



Clinical trial results:

Protocol I6T-MC-AMAF

A Phase 2, Multicenter, Randomized, Parallel-arm, Placebo-Controlled Study of LY3074828 in Subjects with Moderate to Severe Plaque Psoriasis

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2016-001098-34 |
| Trial protocol | DE PL |
| Global end of trial date | 08 May 2019 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 21 May 2020 |
| First version publication date | 21 May 2020 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | I6T-MC-AMAF |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|---------------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02899988 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Trial Number: 16481 |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Eli Lilly and Company |
| Sponsor organisation address | Lilly Corporate Center, Indianapolis, IN, United States, 46285 |
| Public contact | Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877CTLilly, |
| Scientific contact | Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559, |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|-------------|
| Analysis stage | Final |
| Date of interim/final analysis | 08 May 2019 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 08 May 2019 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this study is to evaluate the efficacy of the study drug mirikizumab in participants with moderate to severe plaque psoriasis.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------------|
| Actual start date of recruitment | 14 September 2016 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety, Efficacy |
| Long term follow-up duration | 4 Months |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Canada: 23 |
| Country: Number of subjects enrolled | United States: 82 |
| Country: Number of subjects enrolled | Japan: 20 |
| Country: Number of subjects enrolled | Poland: 65 |
| Country: Number of subjects enrolled | Germany: 15 |
| Worldwide total number of subjects | 205 |
| EEA total number of subjects | 80 |

Notes:

Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |

| | |
|---------------------------|-----|
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 183 |
| From 65 to 84 years | 22 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

No Text Available

Period 1

| | |
|------------------------------|-----------------------------|
| Period 1 title | Induction Period (16 Weeks) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

Arms

| | |
|------------------------------|--------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Induction: Placebo |

Arm description:

Induction: Participants received placebo subcutaneously (SC) every 8 weeks (Q8W) during Induction period.

| | |
|--|------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Placebo subcutaneously (SC) every 8 weeks (Q8W).

| | |
|------------------|----------------------------------|
| Arm title | Induction: 30 mg Mirikizumab Q8W |
|------------------|----------------------------------|

Arm description:

Induction: Participants received 30 mg mirikizumab SC Q8W during Induction period.

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | |
| Other name | LY3074828 |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

30 mg mirikizumab SC Q8W.

| | |
|------------------|----------------------------------|
| Arm title | Induction:100 mg Mirikizumab Q8W |
|------------------|----------------------------------|

Arm description:

Induction:Participants received 100 mg mirikizumab SC Q8W during Induction period.

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | |
| Other name | LY3074828 |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

100 mg mirikizumab SC Q8W.

| | |
|--|-----------------------------------|
| Arm title | Induction: 300 mg Mirikizumab Q8W |
| Arm description: | |
| Induction: | |
| Participants received 300 mg mirikizumab SC Q8W during Induction period. | |
| Arm type | Experimental |
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | |
| Other name | LY3074828 |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

300 mg mirikizumab SC Q8W.

| Number of subjects in period 1 | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction:100 mg Mirikizumab Q8W |
|--|--------------------|----------------------------------|----------------------------------|
| Started | 52 | 51 | 51 |
| Received at least one dose of study drug | 52 | 51 | 51 |
| Completed | 50 | 49 | 51 |
| Not completed | 2 | 2 | 0 |
| Consent withdrawn by subject | 2 | 1 | - |
| Physician decision | - | 1 | - |
| Adverse event, non-fatal | - | - | - |

| Number of subjects in period 1 | Induction: 300 mg Mirikizumab Q8W |
|--|-----------------------------------|
| Started | 51 |
| Received at least one dose of study drug | 51 |
| Completed | 49 |
| Not completed | 2 |
| Consent withdrawn by subject | - |
| Physician decision | - |
| Adverse event, non-fatal | 2 |

Period 2

| | |
|------------------------------|-------------------------------|
| Period 2 title | Maintenance Period (88 Weeks) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Investigator, Subject |

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|---|
| Arm title | Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN |
|------------------|---|

Arm description:

Maintenance:

Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period.

Participants who had \geq Psoriasis Area and Severity Index (PASI) 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | |
| Other name | LY3074828 |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

30 mg mirikizumab as needed (PRN).

| | |
|------------------|---|
| Arm title | Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN |
|------------------|---|

Arm description:

Maintenance:

Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had \geq PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | |
| Other name | LY3074828 |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

100 mg mirikizumab as needed (PRN).

| | |
|------------------|---|
| Arm title | Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN |
|------------------|---|

Arm description:

Maintenance:

Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had \geq PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|------------------|
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | |
| Other name | LY3074828 |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

300 mg mirikizumab as needed (PRN).

| | |
|------------------|--|
| Arm title | Maintenance: Placebo to 300 mg Mirikizumab Q8W |
|------------------|--|

Arm description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had received placebo during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | |
| Other name | LY3074828 |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

300 mg mirikizumab Q8W.

| | |
|------------------|--|
| Arm title | Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W |
|------------------|--|

Arm description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | |
| Other name | LY3074828 |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

300 mg mirikizumab Q8W.

| | |
|------------------|--|
| Arm title | Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W |
|------------------|--|

Arm description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | |
| Other name | LY3074828 |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

300 mg mirikizumab Q8W.

| | |
|---|-------------------------------------|
| Arm title | Maintenance: 300 mg Mirikizumab Q8W |
| Arm description: | |
| Maintenance: Participants who had < PASI 90 at Week 16 continued to receive 300 mg mirikizumab SC Q8W during maintenance period. | |
| Arm type | Experimental |
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | |
| Other name | LY3074828 |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: | |
| 300 mg mirikizumab SC Q8W. | |

| Number of subjects in period 2 | Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN | Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN | Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN |
|---------------------------------------|---|---|---|
| Started | 15 | 30 | 34 |
| Rescue Participants | 0 ^[1] | 0 ^[2] | 0 ^[3] |
| Roll over to AMAH (NCT03556202) | 9 ^[4] | 18 ^[5] | 26 ^[6] |
| Completed | 13 | 27 | 30 |
| Not completed | 2 | 3 | 4 |
| Consent withdrawn by subject | 1 | - | 3 |
| Adverse event, non-fatal | 1 | 2 | 1 |
| Lost to follow-up | - | 1 | - |

| Number of subjects in period 2 | Maintenance: Placebo to 300 mg Mirikizumab Q8W | Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W | Maintenance: 100 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W |
|---------------------------------------|--|--|---|
| Started | 50 | 34 | 21 |
| Rescue Participants | 0 ^[7] | 0 ^[8] | 0 ^[9] |
| Roll over to AMAH (NCT03556202) | 42 ^[10] | 24 ^[11] | 17 ^[12] |
| Completed | 45 | 30 | 19 |
| Not completed | 5 | 4 | 2 |
| Consent withdrawn by subject | 2 | 2 | - |
| Adverse event, non-fatal | 2 | 2 | 2 |
| Lost to follow-up | 1 | - | - |

| Number of subjects in period 2 | Maintenance: 300 mg Mirikizumab Q8W |
|---------------------------------------|-------------------------------------|
| Started | 15 |
| Rescue Participants | 0 ^[13] |
| Roll over to AMAH (NCT03556202) | 0 ^[14] |

| | |
|------------------------------|----|
| Completed | 13 |
| Not completed | 2 |
| Consent withdrawn by subject | 1 |
| Adverse event, non-fatal | 1 |
| Lost to follow-up | - |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started to maintenance period.

