皮膚乳頭腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 十二指腸の良性新生物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃癌 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 新生物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎癌 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 虫垂炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 丹毒 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 単純ヘルペス | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘルペスウイルス感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| インフルエンザ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪囲炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 誤嚥性肺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膿疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎盂腎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性腎盂腎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膿皮症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 敗血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門膿瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 移植片感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔真菌感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆道感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 穿刺部位感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感染性皮膚嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 仮性動脈瘤感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| せつ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咽頭扁桃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 手白癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚真菌感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨髄炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 0.0 | 0 | 0.0 | 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 | 0 | 0.0 | 0 | 0.0 |
| 皮膚乳頭腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 十二指腸の良性新生物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃癌 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 新生物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎癌 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 虫垂炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 丹毒 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 単純ヘルペス | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘルペスウイルス感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| インフルエンザ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪囲炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 誤嚥性肺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膿疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎盂腎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性腎盂腎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膿皮症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 敗血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門膿瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 移植片感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔真菌感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆道感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 穿刺部位感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感染性皮膚嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 仮性動脈瘤感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| せつ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咽頭扁桃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 手白癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚真菌感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨髄炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 0.0 | 0 | 0.0 | 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 | 0 | 0.0 | 0 | 0.0 |
| 皮膚乳頭腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 十二指腸の良性新生物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃癌 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 新生物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎癌 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 虫垂炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 丹毒 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 単純ヘルペス | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘルペスウイルス感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| インフルエンザ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪囲炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 誤嚥性肺炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膿疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎盂腎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性腎盂腎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膿皮症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 敗血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門膿瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 移植片感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔真菌感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆道感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 穿刺部位感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感染性皮膚嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 仮性動脈瘤感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| せつ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咽頭扁桃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 手白癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚真菌感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨髄炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚感染 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ＣＯＶＩＤ－１９肺炎 | 0 | 0.0 | 0 | 0.0 | 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 | 0 | 0.0 | 0 | 0.0 |
| 皮膚乳頭腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 十二指腸の良性新生物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃癌 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 新生物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎癌 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 虫垂炎 | 0 | 0.0 |
| 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 | 0 | 0.0 |
| 骨髄炎 | 0 | 0.0 |
| 皮膚感染 | 0 | 0.0 |
| ＣＯＶＩＤ－１９肺炎 | 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 |
| 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 |

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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 脂漏性角化症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎明細胞癌 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性骨髄性白血病 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血液およびリンパ系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鉄欠乏性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大球性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 免疫性血小板減少症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 播種性血管内凝固 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 免疫系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 季節性アレルギー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 造影剤アレルギー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アナフィラキシーショック | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 造影剤反応 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 内分泌障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 4.3 |
| 続発性副甲状腺機能亢進症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺機能低下症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 副腎機能不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高プロラクチン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺機能亢進症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 4.3 |
| 代謝および栄養障害 | 0 | 0.0 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高リン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 食欲減退 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低血糖 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高カリウム血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高血糖 | 0 | 0.0 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 |
| 痛風 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 亜鉛欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高コレステロール血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脂質異常症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低カルニチン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高尿酸血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低カリウム血症 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 脂漏性角化症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎明細胞癌 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性骨髄性白血病 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血液およびリンパ系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鉄欠乏性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大球性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 免疫性血小板減少症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 播種性血管内凝固 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 免疫系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 季節性アレルギー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 造影剤アレルギー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アナフィラキシーショック | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 造影剤反応 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 内分泌障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 続発性副甲状腺機能亢進症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺機能低下症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 副腎機能不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高プロラクチン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺機能亢進症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 代謝および栄養障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 糖尿病 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高リン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 食欲減退 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低血糖 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高カリウム血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高血糖 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 痛風 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 亜鉛欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高コレステロール血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脂質異常症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低カルニチン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高尿酸血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低カリウム血症 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 脂漏性角化症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎明細胞癌 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性骨髄性白血病 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血液およびリンパ系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鉄欠乏性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大球性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 免疫性血小板減少症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 播種性血管内凝固 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 免疫系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 季節性アレルギー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 造影剤アレルギー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アナフィラキシーショック | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 造影剤反応 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 内分泌障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.2 |
| 続発性副甲状腺機能亢進症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺機能低下症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.2 |
| 副腎機能不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高プロラクチン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺機能亢進症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 代謝および栄養障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.2 |
| 糖尿病 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高リン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.2 |
| 食欲減退 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低血糖 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高カリウム血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高血糖 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 痛風 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 亜鉛欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高コレステロール血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脂質異常症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低カルニチン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高尿酸血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低カリウム血症 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 脂漏性角化症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎明細胞癌 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性骨髄性白血病 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血液およびリンパ系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鉄欠乏性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大球性貧血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 免疫性血小板減少症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 播種性血管内凝固 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 免疫系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 季節性アレルギー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 造影剤アレルギー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アナフィラキシーショック | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 造影剤反応 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 内分泌障害 | 0 | 0.0 | 1 | 0.6 | 1 | 0.4 | 3 | 0.7 |