[11] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[12] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[13] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

[14] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: It's a milestone independent of the number that started maintenance period.

Period 3

| | |
|------------------------------|-------------------------|
| Period 3 title | Follow-Up (16 Weeks) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

Arms

| | |
|------------------------------|---|
| Are arms mutually exclusive? | Yes |
| Arm title | Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN |

Arm description:

Maintenance:

Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period.

Participants who had \geq PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|---|---|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |
| Arm title | Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN |

Arm description:

Maintenance:

Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had \geq PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|---|---|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |
| Arm title | Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN |

Arm description:

Maintenance:

Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had \geq PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|---|--|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |
| Arm title | Maintenance: Placebo to 300 mg Mirikizumab Q8W |

Arm description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had received placebo during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|---|--|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |
| Arm title | Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W |

Arm description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|---|--|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |
| Arm title | Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W |

Arm description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|---|-----------------|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |

| Number of subjects in period 3^[15] | Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN | Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN | Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN |
|--|---|---|---|
| Started | 2 | 2 | 3 |
| Completed | 2 | 2 | 3 |

| Number of subjects in period 3^[15] | Maintenance: Placebo to 300 mg Mirikizumab Q8W | Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W | Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W |
|--|--|--|--|
| Started | 3 | 6 | 2 |
| Completed | 3 | 6 | 2 |

Notes:

[15] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all participants that completed maintenance period continued to follow-up period.

Baseline characteristics

Reporting groups

| | |
|---|-----------------------------------|
| Reporting group title | Induction: Placebo |
| Reporting group description: | |
| Induction: Participants received placebo subcutaneously (SC) every 8 weeks (Q8W) during Induction period. | |
| Reporting group title | Induction: 30 mg Mirikizumab Q8W |
| Reporting group description: | |
| Induction: Participants received 30 mg mirikizumab SC Q8W during Induction period. | |
| Reporting group title | Induction:100 mg Mirikizumab Q8W |
| Reporting group description: | |
| Induction:Participants received 100 mg mirikizumab SC Q8W during Induction period. | |
| Reporting group title | Induction: 300 mg Mirikizumab Q8W |
| Reporting group description: | |
| Induction: | |
| Participants received 300 mg mirikizumab SC Q8W during Induction period. | |

| Reporting group values | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction:100 mg Mirikizumab Q8W |
|------------------------|--------------------|----------------------------------|----------------------------------|
| Number of subjects | 52 | 51 | 51 |
| Age categorical | | | |
| Units: Subjects | | | |

| | | | |
|---|---------|---------|---------|
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 46.0 | 49.2 | 46.0 |
| standard deviation | ± 12.39 | ± 13.28 | ± 13.18 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 10 | 12 | 16 |
| Male | 42 | 39 | 35 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 8 | 7 | 4 |
| Not Hispanic or Latino | 39 | 37 | 42 |
| Unknown or Not Reported | 5 | 7 | 5 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 6 | 7 | 7 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 1 | 1 | 3 |
| White | 44 | 43 | 41 |
| More than one race | 1 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Region of Enrollment | | | |
| Units: Subjects | | | |
| Canada | 4 | 7 | 7 |

| | | | |
|---------------|----|----|----|
| United States | 21 | 20 | 18 |
| Japan | 4 | 7 | 5 |
| Poland | 19 | 14 | 18 |
| Germany | 4 | 3 | 3 |

| Reporting group values | Induction: 300 mg Mirikizumab Q8W | Total | |
|------------------------------------|--------------------------------------|-------|--|
| Number of subjects | 51 | 205 | |
| Age categorical Units: Subjects | | | |

| | | | |
|---|-----------------|-----|--|
| Age continuous Units: years arithmetic mean standard deviation | 47.5 ± 13.23 | - | |
| Gender categorical Units: Subjects | | | |
| Female | 15 | 53 | |
| Male | 36 | 152 | |
| Ethnicity (NIH/OMB) Units: Subjects | | | |
| Hispanic or Latino | 5 | 24 | |
| Not Hispanic or Latino | 42 | 160 | |
| Unknown or Not Reported | 4 | 21 | |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | |
| Asian | 6 | 26 | |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | |
| Black or African American | 3 | 8 | |
| White | 42 | 170 | |
| More than one race | 0 | 1 | |
| Unknown or Not Reported | 0 | 0 | |
| Region of Enrollment Units: Subjects | | | |
| Canada | 5 | 23 | |
| United States | 23 | 82 | |
| Japan | 4 | 20 | |
| Poland | 14 | 65 | |
| Germany | 5 | 15 | |

End points

End points reporting groups

| | |
|---|---|
| Reporting group title | Induction: Placebo |
| Reporting group description: Induction: Participants received placebo subcutaneously (SC) every 8 weeks (Q8W) during Induction period. | |
| Reporting group title | Induction: 30 mg Mirikizumab Q8W |
| Reporting group description: Induction: Participants received 30 mg mirikizumab SC Q8W during Induction period. | |
| Reporting group title | Induction: 100 mg Mirikizumab Q8W |
| Reporting group description: Induction: Participants received 100 mg mirikizumab SC Q8W during Induction period. | |
| Reporting group title | Induction: 300 mg Mirikizumab Q8W |
| Reporting group description: Induction: Participants received 300 mg mirikizumab SC Q8W during Induction period. | |
| Reporting group title | Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN |
| Reporting group description: Maintenance: Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period. Participants who had \geq Psoriasis Area and Severity Index (PASI) 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period. | |
| Follow-up: participants did not receive drug during the follow-up period. | |
| Reporting group title | Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN |
| Reporting group description: Maintenance: Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period. Participants had \geq PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period. | |
| Follow-up: participants did not receive drug during the follow-up period. | |
| Reporting group title | Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN |
| Reporting group description: Maintenance: Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period. | |
| Participants had \geq PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period. | |
| Follow-up: participants did not receive drug during the follow-up period. | |
| Reporting group title | Maintenance: Placebo to 300 mg Mirikizumab Q8W |
| Reporting group description: Maintenance: Participants received 300 mg mirikizumab Q8W during the maintenance period. Participants had received placebo during induction period. | |
| Follow-up: Participants did not receive drug during the follow-up period. | |
| Reporting group title | Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W |
| Reporting group description: Maintenance: Participants received 300 mg mirikizumab Q8W during the maintenance period. Participants had $<$ PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period. | |

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|-----------------------|--|
| Reporting group title | Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W |
|-----------------------|--|

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|-----------------------|-------------------------------------|
| Reporting group title | Maintenance: 300 mg Mirikizumab Q8W |
|-----------------------|-------------------------------------|

Reporting group description:

Maintenance:

Participants who had < PASI 90 at Week 16 continued to receive 300 mg mirikizumab SC Q8W during maintenance period.

| | |
|-----------------------|---|
| Reporting group title | Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN |
|-----------------------|---|

Reporting group description:

Maintenance:

Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period.

Participants who had \geq PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|-----------------------|---|
| Reporting group title | Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN |
|-----------------------|---|

Reporting group description:

Maintenance:

Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had \geq PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|-----------------------|---|
| Reporting group title | Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN |
|-----------------------|---|

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had \geq PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|-----------------------|--|
| Reporting group title | Maintenance: Placebo to 300 mg Mirikizumab Q8W |
|-----------------------|--|

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had received placebo during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|-----------------------|--|
| Reporting group title | Maintenance: 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W |
|-----------------------|--|

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|-----------------------|--|
| Reporting group title | Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W |
|-----------------------|--|

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

Follow-up: participants did not receive drug during the follow-up period.

| | |
|----------------------------|------------------------------|
| Subject analysis set title | Induction: 30 mg Mirikizumab |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Induction: 30 mg Mirikizumab administered SC every 8 weeks (Q8W).

| | |
|----------------------------|-------------------------------|
| Subject analysis set title | Induction: 100 mg Mirikizumab |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Induction: 100 mg Mirikizumab administered SC Q8W.

| | |
|----------------------------|-------------------------------|
| Subject analysis set title | Induction: 300 mg Mirikizumab |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Induction: 300 mg Mirikizumab administered SC Q8W.

| | |
|----------------------------|--|
| Subject analysis set title | 30 mg mirikizumab Q8W To 30 mg mirikizumab PRN |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had \geq PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

| | |
|----------------------------|--|
| Subject analysis set title | 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had \geq PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

| | |
|----------------------------|--|
| Subject analysis set title | 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had \geq PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period.

| | |
|----------------------------|-----------------------------------|
| Subject analysis set title | Placebo to 300 mg Mirikizumab Q8W |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had received placebo during induction period.

| | |
|----------------------------|---|
| Subject analysis set title | 30 mg mirikizumab Q8W to 300 mg mirikizumab Q8W |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

| | |
|----------------------------|--|
| Subject analysis set title | 100 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants received 300 mg mirikizumab Q8W during the maintenance period.

Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

| | |
|----------------------------|--|
| Subject analysis set title | 300 mg mirikizumab SC Q8W To 300 mg mirikizumab SC Q8W |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants received 300 mg mirikizumab SC Q8W during Induction period.

Participants had < PASI 90 at Week 16 continued to receive 300 mg mirikizumab SC Q8W during maintenance period.

Primary: Percentage of Participants with a $\geq 90\%$ Improvement in Psoriasis Area and Severity Index (PASI 90)

| | |
|-----------------|--|
| End point title | Percentage of Participants with a $\geq 90\%$ Improvement in Psoriasis Area and Severity Index (PASI 90) |
|-----------------|--|

End point description:

PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no psoriasis (PsO) to 72 for the most severe disease. For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no PsO) to 72 (the most severe disease).

Analysis Population Description: All participants who received at least one dose of study drug.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Week 16

| End point values | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction: 100 mg Mirikizumab Q8W | Induction: 300 mg Mirikizumab Q8W |
|-----------------------------------|--------------------|----------------------------------|-----------------------------------|-----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 52 | 51 | 51 | 51 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0 to 0) | 29.4 (16.9 to 41.9) | 58.8 (45.3 to 72.3) | 66.7 (53.7 to 79.6) |

Statistical analyses

| | |
|----------------------------|--|
| Statistical analysis title | Participants With a $\geq 90\%$ Improvement in PASI 90 |
|----------------------------|--|

Statistical analysis description:

Participants With a $\geq 90\%$ Improvement in PASI 90

| | |
|---|---|
| Comparison groups | Induction: Placebo v Induction: 30 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.009 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 29.4 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 16.9 |
| upper limit | 41.9 |

| | |
|---|--|
| Statistical analysis title | Participants With a $\geq 90\%$ Improvement in PASI 90 |
| Comparison groups | Induction: Placebo v Induction: 100 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 58.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 45.3 |
| upper limit | 72.3 |

| | |
|---|--|
| Statistical analysis title | Participants With a $\geq 90\%$ Improvement in PASI 90 |
| Comparison groups | Induction: Placebo v Induction: 300 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 66.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 53.7 |
| upper limit | 79.6 |

Secondary: Percentage of Participants with a 100% Improvement in Psoriasis Area and Severity Index (PASI 100)

| | |
|-----------------|--|
| End point title | Percentage of Participants with a 100% Improvement in Psoriasis Area and Severity Index (PASI 100) |
|-----------------|--|

End point description:

The PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no PsO to 72 for the most severe disease. For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated

by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no PsO) to 72 (the most severe disease).

Analysis Population Description: All participants who received at least one dose of study drug.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 16 | |

| End point values | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction:100 mg Mirikizumab Q8W | Induction: 300 mg Mirikizumab Q8W |
|-----------------------------------|--------------------|----------------------------------|----------------------------------|-----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 52 | 51 | 51 | 51 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0 to 0) | 15.7 (5.7 to 25.7) | 31.4 (18.6 to 44.1) | 31.4 (18.6 to 44.1) |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Participants with a 100% Improvement in PASI 100 |
| Comparison groups | Induction: Placebo v Induction: 30 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.039 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 15.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.7 |
| upper limit | 25.7 |

| | |
|---|---|
| Statistical analysis title | Participants with a 100% Improvement in PASI 100 |
| Comparison groups | Induction: Placebo v Induction:100 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.007 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 31.4 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 18.6 |
| upper limit | 44.1 |

| | |
|---|--|
| Statistical analysis title | Participants with a 100% Improvement in PASI 100 |
| Comparison groups | Induction: Placebo v Induction: 300 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.007 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 31.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 18.6 |
| upper limit | 44.1 |

Secondary: Percentage of Participants with a $\geq 75\%$ Improvement in Psoriasis Area and Severity Index (PASI 75)

| | |
|-----------------|--|
| End point title | Percentage of Participants with a $\geq 75\%$ Improvement in Psoriasis Area and Severity Index (PASI 75) |
|-----------------|--|

End point description:

The PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no PsO to 72 for the most severe disease. For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no PsO) to 72 (the most severe disease).