| 続発性副甲状腺機能亢進症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺機能低下症 | 0 | 0.0 | 1 | 0.6 | 1 | 0.4 | 2 | 0.5 |
| 副腎機能不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高プロラクチン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺機能亢進症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 代謝および栄養障害 | 1 | 1.2 | 2 | 1.2 | 3 | 1.2 | 4 | 0.9 |
| 糖尿病 | 1 | 1.2 | 1 | 0.6 | 1 | 0.4 | 1 | 0.2 |
| 高リン血症 | 0 | 0.0 | 1 | 0.6 | 1 | 0.4 | 1 | 0.2 |
| 食欲減退 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低血糖 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高カリウム血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高血糖 | 0 | 0.0 | 0 | 0.0 | 1 | 0.4 | 2 | 0.5 |
| 痛風 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 亜鉛欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高コレステロール血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脂質異常症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低カルニチン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高尿酸血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低カリウム血症 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 脂漏性角化症 | 0 | 0.0 |
| 腎明細胞癌 | 0 | 0.0 |
| 慢性骨髄性白血病 | 0 | 0.0 |
| 血液およびリンパ系障害 | 0 | 0.0 |
| 腎性貧血 | 0 | 0.0 |
| 鉄欠乏性貧血 | 0 | 0.0 |
| 貧血 | 0 | 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 | 0.0 |
| 免疫系障害 | 0 | 0.0 |
| 季節性アレルギー | 0 | 0.0 |
| 造影剤アレルギー | 0 | 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 | 0 | 0.0 |
| 続発性副甲状腺機能亢進症 | 0 | 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 | 0 | 0.0 |
| 糖尿病 | 0 | 0.0 |
| 高リン血症 | 0 | 0.0 |
| 食欲減退 | 0 | 0.0 |
| 低血糖 | 0 | 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 | 0 | 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 |

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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 低リン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低蛋白血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血液量減少症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低亜鉛血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ビタミンK欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高脂血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鉄欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高カルシウム血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 精神障害 | 1 | 4.8 | 3 | 14.3 | 0 | 0.0 | 1 | 4.3 |
| 不眠症 | 1 | 4.8 | 2 | 9.5 | 0 | 0.0 | 0 | 0.0 |
| 不安 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 4.3 |
| 譫妄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 多幸気分 | 0 | 0.0 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 |
| 幻覚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 初期不眠症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 易刺激性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 中期不眠症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 4.3 |
| 神経症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 無為 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経系障害 | 3 | 14.3 | 3 | 14.3 | 2 | 10.5 | 9 | 39.1 |
| 浮動性めまい | 1 | 4.8 | 2 | 9.5 | 2 | 10.5 | 4 | 17.4 |
| 頭痛 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 | 2 | 8.7 |
| 傾眠 | 1 | 4.8 | 1 | 4.8 | 0 | 0.0 | 3 | 13.0 |
| 感覚鈍麻 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 下肢静止不能症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 意識消失 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 失神 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脳梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 片頭痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ラクナ梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 起立不耐性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 意識変容状態 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頚動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 低リン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低蛋白血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血液量減少症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低亜鉛血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ビタミンK欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高脂血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鉄欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高カルシウム血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 精神障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 不眠症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 不安 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 譫妄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 多幸気分 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 幻覚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 初期不眠症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 易刺激性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 中期不眠症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 無為 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経系障害 | 0 | 0.0 | 5 | 8.2 | 5 | 8.2 | 8 | 12.9 |
| 浮動性めまい | 0 | 0.0 | 2 | 3.3 | 1 | 1.6 | 2 | 3.2 |
| 頭痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 傾眠 | 0 | 0.0 | 2 | 3.3 | 3 | 4.9 | 5 | 8.1 |
| 感覚鈍麻 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 下肢静止不能症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 意識消失 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 失神 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脳梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 片頭痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ラクナ梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 起立不耐性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭部不快感 | 0 | 0.0 | 1 | 1.6 | 0 | 0.0 | 0 | 0.0 |
| 意識変容状態 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 | 0 | 0.0 |
| 頚動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 低リン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低蛋白血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血液量減少症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低亜鉛血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ビタミンK欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高脂血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鉄欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高カルシウム血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 精神障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 不眠症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 不安 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 譫妄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 多幸気分 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 幻覚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 初期不眠症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 易刺激性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 中期不眠症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 無為 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経系障害 | 4 | 6.3 | 2 | 2.2 | 2 | 2.2 | 4 | 4.7 |
| 浮動性めまい | 2 | 3.2 | 0 | 0.0 | 1 | 1.1 | 1 | 1.2 |
| 頭痛 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 1 | 1.2 |
| 傾眠 | 2 | 3.2 | 1 | 1.1 | 1 | 1.1 | 2 | 2.4 |
| 感覚鈍麻 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 下肢静止不能症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 意識消失 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 失神 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脳梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 片頭痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ラクナ梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 起立不耐性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 意識変容状態 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頚動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 低リン血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低蛋白血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血液量減少症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低亜鉛血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ビタミンK欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高脂血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鉄欠乏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高カルシウム血症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 精神障害 | 1 | 1.2 | 1 | 0.6 | 4 | 1.6 | 7 | 1.6 |
| 不眠症 | 0 | 0.0 | 0 | 0.0 | 2 | 0.8 | 3 | 0.7 |
| 不安 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 2 | 0.5 |
| 譫妄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 多幸気分 | 0 | 0.0 | 0 | 0.0 | 1 | 0.4 | 1 | 0.2 |
| 幻覚 | 1 | 1.2 | 1 | 0.6 | 1 | 0.4 | 1 | 0.2 |
| 初期不眠症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 易刺激性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 中期不眠症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 神経症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 無為 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経系障害 | 5 | 6.0 | 8 | 4.7 | 16 | 6.3 | 43 | 9.8 |
| 浮動性めまい | 2 | 2.4 | 3 | 1.7 | 6 | 2.4 | 17 | 3.9 |
| 頭痛 | 1 | 1.2 | 2 | 1.2 | 2 | 0.8 | 5 | 1.1 |
| 傾眠 | 2 | 2.4 | 3 | 1.7 | 7 | 2.8 | 18 | 4.1 |
| 感覚鈍麻 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 下肢静止不能症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 意識消失 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 失神 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脳梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 片頭痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ラクナ梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 起立不耐性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 意識変容状態 | 0 | 0.0 | 0 | 0.0 | 1 | 0.4 | 1 | 0.2 |
| 頚動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 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 |
| 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 | 0 | 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 | 6 | 3.5 |
| 浮動性めまい | 3 | 1.7 |
| 頭痛 | 0 | 0.0 |
| 傾眠 | 3 | 1.7 |
| 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 |

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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 手根管症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頚腕症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ジスキネジア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| てんかん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢性ニューロパチー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 錯感覚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘルペス後神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| てんかん重積状態 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ミオクロニーてんかん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病性ニューロパチー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感覚障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 振戦 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 三叉神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 幻肢症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 4.3 |
| 脳幹梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 一過性脳虚血発作 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋間神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白内障 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性結膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ドライアイ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結膜出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜上膜 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 霰粒腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病網膜症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 複視 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 流涙増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 黄斑浮腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜裂孔 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 加齢黄斑変性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 霧視 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高眼圧症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 硝子体混濁 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼そう痒症 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 手根管症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頚腕症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ジスキネジア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| てんかん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢性ニューロパチー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 錯感覚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘルペス後神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| てんかん重積状態 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ミオクロニーてんかん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病性ニューロパチー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感覚障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 振戦 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 三叉神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 幻肢症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脳幹梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 一過性脳虚血発作 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋間神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白内障 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性結膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ドライアイ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結膜出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜上膜 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 霰粒腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病網膜症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 複視 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 流涙増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 黄斑浮腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜裂孔 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 加齢黄斑変性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 霧視 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高眼圧症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 硝子体混濁 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼そう痒症 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 手根管症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頚腕症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ジスキネジア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| てんかん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢性ニューロパチー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 錯感覚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘルペス後神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| てんかん重積状態 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ミオクロニーてんかん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病性ニューロパチー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感覚障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 振戦 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 三叉神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 幻肢症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脳幹梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 一過性脳虚血発作 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋間神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白内障 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性結膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ドライアイ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結膜出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜上膜 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 霰粒腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病網膜症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 複視 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 流涙増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 黄斑浮腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜裂孔 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 加齢黄斑変性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 霧視 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高眼圧症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 硝子体混濁 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼そう痒症 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 手根管症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頚腕症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ジスキネジア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| てんかん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢性ニューロパチー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 錯感覚 | 1 | 1.2 | 1 | 0.6 | 1 | 0.4 | 1 | 0.2 |
| ヘルペス後神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| てんかん重積状態 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ミオクロニーてんかん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病性ニューロパチー | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 感覚障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 振戦 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 三叉神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 幻肢症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 脳幹梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 一過性脳虚血発作 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋間神経痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白内障 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性結膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ドライアイ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結膜出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜上膜 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 霰粒腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病網膜症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 複視 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 流涙増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 黄斑浮腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 網膜裂孔 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 加齢黄斑変性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 霧視 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 高眼圧症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 硝子体混濁 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼そう痒症 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 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 |
| 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 | 0 | 0.0 |
| 一過性脳虚血発作 | 0 | 0.0 |
| 肋間神経痛 | 0 | 0.0 |
| 眼障害 | 0 | 0.0 |
| 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 | 0 | 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 |

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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 後嚢部混濁 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳および迷路障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 4.3 |
| 回転性めまい | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 4.3 |
| 耳鳴 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭位性回転性めまい | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 突発性難聴 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳管狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外耳道びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳垢栓塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心臓障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 動悸 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 狭心症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 不安定狭心症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性心筋梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 冠動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心房細動 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心室性期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 徐脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心筋虚血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 洞性頻脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上室性期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発作性房室ブロック | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心機能障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大動脈弁狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頻脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| うっ血性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管障害 | 1 | 4.8 | 3 | 14.3 | 1 | 5.3 | 3 | 13.0 |
| 透析低血圧 | 0 | 0.0 | 1 | 4.8 | 1 | 5.3 | 1 | 4.3 |
| 低血圧 | 0 | 0.0 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 |
| 末梢動脈閉塞性疾患 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 後嚢部混濁 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳および迷路障害 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 | 0 | 0.0 |
| 回転性めまい | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 | 0 | 0.0 |
| 耳鳴 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭位性回転性めまい | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 突発性難聴 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳管狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外耳道びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳垢栓塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心臓障害 | 0 | 0.0 | 2 | 3.3 | 0 | 0.0 | 0 | 0.0 |
| 動悸 | 0 | 0.0 | 2 | 3.3 | 0 | 0.0 | 0 | 0.0 |
| 狭心症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 不安定狭心症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性心筋梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 冠動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心房細動 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心室性期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 徐脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心筋虚血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 洞性頻脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上室性期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発作性房室ブロック | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心機能障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大動脈弁狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頻脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| うっ血性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管障害 | 2 | 9.5 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 透析低血圧 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低血圧 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢動脈閉塞性疾患 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 後嚢部混濁 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳および迷路障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.2 |
| 回転性めまい | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.2 |
| 耳鳴 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭位性回転性めまい | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 突発性難聴 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳管狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外耳道びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳垢栓塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心臓障害 | 1 | 1.6 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 動悸 | 1 | 1.6 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 狭心症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 不安定狭心症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性心筋梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 冠動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心房細動 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心室性期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 徐脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心筋虚血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 洞性頻脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上室性期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発作性房室ブロック | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心機能障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大動脈弁狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頻脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| うっ血性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管障害 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 0 | 0.0 |
| 透析低血圧 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 低血圧 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢動脈閉塞性疾患 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 後嚢部混濁 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳および迷路障害 | 0 | 0.0 | 1 | 0.6 | 2 | 0.8 | 3 | 0.7 |
| 回転性めまい | 0 | 0.0 | 1 | 0.6 | 2 | 0.8 | 3 | 0.7 |
| 耳鳴 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭位性回転性めまい | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 突発性難聴 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳管狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外耳道びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 耳垢栓塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心臓障害 | 1 | 1.2 | 1 | 0.6 | 1 | 0.4 | 3 | 0.7 |
| 動悸 | 1 | 1.2 | 1 | 0.6 | 1 | 0.4 | 3 | 0.7 |
| 狭心症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 不安定狭心症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性心筋梗塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 冠動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心房細動 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心室性期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 徐脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心筋虚血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 洞性頻脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上室性期外収縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発作性房室ブロック | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心機能障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大動脈弁狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頻脈 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| うっ血性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性心不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管障害 | 1 | 1.2 | 2 | 1.2 | 5 | 2.0 | 11 | 2.5 |
| 透析低血圧 | 0 | 0.0 | 0 | 0.0 | 1 | 0.4 | 3 | 0.7 |
| 低血圧 | 0 | 0.0 | 0 | 0.0 | 1 | 0.4 | 1 | 0.2 |
| 末梢動脈閉塞性疾患 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 後嚢部混濁 | 0 | 0.0 |
| 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 |
| 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 | 1 | 0.6 |
| 動悸 | 1 | 0.6 |
| 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 | 0.0 |
| 心房細動 | 0 | 0.0 |
| 心室性期外収縮 | 0 | 0.0 |
| 心不全 | 0 | 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 | 0 | 0.0 |
| 慢性心不全 | 0 | 0.0 |
| 血管障害 | 2 | 1.2 |
| 透析低血圧 | 0 | 0.0 |
| 低血圧 | 0 | 0.0 |
| 末梢動脈閉塞性疾患 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 高血圧 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 4.3 |