Analysis Population Description: All participants who received at least one dose of study drug.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 16 | |

| End point values | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction:100 mg Mirikizumab Q8W | Induction: 300 mg Mirikizumab Q8W |
|-----------------------------------|-----------------------|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 52 | 51 | 51 | 51 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 3.8 (0 to 9.1) | 52.9 (39.2 to 66.6) | 78.4 (67.1 to 89.7) | 74.5 (62.5 to 86.5) |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Participants With a $\geq 75\%$ Improvement in PASI 75 |
| Comparison groups | Induction: Placebo v Induction: 30 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 22.49 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.62 |
| upper limit | 89.97 |

| | |
|---|--|
| Statistical analysis title | Participants With a $\geq 75\%$ Improvement in PASI 75 |
| Comparison groups | Induction: Placebo v Induction:100 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 74.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 62.1 |
| upper limit | 87 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Participants With a $\geq 75\%$ Improvement in PASI 75 |
| Comparison groups | Induction: Placebo v Induction: 300 mg Mirikizumab Q8W |

| | |
|---|----------------------|
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 70.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 57.6 |
| upper limit | 83.7 |

Secondary: Percentage of Participants with a Static Physician Global Assessment (sPGA) 0 and 0/1

| | |
|-----------------|---|
| End point title | Percentage of Participants with a Static Physician Global Assessment (sPGA) 0 and 0/1 |
|-----------------|---|

End point description:

The sPGA is the physician's determination of the participant's PsO lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participant's PsO was assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe). An sPGA responder was defined as having a post-baseline sPGA score of "0" or "1" with at least a 2-point improvement from baseline. Participants who did not meet the clinical response criteria or had missing data at Week 16 were considered non-responders for non-responder Imputation (NRI) analysis.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 16 | |

| End point values | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction: 100 mg Mirikizumab Q8W | Induction: 300 mg Mirikizumab Q8W |
|-----------------------------------|--------------------|----------------------------------|-----------------------------------|-----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 52 | 51 | 51 | 51 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| sPGA (0) | 0 (0 to 0) | 15.7 (5.7 to 25.7) | 31.4 (18.6 to 44.1) | 31.4 (18.6 to 44.1) |
| sPGA (0/1) | 1.9 (0 to 5.7) | 37.3 (24.0 to 50.5) | 70.6 (58.1 to 83.1) | 68.6 (55.9 to 81.4) |

Statistical analyses

| | |
|-----------------------------------|---|
| Statistical analysis title | Participants With sPGA 0 and 0/1 |
| Statistical analysis description: | |
| sPGA (0) | |
| Comparison groups | Induction: Placebo v Induction: 30 mg Mirikizumab Q8W |

| | |
|---|----------------------------|
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[1] |
| P-value | = 0.041 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 15.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.7 |
| upper limit | 25.7 |

Notes:

[1] - sPGA (0)

| | |
|---|---|
| Statistical analysis title | Participants With sPGA 0 and 0/1 |
| Statistical analysis description: sPGA (0) | |
| Comparison groups | Induction: Placebo v Induction:100 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[2] |
| P-value | = 0.007 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 31.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 18.6 |
| upper limit | 44.1 |

Notes:

[2] - sPGA (0)

| | |
|---|--|
| Statistical analysis title | Participants With sPGA 0 and 0/1 |
| Statistical analysis description: sPGA (0) | |
| Comparison groups | Induction: Placebo v Induction: 300 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[3] |
| P-value | = 0.008 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 31.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 18.6 |
| upper limit | 44.1 |

Notes:

[3] - sPGA (0)

| | |
|---|---|
| Statistical analysis title | Participants With sPGA 0 and 0/1 |
| Statistical analysis description: sPGA (0/1) | |
| Comparison groups | Induction: Placebo v Induction: 30 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[4] |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 35.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 21.5 |
| upper limit | 49.1 |

Notes:

[4] - sPGA (0/1)

| | |
|---|---|
| Statistical analysis title | Participants With sPGA 0 and 0/1 |
| Statistical analysis description: sPGA (0/1) | |
| Comparison groups | Induction: Placebo v Induction:100 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[5] |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 68.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 55.6 |
| upper limit | 81.7 |

Notes:

[5] - sPGA (0/1)

| | |
|---|--|
| Statistical analysis title | Participants With sPGA 0 and 0/1 |
| Statistical analysis description: sPGA (0/1) | |
| Comparison groups | Induction: Placebo v Induction: 300 mg Mirikizumab Q8W |

| | |
|---|----------------------------|
| Number of subjects included in analysis | 103 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[6] |
| P-value | < 0.001 |
| Method | Regression, Logistic |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 66.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 53.4 |
| upper limit | 80 |

Notes:

[6] - sPGA (0/1)

Secondary: Mean Change from Baseline on the Psoriasis Symptom Scale (PSS)

| | |
|-----------------|--|
| End point title | Mean Change from Baseline on the Psoriasis Symptom Scale (PSS) |
|-----------------|--|

End point description:

The Psoriasis Symptoms Scale is a patient-administered assessment of 4 symptoms (itch,pain,stinging,and burning); 3 signs(redness,scaling, and cracking); and 1 item on the discomfort related to symptoms/signs.The overall severity for each individual symptom/sign from the patient's psoriasis is indicated by selecting the number from a numeric rating scale(NRS) of 0 to 10 that best describes the worst

level of each symptom/sign in the past 24 hours, where 0=no symptom/sign and 10=worst imaginable symptom/sign. Least Square (LS) Mean was calculated using Mixed Model Repeated Measures (MMRM) model with treatment, geographic region [United States/Outside United States(US/OUS)], previous therapy(yes/no), baseline value,visit, and the interaction treatment-by-visit as fixed factors,covariance structure=heterogeneous autoregressive.

Analysis Population Description:All participants who received at least one dose of study drug who had baseline and at least one post-baseline PSS observation.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 16 | |

| End point values | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction:100 mg Mirikizumab Q8W | Induction: 300 mg Mirikizumab Q8W |
|-------------------------------------|--------------------|----------------------------------|----------------------------------|-----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 43 | 43 | 44 | 44 |
| Units: units on a scale | | | | |
| least squares mean (standard error) | -4.35 (± 2.29) | -31.19 (± 2.34) | -42.33 (± 2.37) | -33.66 (± 2.27) |

Statistical analyses

| | |
|----------------------------|-----------------------------|
| Statistical analysis title | Change from Baseline on PSS |
|----------------------------|-----------------------------|

Statistical analysis description:

Change from Baseline on PSS.

| | |
|---|---|
| Comparison groups | Induction: Placebo v Induction: 30 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 86 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -26.84 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -33.27 |
| upper limit | -20.42 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 3.26 |

| | |
|---|---|
| Statistical analysis title | Change from Baseline on PSS |
| Comparison groups | Induction: Placebo v Induction:100 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 87 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -37.99 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -44.47 |
| upper limit | -31.51 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 3.29 |

| | |
|---|--|
| Statistical analysis title | Change from Baseline on PSS. |
| Comparison groups | Induction: Placebo v Induction: 300 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 87 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -29.32 |

| | |
|----------------------|----------------------------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -35.66 |
| upper limit | -22.97 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 3.22 |

Secondary: Mean Change (Improvement) from Baseline on the Patient Global Assessment (PGA)

| | |
|-----------------|--|
| End point title | Mean Change (Improvement) from Baseline on the Patient Global Assessment (PGA) |
|-----------------|--|

End point description:

The Patient's Global Assessment of Disease Severity is a single-item participant-reported outcome measure on which participants are asked to rate the severity of their psoriasis "today" from 0 (Clear) = no psoriasis, to 5 (Severe) = the worst their psoriasis has ever been. Least Square (LS) Mean was calculated using Mixed Model Repeated Measures (MMRM) model with treatment, geographic region (US/OUS), previous therapy (yes/no), baseline value, visit, and the interaction treatment-by-visit as fixed factors, covariance structure = unstructured.