| ほてり | 1 | 4.8 | 1 | 4.8 | 0 | 0.0 | 1 | 4.3 |
| 内出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 起立性低血圧 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢冷感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アテローム塞栓症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸器、胸郭および縦隔障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上気道の炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔咽頭痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻漏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 誤嚥 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喘息 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸困難 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咳嗽 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻閉 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 湿性咳嗽 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発声障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸水 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性鼻炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 睡眠時無呼吸症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喀痰増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咳喘息 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔咽頭不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 過換気 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻の炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喀血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸窮迫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸障害 | 2 | 9.5 | 0 | 0.0 | 1 | 5.3 | 7 | 30.4 |
| 便秘 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 | 2 | 8.7 |
| 下痢 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 高血圧 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ほてり | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 内出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 起立性低血圧 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢冷感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アテローム塞栓症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸器、胸郭および縦隔障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上気道の炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔咽頭痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻漏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 誤嚥 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喘息 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸困難 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咳嗽 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻閉 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 湿性咳嗽 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発声障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸水 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性鼻炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 睡眠時無呼吸症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喀痰増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咳喘息 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔咽頭不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 過換気 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻の炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喀血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸窮迫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸障害 | 1 | 4.8 | 1 | 1.6 | 3 | 4.9 | 5 | 8.1 |
| 便秘 | 0 | 0.0 | 1 | 1.6 | 1 | 1.6 | 1 | 1.6 |
| 下痢 | 1 | 4.8 | 0 | 0.0 | 1 | 1.6 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 高血圧 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ほてり | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 0 | 0.0 |
| 内出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 起立性低血圧 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢冷感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アテローム塞栓症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸器、胸郭および縦隔障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上気道の炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔咽頭痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻漏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 誤嚥 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喘息 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸困難 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咳嗽 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻閉 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 湿性咳嗽 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発声障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸水 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性鼻炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 睡眠時無呼吸症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喀痰増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咳喘息 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔咽頭不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 過換気 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻の炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喀血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸窮迫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸障害 | 1 | 1.6 | 7 | 7.9 | 0 | 0.0 | 6 | 7.1 |
| 便秘 | 0 | 0.0 | 4 | 4.5 | 0 | 0.0 | 4 | 4.7 |
| 下痢 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 高血圧 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| ほてり | 1 | 1.2 | 2 | 1.2 | 3 | 1.2 | 6 | 1.4 |
| 内出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 起立性低血圧 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大動脈狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢冷感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アテローム塞栓症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸器、胸郭および縦隔障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上気道の炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔咽頭痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻漏 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 誤嚥 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喘息 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸困難 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咳嗽 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻閉 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 湿性咳嗽 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発声障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸水 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性鼻炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 睡眠時無呼吸症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喀痰増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 咳喘息 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口腔咽頭不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 過換気 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼻の炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 喀血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 呼吸窮迫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸障害 | 0 | 0.0 | 7 | 4.1 | 10 | 3.9 | 26 | 5.9 |
| 便秘 | 0 | 0.0 | 4 | 2.3 | 5 | 2.0 | 10 | 2.3 |
| 下痢 | 0 | 0.0 | 0 | 0.0 | 1 | 0.4 | 1 | 0.2 |

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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 高血圧 | 1 | 0.6 |
| ほてり | 0 | 0.0 |
| 内出血 | 0 | 0.0 |
| 血管痛 | 0 | 0.0 |
| 血腫 | 0 | 0.0 |
| 起立性低血圧 | 1 | 0.6 |
| 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 | 0 | 0.0 |
| 上気道の炎症 | 0 | 0.0 |
| 口腔咽頭痛 | 0 | 0.0 |
| 鼻漏 | 0 | 0.0 |
| 誤嚥 | 0 | 0.0 |
| 喘息 | 0 | 0.0 |
| 呼吸困難 | 0 | 0.0 |
| 咳嗽 | 0 | 0.0 |
| 鼻閉 | 0 | 0.0 |
| 湿性咳嗽 | 0 | 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 | 0 | 0.0 |
| 呼吸窮迫 | 0 | 0.0 |
| 胃腸障害 | 2 | 1.2 |
| 便秘 | 0 | 0.0 |
| 下痢 | 1 | 0.6 |

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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 悪心 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 | 4 | 17.4 |
| 嘔吐 | 1 | 4.8 | 0 | 0.0 | 1 | 5.3 | 1 | 4.3 |
| 痔核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 齲歯 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃食道逆流性疾患 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上腹部痛 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 | 1 | 4.3 |
| 腹部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大腸ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腹痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性胃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腹部膨満 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 軟便 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門脱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口内炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血便排泄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 消化不良 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 裂孔ヘルニア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 虚血性大腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性腸憩室 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性胃潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯肉出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 吐血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血栓性痔核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃酸過多 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 単径ヘルニア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膵炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯周病 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門周囲痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 直腸炎 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 悪心 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 2 | 3.2 |
| 嘔吐 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 | 2 | 3.2 |
| 痔核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 齲歯 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃食道逆流性疾患 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 上腹部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腹部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大腸ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腹痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性胃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腹部膨満 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 軟便 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門脱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口内炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血便排泄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 消化不良 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 裂孔ヘルニア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 虚血性大腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性腸憩室 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性胃潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯肉出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 吐血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血栓性痔核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃酸過多 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 単径ヘルニア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膵炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯周病 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門周囲痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 直腸炎 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 悪心 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 嘔吐 | 1 | 1.6 | 1 | 1.1 | 0 | 0.0 | 0 | 0.0 |
| 痔核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 齲歯 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃食道逆流性疾患 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 1 | 1.2 |
| 上腹部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腹部不快感 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 1 | 1.2 |
| 大腸ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腹痛 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 0 | 0.0 |
| 歯痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性胃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腹部膨満 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 軟便 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門脱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口内炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血便排泄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 消化不良 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 裂孔ヘルニア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 虚血性大腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性腸憩室 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性胃潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯肉出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 吐血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血栓性痔核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃酸過多 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼠径ヘルニア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膵炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯周病 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門周囲痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 直腸炎 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 悪心 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 7 | 1.6 |
| 嘔吐 | 0 | 0.0 | 1 | 0.6 | 2 | 0.8 | 7 | 1.6 |
| 痔核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 齲歯 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃食道逆流性疾患 | 0 | 0.0 | 1 | 0.6 | 1 | 0.4 | 1 | 0.2 |
| 上腹部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 2 | 0.5 |
| 腹部不快感 | 0 | 0.0 | 1 | 0.6 | 1 | 0.4 | 1 | 0.2 |
| 大腸ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腹痛 | 0 | 0.0 | 1 | 0.6 | 1 | 0.4 | 1 | 0.2 |
| 歯痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 慢性胃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腹部膨満 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 軟便 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門脱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口内炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血便排泄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 消化不良 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 裂孔ヘルニア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 虚血性大腸炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性腸憩室 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性胃潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃腸出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯肉出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 吐血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血栓性痔核 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胃酸過多 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼠径ヘルニア | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膵炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯周病 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門周囲痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 直腸炎 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 悪心 | 0 | 0.0 |
| 嘔吐 | 1 | 0.6 |
| 痔核 | 0 | 0.0 |
| 齲歯 | 0 | 0.0 |
| 胃食道逆流性疾患 | 0 | 0.0 |
| 上腹部痛 | 0 | 0.0 |
| 腹部不快感 | 0 | 0.0 |
| 大腸ポリープ | 0 | 0.0 |
| 腹痛 | 0 | 0.0 |
| 歯痛 | 0 | 0.0 |
| 慢性胃炎 | 0 | 0.0 |
| 胃炎 | 0 | 0.0 |
| 腹部膨満 | 0 | 0.0 |
| 腸炎 | 0 | 0.0 |
| 軟便 | 0 | 0.0 |
| 肛門脱 | 0 | 0.0 |
| 口内炎 | 0 | 0.0 |
| 血便排泄 | 0 | 0.0 |
| 消化不良 | 0 | 0.0 |
| 裂孔ヘルニア | 0 | 0.0 |
| 虚血性大腸炎 | 0 | 0.0 |
| 出血性腸憩室 | 0 | 0.0 |
| 胃ポリープ | 0 | 0.0 |
| 胃潰瘍 | 0 | 0.0 |
| 出血性胃潰瘍 | 0 | 0.0 |
| 胃腸出血 | 0 | 0.0 |
| 歯肉出血 | 0 | 0.0 |
| 吐血 | 0 | 0.0 |
| 血栓性痔核 | 0 | 0.0 |
| 胃酸過多 | 0 | 0.0 |
| 鼠径ヘルニア | 0 | 0.0 |
| 膵炎 | 0 | 0.0 |
| 歯周病 | 0 | 0.0 |
| 肛門周囲痛 | 0 | 0.0 |
| 直腸炎 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 流涎過多 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 憩室穿孔 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口唇血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口角口唇炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 硬便 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼓腸 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 小腸閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心窩部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 消化管壁肥厚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝胆道系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝機能異常 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性胆管炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆嚢炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆嚢ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性胆嚢炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆石症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝硬変 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆道閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝腫瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚および皮下組織障害 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 過角化 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚剥脱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 接触皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚乾燥 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮脂欠乏性湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 紅斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 陥入爪 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 流涎過多 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 憩室穿孔 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口唇血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口角口唇炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 硬便 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 鼓腸 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 小腸閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 心窩部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 消化管壁肥厚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝胆道系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝機能異常 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性胆管炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆嚢炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆嚢ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性胆嚢炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆石症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝硬変 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆道閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝腫瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚および皮下組織障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 過角化 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚剥脱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 接触皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚乾燥 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮脂欠乏性湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 紅斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 陥入爪 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 流涎過多 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 憩室穿孔 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口唇血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口角口唇炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 硬便 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼓腸 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 小腸閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 心窩部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 消化管壁肥厚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝胆道系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝機能異常 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性胆管炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆嚢炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆嚢ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性胆嚢炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆石症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝硬変 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆道閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝腫瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚および皮下組織障害 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 0 | 0.0 |
| 湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 過角化 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚剥脱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 接触皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚乾燥 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮脂欠乏性湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 紅斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 陥入爪 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 流涎過多 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 憩室穿孔 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口唇血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 口角口唇炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 硬便 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 鼓腸 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 小腸閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 心窩部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肛門びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 消化管壁肥厚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝胆道系障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝機能異常 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性胆管炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆嚢炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆嚢ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 急性胆嚢炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆石症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝硬変 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胆道閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝腫瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚および皮下組織障害 | 1 | 1.2 | 2 | 1.2 | 2 | 0.8 | 4 | 0.9 |
| 湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 過角化 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚剥脱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 接触皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚乾燥 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮脂欠乏性湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 紅斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 発疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚びらん | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 陥入爪 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 流涎過多 | 0 | 0.0 |
| 憩室穿孔 | 0 | 0.0 |
| 口唇血腫 | 0 | 0.0 |
| 口角口唇炎 | 0 | 0.0 |
| 硬便 | 0 | 0.0 |
| 鼓腸 | 0 | 0.0 |
| 小腸閉塞 | 0 | 0.0 |
| 心窩部不快感 | 0 | 0.0 |
| 肛門びらん | 0 | 0.0 |
| 消化管壁肥厚 | 0 | 0.0 |
| 肝胆道系障害 | 0 | 0.0 |
| 肝機能異常 | 0 | 0.0 |
| 急性胆管炎 | 0 | 0.0 |
| 胆嚢炎 | 0 | 0.0 |
| 胆嚢ポリープ | 0 | 0.0 |
| 急性胆嚢炎 | 0 | 0.0 |
| 胆石症 | 0 | 0.0 |
| 肝硬変 | 0 | 0.0 |
| 肝損傷 | 0 | 0.0 |
| 胆道閉塞 | 0 | 0.0 |
| 肝腫瘤 | 0 | 0.0 |
| 皮膚および皮下組織障害 | 0 | 0.0 |
| 湿疹 | 0 | 0.0 |
| 過角化 | 0 | 0.0 |
| 皮膚剥脱 | 0 | 0.0 |
| 接触皮膚炎 | 0 | 0.0 |
| 皮下出血 | 0 | 0.0 |
| 皮膚乾燥 | 0 | 0.0 |
| 皮脂欠乏性湿疹 | 0 | 0.0 |
| 皮膚炎 | 0 | 0.0 |
| 紅斑 | 0 | 0.0 |
| 皮膚嚢腫 | 0 | 0.0 |
| 発疹 | 0 | 0.0 |
| 皮膚びらん | 0 | 0.0 |
| 陥入爪 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 脂漏性皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 水疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 褥瘡性潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 薬疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚亀裂 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 蕁麻疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 手皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性そう痒症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚腫瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 円形脱毛症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ざ瘡 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血性水疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 冷汗 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乾癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 紅斑性皮疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 丘疹性皮疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 痂皮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪床出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚灼熱感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病性足病変 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪肥厚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| そう痒症 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 紫斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格系および結合組織障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 背部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋肉痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 変形性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋痙縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頚部痛 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 脂漏性皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 水疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 褥瘡性潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 薬疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚亀裂 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 蕁麻疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 手皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性そう痒症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚腫瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 円形脱毛症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ざ瘡 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血性水疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 冷汗 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 神経皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乾癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 紅斑性皮疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 丘疹性皮疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 痂皮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪床出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚灼熱感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病性足病変 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 爪肥厚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| そう痒症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 紫斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格系および結合組織障害 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 背部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋肉痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 変形性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋痙縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頚部痛 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 脂漏性皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 水疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 褥瘡性潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 薬疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚亀裂 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 蕁麻疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 手皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性そう痒症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚腫瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 円形脱毛症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ざ瘡 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血性水疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 冷汗 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 0 | 0.0 |