Analysis Population Description: All participants who received at least one dose of study drug who had baseline and at least one post-baseline Patient Global Assessment observation.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

| End point values | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction: 100 mg Mirikizumab Q8W | Induction: 300 mg Mirikizumab Q8W |
|-------------------------------------|--------------------|----------------------------------|-----------------------------------|-----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 51 | 48 | 51 | 49 |
| Units: units on a scale | | | | |
| least squares mean (standard error) | 0.35 (± 0.16) | 2.24 (± 0.16) | 2.91 (± 0.16) | 2.82 (± 0.16) |

Statistical analyses

| | |
|----------------------------|--|
| Statistical analysis title | Mean Change (Improvement) From Baseline on PGA |
|----------------------------|--|

Statistical analysis description:

Mean Change (Improvement) From Baseline on PGA

| | |
|-------------------|---|
| Comparison groups | Induction: Placebo v Induction: 30 mg Mirikizumab Q8W |
|-------------------|---|

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 99 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 1.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.45 |
| upper limit | 2.34 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.22 |

| | |
|---|---|
| Statistical analysis title | Mean Change (Improvement) From Baseline on PGA |
| Comparison groups | Induction:100 mg Mirikizumab Q8W v Induction: Placebo |
| Number of subjects included in analysis | 102 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 2.56 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.23 |
| upper limit | 3 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.22 |

| | |
|---|--|
| Statistical analysis title | Mean Change (Improvement) From Baseline on PGA |
| Comparison groups | Induction: Placebo v Induction: 300 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 100 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 2.47 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.03 |
| upper limit | 2.91 |

| | |
|----------------------|----------------------------|
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.22 |

Secondary: Mean Change from Baseline on the Dermatology Life Quality Index (DLQI) Total Score

| | |
|-----------------|--|
| End point title | Mean Change from Baseline on the Dermatology Life Quality Index (DLQI) Total Score |
|-----------------|--|

End point description:

The DLQI is patient-reported, 10-question, validated, quality-of-life questionnaire that covers 6 domains including symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Response categories include "Not at all," "A little," "A lot," and "Very much," with corresponding scores of 0, 1, 2, and 3 respectively. Questions 3-10 also have an additional response category of "Not relevant" which is scored as "0". For all questions, if unanswered the question is scored as "0". Totals range from 0 to 30 (less to more impairment). Least Square (LS) Mean was calculated using Mixed Model Repeated Measures (MMRM) model with treatment, geographic region (US/OUS), previous therapy (yes/no), baseline value, visit, and the interaction treatment-by-visit as fixed factors, covariance structure = unstructured.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

Analysis Population Description: All participants who received at least one dose of study drug who had baseline and at least one post-baseline DLQI observation.

| End point values | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction: 100 mg Mirikizumab Q8W | Induction: 300 mg Mirikizumab Q8W |
|-------------------------------------|--------------------|----------------------------------|-----------------------------------|-----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 51 | 48 | 51 | 49 |
| Units: score on a scale | | | | |
| least squares mean (standard error) | -1.07 (± 0.69) | -9.19 (± 0.71) | -10.18 (± 0.69) | -9.64 (± 0.70) |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Mean Change From Baseline on DLQI Total Score |
| Comparison groups | Induction: Placebo v Induction: 30 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 99 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -8.12 |

| | |
|----------------------|----------------------------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.05 |
| upper limit | -6.19 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.98 |

| | |
|---|---|
| Statistical analysis title | Mean Change From Baseline on DLQI Total Score |
| Comparison groups | Induction: Placebo v Induction:100 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 102 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -9.11 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -11.02 |
| upper limit | -7.2 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.97 |

| | |
|---|--|
| Statistical analysis title | Mean Change From Baseline on DLQI Total Score |
| Comparison groups | Induction: Placebo v Induction: 300 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 100 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -8.57 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.5 |
| upper limit | -6.65 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.98 |

Secondary: Mean Change from Baseline on the 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary

(MCS) Scores

| | |
|-----------------|--|
| End point title | Mean Change from Baseline on the 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores |
|-----------------|--|

End point description:

The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (MCS and PCS). MCS consisted of social functioning, vitality, mental health, and role-emotional scales. PCS consisted of physical functioning, bodily pain, role-physical, and general health scales. Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning. Least Squares Mean (LS Mean) was calculated using Analysis of covariance (ANCOVA) model with treatment, geographic region (US/OUS), and previous therapy (yes/no) as fixed factors and baseline value as covariate.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 16

Analysis Population Description: All participants who received at least one dose of study drug with a baseline value and at least 1 post-baseline value.

| End point values | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction: 100 mg Mirikizumab Q8W | Induction: 300 mg Mirikizumab Q8W |
|-------------------------------------|--------------------|----------------------------------|-----------------------------------|-----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 51 | 48 | 51 | 49 |
| Units: score on a scale | | | | |
| least squares mean (standard error) | | | | |
| MCS | 0.28 (± 0.87) | 2.39 (± 0.90) | 2.74 (± 0.88) | 1.52 (± 0.88) |
| PCS | 1.23 (± 0.84) | 4.58 (± 0.88) | 4.40 (± 0.85) | 5.09 (± 0.85) |

Statistical analyses

| | |
|----------------------------|--|
| Statistical analysis title | Mean Change From Baseline on SF-36 PCS and MCS |
|----------------------------|--|

Statistical analysis description:

Mental Component Summary (MCS).

| | |
|---|---|
| Comparison groups | Induction: Placebo v Induction: 30 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 99 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[7] |
| P-value | = 0.009 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 2.11 |

| | |
|----------------------|----------------------------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.34 |
| upper limit | 4.56 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.24 |

Notes:

[7] - Mental Component Summary (MCS).

| | |
|--|---|
| Statistical analysis title | Mean Change From Baseline on SF-36 PCS and MCS |
| Statistical analysis description: Mental Component Summary (MCS). | |
| Comparison groups | Induction: Placebo v Induction:100 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 102 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[8] |
| P-value | = 0.002 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 2.74 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.06 |
| upper limit | 4.88 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.22 |