| 神経皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乾癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 紅斑性皮疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 丘疹性皮疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 痂皮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪床出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚灼熱感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病性足病変 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪肥厚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| そう痒症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 紫斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格系および結合組織障害 | 0 | 0.0 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 |
| 背部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋肉痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 変形性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋痙縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頚部痛 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 脂漏性皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 水疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 褥瘡性潰瘍 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 薬疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚亀裂 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 蕁麻疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 手皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性そう痒症 | 1 | 1.2 | 1 | 0.6 | 1 | 0.4 | 1 | 0.2 |
| 皮膚腫瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 円形脱毛症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ざ瘡 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血性水疱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 冷汗 | 0 | 0.0 | 1 | 0.6 | 1 | 0.4 | 1 | 0.2 |
| 神経皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乾癬 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 紅斑性皮疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 丘疹性皮疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 痂皮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪床出血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚灼熱感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 糖尿病性足病変 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アレルギー性皮膚炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 爪肥厚 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| そう痒症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 紫斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格系および結合組織障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 背部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋肉痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 変形性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋痙縮 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頚部痛 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 脂漏性皮膚炎 | 0 | 0.0 |
| 水疱 | 0 | 0.0 |
| 皮膚潰瘍 | 0 | 0.0 |
| 褥瘡性潰瘍 | 0 | 0.0 |
| 薬疹 | 0 | 0.0 |
| 皮膚亀裂 | 0 | 0.0 |
| 蕁麻疹 | 0 | 0.0 |
| 手皮膚炎 | 0 | 0.0 |
| アレルギー性そう痒症 | 0 | 0.0 |
| 皮膚腫瘤 | 0 | 0.0 |
| 円形脱毛症 | 0 | 0.0 |
| ざ瘡 | 0 | 0.0 |
| 血性水疱 | 0 | 0.0 |
| 冷汗 | 0 | 0.0 |
| 神経皮膚炎 | 0 | 0.0 |
| 乾癬 | 0 | 0.0 |
| 紅斑性皮疹 | 0 | 0.0 |
| 丘疹性皮疹 | 0 | 0.0 |
| 痂皮 | 0 | 0.0 |
| 爪床出血 | 0 | 0.0 |
| 皮膚灼熱感 | 0 | 0.0 |
| 糖尿病性足病変 | 0 | 0.0 |
| アレルギー性皮膚炎 | 0 | 0.0 |
| 爪肥厚 | 0 | 0.0 |
| そう痒症 | 0 | 0.0 |
| 紫斑 | 0 | 0.0 |
| 筋骨格系および結合組織障害 | 2 | 1.2 |
| 背部痛 | 0 | 0.0 |
| 関節痛 | 0 | 0.0 |
| 四肢痛 | 0 | 0.0 |
| 筋肉痛 | 0 | 0.0 |
| 変形性関節症 | 0 | 0.0 |
| 関節炎 | 0 | 0.0 |
| 筋痙縮 | 0 | 0.0 |
| 頚部痛 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 頚部脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格硬直 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尾骨痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腰部脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨粗鬆症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 椎間板突出 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節周囲炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 側腹部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼠径部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節滲出液 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨壊死 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足底筋膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 変形性脊椎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 顎関節症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腱鞘炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋膜疼痛症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格系胸痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊椎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋力低下 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節腫脹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結節性変形性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 弾発指 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎および尿路障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血尿 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性膀胱炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 夜間頻尿 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尿管結石症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 生殖系および乳房障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 女性化乳房 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乳頭痛 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 頚部脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格硬直 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尾骨痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腰部脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨粗鬆症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 椎間板突出 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節周囲炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 側腹部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼠径部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節滲出液 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨壊死 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足底筋膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 変形性脊椎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 顎関節症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腱鞘炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋膜疼痛症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格系胸痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊椎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋力低下 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節腫脹 | 1 | 4.8 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結節性変形性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 弾発指 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎および尿路障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血尿 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性膀胱炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 夜間頻尿 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尿管結石症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 生殖系および乳房障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 女性化乳房 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乳頭痛 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 頚部脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格硬直 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尾骨痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腰部脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨粗鬆症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 椎間板突出 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節周囲炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 側腹部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼠径部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節滲出液 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨壊死 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足底筋膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 変形性脊椎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 顎関節症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腱鞘炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋膜疼痛症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格系胸痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊椎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋力低下 | 0 | 0.0 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 |
| 筋骨格不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節腫脹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結節性変形性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 弾発指 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎および尿路障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血尿 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性膀胱炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 夜間頻尿 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尿管結石症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 生殖系および乳房障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 女性化乳房 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乳頭痛 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 頚部脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格硬直 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尾骨痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腰部脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨粗鬆症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 椎間板突出 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節周囲炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 側腹部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 鼠径部痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節滲出液 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨壊死 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足底筋膜炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 変形性脊椎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 顎関節症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腱鞘炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋膜疼痛症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格系胸痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊椎炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊柱管狭窄症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋力低下 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋骨格不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節腫脹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 結節性変形性関節症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 弾発指 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腎および尿路障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血尿 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 出血性膀胱炎 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 夜間頻尿 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尿管結石症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 生殖系および乳房障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 女性化乳房 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乳頭痛 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 頚部脊柱管狭窄症 | 0 | 0.0 |
| 筋骨格硬直 | 0 | 0.0 |
| 尾骨痛 | 0 | 0.0 |
| 腰部脊柱管狭窄症 | 0 | 0.0 |
| 骨粗鬆症 | 0 | 0.0 |
| 椎間板突出 | 0 | 0.0 |
| 筋骨格痛 | 0 | 0.0 |
| 関節周囲炎 | 0 | 0.0 |
| 側腹部痛 | 0 | 0.0 |
| 単径部痛 | 0 | 0.0 |
| 出血性関節症 | 0 | 0.0 |
| 関節滲出液 | 0 | 0.0 |
| 骨壊死 | 0 | 0.0 |
| 足底筋膜炎 | 0 | 0.0 |
| 変形性脊椎症 | 0 | 0.0 |
| 顎関節症候群 | 0 | 0.0 |
| 腱鞘炎 | 0 | 0.0 |
| 筋膜疼痛症候群 | 0 | 0.0 |
| 筋骨格系胸痛 | 0 | 0.0 |
| 脊椎炎 | 0 | 0.0 |
| 脊柱管狭窄症 | 0 | 0.0 |
| 筋力低下 | 1 | 0.6 |
| 筋骨格不快感 | 0 | 0.0 |
| 関節腫脹 | 1 | 0.6 |
| 結節性変形性関節症 | 0 | 0.0 |
| 弾発指 | 0 | 0.0 |
| 四肢不快感 | 0 | 0.0 |
| 腎および尿路障害 | 0 | 0.0 |
| 血尿 | 0 | 0.0 |
| 出血性膀胱炎 | 0 | 0.0 |
| 夜間頻尿 | 0 | 0.0 |
| 尿管結石症 | 0 | 0.0 |
| 生殖系および乳房障害 | 0 | 0.0 |
| 女性化乳房 | 0 | 0.0 |
| 乳頭痛 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 外陰部湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 先天性、家族性および遺伝性障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮様嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 先天性嚢胞性腎疾患 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 一般・全身障害および投与部位の状態 | 0 | 0.0 | 3 | 14.3 | 1 | 5.3 | 6 | 26.1 |
| 発熱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 倦怠感 | 0 | 0.0 | 2 | 9.5 | 1 | 5.3 | 2 | 8.7 |