Notes:

[8] - Mental Component Summary (MCS)

| | |
|--|--|
| Statistical analysis title | Mean Change From Baseline on SF-36 PCS and MCS |
| Statistical analysis description: Mental Component Summary (MCS). | |
| Comparison groups | Induction: Placebo v Induction: 300 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 100 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[9] |
| P-value | = 0.087 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 1.52 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.19 |
| upper limit | 3.68 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.24 |

Notes:

[9] - Mental Component Summary (MCS).

| | |
|---|---|
| Statistical analysis title | Mean Change From Baseline on SF-36 PCS and MCS |
| Statistical analysis description: Physical Component Summary | |
| Comparison groups | Induction: Placebo v Induction: 30 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 99 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[10] |
| P-value | < 0.001 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 3.35 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.98 |
| upper limit | 5.72 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.2 |

Notes:

[10] - Physical Component Summary

| | |
|---|---|
| Statistical analysis title | Mean Change From Baseline on SF-36 PCS and MCS |
| Statistical analysis description: Physical Component Summary | |
| Comparison groups | Induction: Placebo v Induction:100 mg Mirikizumab Q8W |
| Number of subjects included in analysis | 102 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[11] |
| P-value | < 0.001 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 3.16 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.84 |
| upper limit | 5.49 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.18 |

Notes:

[11] - Physical Component Summary

| | |
|---|--|
| Statistical analysis title | Mean Change From Baseline on SF-36 PCS and MCS |
| Statistical analysis description: Physical Component Summary | |
| Comparison groups | Induction: Placebo v Induction: 300 mg Mirikizumab Q8W |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 100 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[12] |
| P-value | < 0.001 |
| Method | ANCOVA |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 3.86 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.51 |
| upper limit | 6.21 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.19 |

Notes:

[12] - Physical Component Summary

Secondary: Pharmacokinetics (PK): Area Under the Curve (AUC) of Mirikizumab From Baseline through Week 104

| | |
|-----------------|---|
| End point title | Pharmacokinetics (PK): Area Under the Curve (AUC) of Mirikizumab From Baseline through Week 104 |
|-----------------|---|

End point description:

Pharmacokinetics (PK): Area Under the Curve (AUC) of Mirikizumab From Baseline Through Week 104.

Analysis Population Description: All participants who received at least one dose of study drug and had evaluable PK data.

The geometric coefficient of variation presented is "%" and not "±". Due to system limitation, the system populates data field with "±".

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Week 0, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 32, Week 40, Week 48, Week 52, Week 56, Week 64, Week 72, Week 80, Week 88, Week 96, Week 100, Week 104

| End point values | 30 mg mirikizumab Q8W To 30 mg mirikizumab PRN | 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN | 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN | Placebo to 300 mg Mirikizumab Q8W |
|---|--|--|--|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 13 | 23 | 33 | 50 |
| Units: nanogram*hour per milliliter (ng*hr/mL) | | | | |
| geometric mean (geometric coefficient of variation) | 3.22 (± 46.33) | 8.94 (± 79.19) | 22.96 (± 55.80) | 46.4 (± 62.8) |

| End point values | 30 mg mirikizumab Q8W to 300 | 100 mg Mirikizumab Q8W to 300 | 300 mg mirikizumab SC Q8W To | |
|------------------|------------------------------|-------------------------------|------------------------------|--|
|------------------|------------------------------|-------------------------------|------------------------------|--|

| | mg mirikizumab Q8W | mg MirikizumabQ8 W | 300 mg mirikizumab SC Q8W | |
|--|--------------------------|--------------------------|---------------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 34 | 21 | 15 | |
| Units: nanogram*hour per milliliter (ng*hr/mL) | | | | |
| geometric mean (geometric coefficient of variation) | 34.83 (± 92.13) | 47.66 (± 70.08) | 51.30 (± 43.54) | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up To 120 Weeks

Adverse event reporting additional description:

All participants who received at least one dose of study drug.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 22.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--------------------|
| Reporting group title | Induction: Placebo |
|-----------------------|--------------------|

Reporting group description:

Induction: Participants received placebo SC Q8W during Induction period.

| | |
|-----------------------|----------------------------------|
| Reporting group title | Induction: 30 mg Mirikizumab Q8W |
|-----------------------|----------------------------------|

Reporting group description:

Induction: Participants received 30 mg mirikizumab Q8W during Induction period.

| | |
|-----------------------|-----------------------------------|
| Reporting group title | Induction: 100 mg Mirikizumab Q8W |
|-----------------------|-----------------------------------|

Reporting group description:

Induction: Participants received 100 mg mirikizumab SC Q8W during Induction period.

| | |
|-----------------------|-----------------------------------|
| Reporting group title | Induction: 300 mg Mirikizumab Q8W |
|-----------------------|-----------------------------------|

Reporting group description:

Induction: Participants received 300 mg mirikizumab SC Q8W during Induction period.

| | |
|-----------------------|---|
| Reporting group title | Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN |
|-----------------------|---|

Reporting group description:

Maintenance:

Participants received 30 mg mirikizumab as needed (PRN) during the maintenance period.

Participants who had \geq PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

| | |
|-----------------------|---|
| Reporting group title | Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN |
|-----------------------|---|

Reporting group description:

Maintenance:

Participants received 100 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had \geq PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

| | |
|-----------------------|---|
| Reporting group title | Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN |
|-----------------------|---|

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab as needed (PRN) during the maintenance period.

Participants had \geq PASI 90 at Week 16 after receiving 300 mg mirikizumab Q8W during induction period.

| | |
|-----------------------|--|
| Reporting group title | Maintenance: Placebo to 300 mg Mirikizumab Q8W |
|-----------------------|--|

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period. Participants had

received placebo during induction period.

| | |
|-----------------------|--|
| Reporting group title | Maintenance: 30 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W |
|-----------------------|--|

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period. Participants had < PASI 90 at Week 16 after receiving 30 mg mirikizumab Q8W during induction period.

| | |
|-----------------------|---|
| Reporting group title | Maintenance: 100 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W |
|-----------------------|---|

Reporting group description:

Maintenance:

Participants received 300 mg mirikizumab Q8W during the maintenance period. Participants had < PASI 90 at Week 16 after receiving 100 mg mirikizumab Q8W during induction period.

| | |
|-----------------------|-------------------------------------|
| Reporting group title | Maintenance: 300 mg Mirikizumab Q8W |
|-----------------------|-------------------------------------|

Reporting group description:

Maintenance:

Participants who had < PASI 90 at Week 16 continued to receive 300 mg mirikizumab SC Q8W during maintenance period.

| | |
|-----------------------|-------------------------------|
| Reporting group title | 300 mg Mirikizumab Q8W-Rescue |
|-----------------------|-------------------------------|