| ワクチン接種部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 異常感 | 0 | 0.0 | 1 | 4.8 | 0 | 0.0 | 4 | 17.4 |
| 注射部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歩行障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 無力症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢腫脹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢性浮腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管穿刺部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 穿刺部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腫脹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 圧痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腋窩痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管穿刺部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ワクチン接種部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 顔面不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 注射部位紅斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| カテーテル留置部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乾燥症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 臨床検査 | 3 | 14.3 | 4 | 19.0 | 6 | 31.6 | 8 | 34.8 |
| 血中甲状腺刺激ホルモン減少 | 2 | 9.5 | 0 | 0.0 | 6 | 31.6 | 7 | 30.4 |
| 血圧低下 | 1 | 4.8 | 2 | 9.5 | 0 | 0.0 | 0 | 0.0 |
| Ｃ－反応性蛋白増加 | 0 | 0.0 | 0 | 0.0 | 1 | 5.3 | 0 | 0.0 |
| 血中プロラクチン増加 | 1 | 4.8 | 1 | 4.8 | 1 | 5.3 | 3 | 13.0 |
| 遊離サイロキシン減少 | 1 | 4.8 | 1 | 4.8 | 1 | 5.3 | 1 | 4.3 |

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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 外陰部湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 先天性、家族性および遺伝性障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮様嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 先天性嚢胞性腎疾患 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 一般・全身障害および投与部位の状態 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 | 2 | 3.2 |
| 発熱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 倦怠感 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 | 1 | 1.6 |
| ワクチン接種部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 異常感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 注射部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歩行障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 無力症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢腫脹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢性浮腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管穿刺部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 穿刺部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腫脹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 圧痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腋窩痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管穿刺部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ワクチン接種部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 顔面不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 注射部位紅斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| カテーテル留置部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乾燥症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 臨床検査 | 0 | 0.0 | 2 | 3.3 | 2 | 3.3 | 2 | 3.2 |
| 血中甲状腺刺激ホルモン減少 | 0 | 0.0 | 2 | 3.3 | 1 | 1.6 | 0 | 0.0 |
| 血圧低下 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Ｃ－反応性蛋白増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中プロラクチン増加 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 | 0 | 0.0 |
| 遊離サイロキシン減少 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 外陰部湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 先天性、家族性および遺伝性障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮様嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 先天性嚢胞性腎疾患 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 一般・全身障害および投与部位の状態 | 0 | 0.0 | 2 | 2.2 | 0 | 0.0 | 1 | 1.2 |
| 発熱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 倦怠感 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 0 | 0.0 |
| ワクチン接種部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 異常感 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 1 | 1.2 |
| 注射部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歩行障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 無力症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢腫脹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢性浮腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管穿刺部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 穿刺部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腫脹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 圧痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腋窩痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管穿刺部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ワクチン接種部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 顔面不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 注射部位紅斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| カテーテル留置部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乾燥症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 臨床検査 | 1 | 1.6 | 4 | 4.5 | 1 | 1.1 | 2 | 2.4 |
| 血中甲状腺刺激ホルモン減少 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 1 | 1.2 |
| 血圧低下 | 0 | 0.0 | 2 | 2.2 | 1 | 1.1 | 0 | 0.0 |
| Ｃ－反応性蛋白増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中プロラクチン増加 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 1 | 1.2 |
| 遊離サイロキシン減少 | 0 | 0.0 | 1 | 1.1 | 0 | 0.0 | 1 | 1.2 |

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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 外陰部湿疹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 先天性、家族性および遺伝性障害 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮様嚢腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 先天性嚢胞性腎疾患 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 一般・全身障害および投与部位の状態 | 1 | 1.2 | 3 | 1.7 | 7 | 2.8 | 16 | 3.6 |
| 発熱 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 倦怠感 | 0 | 0.0 | 1 | 0.6 | 4 | 1.6 | 8 | 1.8 |
| ワクチン接種部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 異常感 | 0 | 0.0 | 1 | 0.6 | 2 | 0.8 | 7 | 1.6 |
| 注射部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歩行障害 | 1 | 1.2 | 1 | 0.6 | 1 | 0.4 | 2 | 0.5 |
| 無力症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢腫脹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 末梢性浮腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管穿刺部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 胸部不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 穿刺部位疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腫脹 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 圧痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 腋窩痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ポリープ | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管穿刺部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ワクチン接種部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 顔面不快感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 注射部位紅斑 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| カテーテル留置部位そう痒感 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 乾燥症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 臨床検査 | 3 | 3.6 | 6 | 3.5 | 12 | 4.7 | 33 | 7.5 |
| 血中甲状腺刺激ホルモン減少 | 1 | 1.2 | 2 | 1.2 | 3 | 1.2 | 20 | 4.5 |
| 血圧低下 | 1 | 1.2 | 2 | 1.2 | 4 | 1.6 | 5 | 1.1 |
| Ｃ－反応性蛋白増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 血中プロラクチン増加 | 0 | 0.0 | 1 | 0.6 | 3 | 1.2 | 8 | 1.8 |
| 遊離サイロキシン減少 | 0 | 0.0 | 1 | 0.6 | 2 | 0.8 | 5 | 1.1 |

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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 外陰部湿疹 | 0 | 0.0 |
| 先天性、家族性および遺伝性障害 | 0 | 0.0 |
| 皮様嚢腫 | 0 | 0.0 |
| 先天性嚢胞性腎疾患 | 0 | 0.0 |
| 一般・全身障害および投与部位の状態 | 0 | 0.0 |
| 発熱 | 0 | 0.0 |
| 倦怠感 | 0 | 0.0 |
| ワクチン接種部位疼痛 | 0 | 0.0 |
| 異常感 | 0 | 0.0 |
| 注射部位疼痛 | 0 | 0.0 |
| 胸痛 | 0 | 0.0 |
| 歩行障害 | 0 | 0.0 |
| 無力症 | 0 | 0.0 |
| 末梢腫脹 | 0 | 0.0 |
| 末梢性浮腫 | 0 | 0.0 |
| 疼痛 | 0 | 0.0 |
| 血管穿刺部位疼痛 | 0 | 0.0 |
| 胸部不快感 | 0 | 0.0 |
| 穿刺部位疼痛 | 0 | 0.0 |
| 腫脹 | 0 | 0.0 |
| 圧痛 | 0 | 0.0 |
| 腋窩痛 | 0 | 0.0 |
| ポリープ | 0 | 0.0 |
| 血管穿刺部位そう痒感 | 0 | 0.0 |
| ワクチン接種部位そう痒感 | 0 | 0.0 |
| 顔面不快感 | 0 | 0.0 |
| 注射部位紅斑 | 0 | 0.0 |
| カテーテル留置部位そう痒感 | 0 | 0.0 |
| 乾燥症 | 0 | 0.0 |
| 臨床検査 | 2 | 1.2 |
| 血中甲状腺刺激ホルモン減少 | 0 | 0.0 |
| 血圧低下 | 1 | 0.6 |
| Ｃ－反応性蛋白増加 | 0 | 0.0 |
| 血中プロラクチン増加 | 0 | 0.0 |
| 遊離サイロキシン減少 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 血中クレアチンホスホキナーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘリコバクター検査陽性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アラニンアミノトランスフェラーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 4.3 |
| 血中カリウム増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 便潜血陽性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺ホルモン減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 4.3 |
| 血小板数減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アスパラギン酸アミノトランスフェラーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中カルシウム減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中ブドウ糖減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘモグロビン増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 赤血球数増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中リン減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血圧上昇 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白血球数増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中アルカリホスファターゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 便潜血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝機能検査値上昇 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 国際標準比増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 遊離トリヨードチロニン減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 傷害、中毒および処置合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ワクチン接種合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 挫傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚擦過傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 転倒 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 創傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 熱傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 熱中症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント機能不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 節足動物刺傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 靭帯捻挫 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 血中クレアチンホスホキナーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘリコバクター検査陽性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アラニンアミノトランスフェラーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中カリウム増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 便潜血陽性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺ホルモン減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血小板数減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アスパラギン酸アミノトランスフェラーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中カルシウム減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中ブドウ糖減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘモグロビン増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 赤血球数増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中リン減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血圧上昇 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 白血球数増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中アルカリホスファターゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 便潜血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝機能検査値上昇 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.6 |
| 国際標準比増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 遊離トリヨードチロニン減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 傷害、中毒および処置合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ワクチン接種合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 挫傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚擦過傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 転倒 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 創傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 熱傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 熱中症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント機能不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 節足動物刺傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 靭帯捻挫 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 血中クレアチンホスホキナーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘリコバクター検査陽性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アラニンアミノトランスフェラーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中カリウム増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 便潜血陽性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺ホルモン減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血小板数減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アスパラギン酸アミノトランスフェラーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中カルシウム減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中ブドウ糖減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘモグロビン増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 赤血球数増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中リン減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血圧上昇 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白血球数増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中アルカリホスファターゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 便潜血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝機能検査値上昇 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 国際標準比増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 遊離トリヨードチロニン減少 | 1 | 1.6 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 傷害、中毒および処置合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 2 | 2.4 |