Reporting group description:

Participants received 300 mg Q8W mirikizumab during rescue.

| | |
|-----------------------|--|
| Reporting group title | 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN-Follow-up |
|-----------------------|--|

Reporting group description:

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|-----------------------|--|
| Reporting group title | 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN-Follow-up |
|-----------------------|--|

Reporting group description:

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|-----------------------|--|
| Reporting group title | 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN-Follow-up |
|-----------------------|--|

Reporting group description:

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|-----------------------|---|
| Reporting group title | Placebo to 300 mg Mirikizumab Q8W-Follow-up |
|-----------------------|---|

Reporting group description:

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|-----------------------|---|
| Reporting group title | 30 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W-Follow-up |
|-----------------------|---|

Reporting group description:

Follow-up: Participants did not receive drug during the follow-up period.

| | |
|-----------------------|--|
| Reporting group title | 100 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W-Follow-up |
|-----------------------|--|

Reporting group description:

100 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W-Follow-up.

| Serious adverse events | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction: 100 mg Mirikizumab Q8W |
|---|--------------------|----------------------------------|-----------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 52 (1.92%) | 1 / 51 (1.96%) | 0 / 51 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| | | | |
|--|----------------|----------------|----------------|
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| colon cancer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intraocular melanoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung neoplasm malignant | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| femur fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Cardiac disorders | | | |
| atrial fibrillation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| nasal septal operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| cerebral haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| enlarged uvula | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| suicidal ideation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 52 (1.92%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| endocarditis bacterial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyelonephritis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|------------------------------------|--------------------------------------|--|--|
| Serious adverse events | Induction: 300 mg Mirikizumab Q8W | Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN | Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN |
| Total subjects affected by serious | | | |

| | | | |
|---|----------------|----------------|----------------|
| adverse events | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 1 / 15 (6.67%) | 2 / 30 (6.67%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| colon cancer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intraocular melanoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung neoplasm malignant | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| femur fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| atrial fibrillation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| nasal septal operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| cerebral haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| enlarged uvula | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |

| | | | |
|--|----------------------------------|----------------------------------|----------------------------------|
| nephrolithiasis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 51 (0.00%) 0 / 0 0 / 0 | 0 / 15 (0.00%) 0 / 0 0 / 0 | 0 / 30 (0.00%) 0 / 0 0 / 0 |
| Psychiatric disorders suicidal ideation alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 51 (1.96%) 0 / 1 0 / 0 | 0 / 15 (0.00%) 0 / 0 0 / 0 | 0 / 30 (0.00%) 0 / 0 0 / 0 |
| Infections and infestations endocarditis bacterial alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 51 (0.00%) 0 / 0 0 / 0 | 0 / 15 (0.00%) 0 / 0 0 / 0 | 1 / 30 (3.33%) 1 / 1 0 / 0 |
| erysipelas alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 51 (0.00%) 0 / 0 0 / 0 | 0 / 15 (0.00%) 0 / 0 0 / 0 | 0 / 30 (0.00%) 0 / 0 0 / 0 |
| pneumonia alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 51 (0.00%) 0 / 0 0 / 0 | 0 / 15 (0.00%) 0 / 0 0 / 0 | 0 / 30 (0.00%) 0 / 0 0 / 0 |
| pyelonephritis acute alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 51 (0.00%) 0 / 0 0 / 0 | 0 / 15 (0.00%) 0 / 0 0 / 0 | 0 / 30 (0.00%) 0 / 0 0 / 0 |

| | | | |
|-------------------------------|---------------------------------|--------------------------------|---------------------------------------|
| Serious adverse events | Maintenance: 300 mg Mirikizumab | Maintenance: Placebo to 300 mg | Maintenance: 30 mg Mirikizumab Q8W to |
|-------------------------------|---------------------------------|--------------------------------|---------------------------------------|

| | Q8W to 300 mg Mirikizumab PRN | Mirikizumab Q8W | 300 mg Mirikizumab Q8W |
|---|----------------------------------|-----------------|---------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 34 (2.94%) | 2 / 50 (4.00%) | 2 / 34 (5.88%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| colon cancer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intraocular melanoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung neoplasm malignant | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|--|----------------------------------|----------------------------------|----------------------------------|
| femur fracture alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 34 (0.00%) 0 / 0 0 / 0 | 0 / 50 (0.00%) 0 / 0 0 / 0 | 0 / 34 (0.00%) 0 / 0 0 / 0 |
| Cardiac disorders atrial fibrillation alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 34 (0.00%) 0 / 0 0 / 0 | 0 / 50 (0.00%) 0 / 0 0 / 0 | 0 / 34 (0.00%) 0 / 0 0 / 0 |
| Surgical and medical procedures nasal septal operation alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 34 (0.00%) 0 / 0 0 / 0 | 0 / 50 (0.00%) 0 / 0 0 / 0 | 1 / 34 (2.94%) 0 / 1 0 / 0 |
| Nervous system disorders cerebral haemorrhage alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 34 (0.00%) 0 / 0 0 / 0 | 0 / 50 (0.00%) 0 / 0 0 / 0 | 0 / 34 (0.00%) 0 / 0 0 / 0 |
| General disorders and administration site conditions non-cardiac chest pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 34 (0.00%) 0 / 0 0 / 0 | 1 / 50 (2.00%) 0 / 1 0 / 0 | 0 / 34 (0.00%) 0 / 0 0 / 0 |
| Gastrointestinal disorders enlarged uvula alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 1 / 34 (2.94%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 34 (2.94%) | 0 / 50 (0.00%) | 1 / 34 (2.94%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| suicidal ideation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| endocarditis bacterial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyelonephritis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 34 (2.94%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W | Maintenance: 300 mg Mirikizumab Q8W | 300 mg Mirikizumab Q8W-Rescue |
|---|--|-------------------------------------|-------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 21 (9.52%) | 3 / 15 (20.00%) | 1 / 10 (10.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| colon cancer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 15 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intraocular melanoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung neoplasm malignant | | | |
| alternative dictionary used: | | | |