| シャント狭窄 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.2 |
| ワクチン接種合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 挫傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚擦過傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 転倒 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 1.2 |
| 創傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 熱傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 熱中症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント機能不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 節足動物刺傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 靭帯捻挫 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 血中クレアチンホスホキナーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘリコバクター検査陽性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アラニンアミノトランスフェラーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 血中カリウム増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 便潜血陽性 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 甲状腺ホルモン減少 | 1 | 1.2 | 1 | 0.6 | 1 | 0.4 | 2 | 0.5 |
| 血小板数減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| アスパラギン酸アミノトランスフェラーゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中カルシウム減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中ブドウ糖減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ヘモグロビン増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 赤血球数増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中リン減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血圧上昇 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 白血球数増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血中アルカリホスファターゼ増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 便潜血 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肝機能検査値上昇 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.2 |
| 国際標準比増加 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 遊離トリヨードチロニン減少 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 傷害、中毒および処置合併症 | 0 | 0.0 | 2 | 1.2 | 2 | 0.8 | 2 | 0.5 |
| シャント狭窄 | 0 | 0.0 | 1 | 0.6 | 1 | 0.4 | 1 | 0.2 |
| ワクチン接種合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 挫傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚擦過傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント閉塞 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 転倒 | 0 | 0.0 | 1 | 0.6 | 1 | 0.4 | 1 | 0.2 |
| 創傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 熱傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 熱中症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント機能不全 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 節足動物刺傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 靭帯捻挫 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 血中クレアチンホスホキナーゼ増加 | 0 | 0.0 |
| ヘリコバクター検査陽性 | 0 | 0.0 |
| アラニンアミノトランスフェラーゼ増加 | 0 | 0.0 |
| 血中カリウム増加 | 0 | 0.0 |
| 便潜血陽性 | 0 | 0.0 |
| 甲状腺ホルモン減少 | 0 | 0.0 |
| 血小板数減少 | 0 | 0.0 |
| アスパラギン酸アミノトランスフェラーゼ増加 | 0 | 0.0 |
| 血中カルシウム減少 | 0 | 0.0 |
| 血中ブドウ糖減少 | 0 | 0.0 |
| ヘモグロビン増加 | 0 | 0.0 |
| 赤血球数増加 | 0 | 0.0 |
| 血中リン減少 | 0 | 0.0 |
| 血圧上昇 | 0 | 0.0 |
| 白血球数増加 | 0 | 0.0 |
| 血中アルカリホスファターゼ増加 | 0 | 0.0 |
| 便潜血 | 0 | 0.0 |
| 肝機能検査値上昇 | 0 | 0.0 |
| 国際標準比増加 | 0 | 0.0 |
| 遊離トリヨードチロニン減少 | 1 | 0.6 |
| 傷害、中毒および処置合併症 | 0 | 0.0 |
| シャント狭窄 | 0 | 0.0 |
| ワクチン接種合併症 | 0 | 0.0 |
| 挫傷 | 0 | 0.0 |
| 皮膚擦過傷 | 0 | 0.0 |
| シャント閉塞 | 0 | 0.0 |
| 転倒 | 0 | 0.0 |
| 創傷 | 0 | 0.0 |
| 肋骨骨折 | 0 | 0.0 |
| 熱傷 | 0 | 0.0 |
| 熱中症 | 0 | 0.0 |
| シャント機能不全 | 0 | 0.0 |
| 節足動物刺傷 | 0 | 0.0 |
| 靭帯捻挫 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | | MR13A9 1.5 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 引っかき傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚裂傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 透析不均衡症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 節足動物咬傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント血栓症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ワクチン接種後症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 動静脈瘻部位合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 動物咬傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 軟骨損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 仙骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭部損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節脱臼 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膝蓋骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊椎圧迫骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 刺創 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管偽動脈瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尾骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白内障手術合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯牙破折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 処置後炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 処置による疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨挫傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼瞼損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚・皮下組織内異物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 圧迫骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 縫合関連合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋軟骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪裂離 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外科および内科処置 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大腸ポリープ切除 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-3 | | MR13A9-4 | | | | | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.25 ug/kg | | MR13A9 0.5 ug/kg | | MR13A9 1.0 ug/kg | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 引っかき傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚裂傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 透析不均衡症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 節足動物咬傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント血栓症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ワクチン接種後症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 動静脈瘻部位合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 動物咬傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 軟骨損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 仙骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭部損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節脱臼 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膝蓋骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊椎圧迫骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 刺創 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管偽動脈瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尾骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白内障手術合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯牙破折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 処置後炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 処置による疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨挫傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼瞼損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚・皮下組織内異物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 圧迫骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 縫合関連合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋軟骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪裂離 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外科および内科処置 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大腸ポリープ切除 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-4 | | MR13A9-5 (DB) | | | | MR13A9-5 (Entire) | |
|---|---|---|---|---|---|---|---|---|
| Group | Placebo | | MR13A9 0.5 ug/kg | | Placebo | | MR-MR | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 引っかき傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚裂傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 透析不均衡症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 節足動物咬傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント血栓症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ワクチン接種後症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 動静脈瘻部位合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 動物咬傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 軟骨損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 仙骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭部損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節脱臼 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膝蓋骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊椎圧迫骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 刺創 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管偽動脈瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尾骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白内障手術合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯牙破折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 処置後炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 処置による疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨挫傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼瞼損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚・皮下組織内異物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 圧迫骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 縫合関連合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋軟骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪裂離 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外科および内科処置 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大腸ポリープ切除 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | MR13A9-5 (Entire) | | MR13A9-5 (Long-term) | | Overall | | | |
|---|---|---|---|---|---|---|---|---|
| Group | P-MR | | MR13A9 0.5 ug/kg (Long-term) | | MR13A9 0.5 ug/kg | | MR13A9 ALL | |
| Primary SOC, PT | n | % | n | % | n | % | n | % |
| 引っかき傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚裂傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 透析不均衡症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮下血腫 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 節足動物咬傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| シャント血栓症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| ワクチン接種後症候群 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 動静脈瘻部位合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 動物咬傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 軟骨損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 足骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 仙骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 頭部損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 関節脱臼 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 筋損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 膝蓋骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 脊椎圧迫骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 刺創 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 血管偽動脈瘤 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 尾骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 白内障手術合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 四肢損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 歯牙破折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 処置後炎症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 処置による疼痛 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 骨挫傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 眼瞼損傷 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 皮膚・皮下組織内異物 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 圧迫骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 縫合関連合併症 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 肋軟骨骨折 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 爪裂離 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 外科および内科処置 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 大腸ポリープ切除 | 0 | 0.0 | 0 | 0.0 | 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 9.3.3-2 Occurrence of Adverse Drug Reactions - Primary SOC and PT

| Study | Overall | |
|---|---|---|
| Group | Placebo | |
| Primary SOC, PT | n | % |
| 引っかき傷 | 0 | 0.0 |
| シャント瘤 | 0 | 0.0 |
| 皮膚裂傷 | 0 | 0.0 |
| 透析不均衡症候群 | 0 | 0.0 |
| 皮下血腫 | 0 | 0.0 |
| 節足動物咬傷 | 0 | 0.0 |
| シャント血栓症 | 0 | 0.0 |
| ワクチン接種後症候群 | 0 | 0.0 |
| 動静脈瘻部位合併症 | 0 | 0.0 |
| 動物咬傷 | 0 | 0.0 |
| 軟骨損傷 | 0 | 0.0 |
| 足骨折 | 0 | 0.0 |
| 仙骨骨折 | 0 | 0.0 |
| 頭部損傷 | 0 | 0.0 |
| 関節脱臼 | 0 | 0.0 |
| 筋損傷 | 0 | 0.0 |
| 膝蓋骨骨折 | 0 | 0.0 |
| 脊椎圧迫骨折 | 0 | 0.0 |
| 刺創 | 0 | 0.0 |
| 血管偽動脈瘤 | 0 | 0.0 |
| 尾骨骨折 | 0 | 0.0 |
| 白内障手術合併症 | 0 | 0.0 |
| 四肢損傷 | 0 | 0.0 |
| 歯牙破折 | 0 | 0.0 |
| 処置後炎症 | 0 | 0.0 |
| 処置による疼痛 | 0 | 0.0 |
| 骨挫傷 | 0 | 0.0 |
| 眼瞼損傷 | 0 | 0.0 |
| 皮膚・皮下組織内異物 | 0 | 0.0 |
| 圧迫骨折 | 0 | 0.0 |
| 縫合関連合併症 | 0 | 0.0 |
| 肋軟骨骨折 | 0 | 0.0 |
| 爪裂離 | 0 | 0.0 |
| 外科および内科処置 | 0 | 0.0 |
| 大腸ポリープ切除 | 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)