| | | | |
|--|----------------|----------------|----------------|
| MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| femur fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| atrial fibrillation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| nasal septal operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| cerebral haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|----------------|----------------|----------------|
| Gastrointestinal disorders | | | |
| enlarged uvula | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| suicidal ideation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| endocarditis bacterial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|----------------|----------------|----------------|
| pyelonephritis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN- Follow-up | 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN- Follow-up | 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN- Follow-up |
|--|--|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| colon cancer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intraocular melanoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|---------------------------------|---------------------------------|---------------------------------|
| lung neoplasm malignant alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 2 (0.00%) 0 / 0 0 / 0 | 0 / 4 (0.00%) 0 / 0 0 / 0 | 0 / 3 (0.00%) 0 / 0 0 / 0 |
| Injury, poisoning and procedural complications femur fracture alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 2 (0.00%) 0 / 0 0 / 0 | 0 / 4 (0.00%) 0 / 0 0 / 0 | 0 / 3 (0.00%) 0 / 0 0 / 0 |
| Cardiac disorders atrial fibrillation alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 2 (0.00%) 0 / 0 0 / 0 | 0 / 4 (0.00%) 0 / 0 0 / 0 | 0 / 3 (0.00%) 0 / 0 0 / 0 |
| Surgical and medical procedures nasal septal operation alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 2 (0.00%) 0 / 0 0 / 0 | 0 / 4 (0.00%) 0 / 0 0 / 0 | 0 / 3 (0.00%) 0 / 0 0 / 0 |
| Nervous system disorders cerebral haemorrhage alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 2 (0.00%) 0 / 0 0 / 0 | 0 / 4 (0.00%) 0 / 0 0 / 0 | 0 / 3 (0.00%) 0 / 0 0 / 0 |
| General disorders and administration site conditions non-cardiac chest pain alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| enlarged uvula | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| suicidal ideation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| endocarditis bacterial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyelonephritis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Placebo to 300 mg Mirikizumab Q8W- Follow-up | 30 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W- Follow-up | 100 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W- Follow-up |
|---|--|---|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| colon cancer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intraocular melanoma | | | |
| alternative dictionary used: | | | |

| | | | |
|---|---------------|---------------|---------------|
| MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung neoplasm malignant | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| femur fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| atrial fibrillation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| nasal septal operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| cerebral haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration | | | |

| | | | |
|--|---------------|---------------|---------------|
| site conditions | | | |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| enlarged uvula | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| suicidal ideation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| endocarditis bacterial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---------------------------------|---------------------------------|---------------------------------|
| pneumonia alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 3 (0.00%) 0 / 0 0 / 0 | 0 / 6 (0.00%) 0 / 0 0 / 0 | 0 / 2 (0.00%) 0 / 0 0 / 0 |
| pyelonephritis acute alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 3 (0.00%) 0 / 0 0 / 0 | 0 / 6 (0.00%) 0 / 0 0 / 0 | 0 / 2 (0.00%) 0 / 0 0 / 0 |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | Induction: Placebo | Induction: 30 mg Mirikizumab Q8W | Induction:100 mg Mirikizumab Q8W |
|--|---------------------|-------------------------------------|-------------------------------------|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 19 / 52 (36.54%) | 24 / 51 (47.06%) | 19 / 51 (37.25%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) skin papilloma alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| Vascular disorders hypertension alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 3 / 51 (5.88%) 3 |
| Surgical and medical procedures cataract operation alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) sinus operation alternative dictionary used: MedDRA 22.0 | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth extraction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 52 (3.85%) | 1 / 51 (1.96%) | 0 / 51 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| General disorders and administration site conditions | | | |
| fatigue | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| injection site pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 52 (1.92%) | 3 / 51 (5.88%) | 3 / 51 (5.88%) |
| occurrences (all) | 2 | 15 | 14 |
| injection site reaction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pyrexia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| dysmenorrhoea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[1] | 0 / 10 (0.00%) | 0 / 12 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| menorrhagia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[2] | 0 / 10 (0.00%) | 0 / 12 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ovarian cyst | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed ^[3] | 0 / 10 (0.00%) | 0 / 12 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| prostatomegaly | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[4] | 0 / 42 (0.00%) | 0 / 39 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| scrotal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[5] | 0 / 42 (0.00%) | 0 / 39 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vaginal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[6] | 0 / 10 (0.00%) | 0 / 12 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vulvovaginal pruritus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[7] | 0 / 10 (0.00%) | 0 / 12 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| asthma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cough | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 52 (1.92%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| dyspnoea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oropharyngeal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 1 / 51 (1.96%) |
| occurrences (all) | 0 | 0 | 1 |
| rhinitis allergic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinus congestion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 1 / 51 (1.96%) |
| occurrences (all) | 0 | 0 | 1 |
| upper respiratory tract congestion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| anxiety | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 1 / 51 (1.96%) |
| occurrences (all) | 0 | 0 | 1 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| blood creatine phosphokinase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| electrocardiogram qt prolonged | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| weight increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| facial bones fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| humerus fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| limb injury | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| maternal exposure during pregnancy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[8] | 0 / 10 (0.00%) | 0 / 12 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle strain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| procedural pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| skin laceration alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| tooth fracture alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| Cardiac disorders atrial fibrillation alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| myocardial infarction alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| Nervous system disorders headache alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 52 (1.92%) 1 | 1 / 51 (1.96%) 1 | 2 / 51 (3.92%) 2 |
| Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| Ear and labyrinth disorders vertigo alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 52 (1.92%) 1 | 1 / 51 (1.96%) 1 | 0 / 51 (0.00%) 0 |
| Eye disorders | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| cataract alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| abdominal pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 1 / 51 (1.96%) 1 | 0 / 51 (0.00%) 0 |
| abdominal tenderness alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| diarrhoea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 52 (1.92%) 1 | 0 / 51 (0.00%) 0 | 1 / 51 (1.96%) 1 |
| duodenal ulcer alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| gastritis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| gastrooesophageal reflux disease alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| irritable bowel syndrome alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| large intestine polyp alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nausea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| periodontal disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| toothache | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 1 / 51 (1.96%) |
| occurrences (all) | 0 | 1 | 1 |
| vomiting | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| cholelithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hyperplastic cholecystopathy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| dermatitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| onycholysis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pruritus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 52 (3.85%) | 1 / 51 (1.96%) | 1 / 51 (1.96%) |
| occurrences (all) | 2 | 1 | 1 |
| psoriasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 52 (1.92%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| stasis dermatitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urticaria | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| haematuria | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pollakiuria | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| proteinuria | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| arthralgia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| arthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| back pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 52 (1.92%) | 1 / 51 (1.96%) | 1 / 51 (1.96%) |
| occurrences (all) | 1 | 1 | 1 |
| exostosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| joint swelling | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 52 (1.92%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| muscle spasms | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 1 / 51 (1.96%) |
| occurrences (all) | 0 | 1 | 1 |
| muscle tightness | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| musculoskeletal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| pain in extremity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---------------------|---------------------|---------------------|
| psoriatic arthropathy alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| tenosynovitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| Infections and infestations appendicitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| body tinea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| bronchitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 52 (1.92%) 1 | 1 / 51 (1.96%) 1 | 1 / 51 (1.96%) 1 |
| conjunctivitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| ear infection alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| erythema migrans alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 52 (0.00%) 0 | 0 / 51 (0.00%) 0 | 0 / 51 (0.00%) 0 |
| gastroenteritis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastrointestinal infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| helicobacter infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis a | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis e | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| influenza | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 1 / 51 (1.96%) |
| occurrences (all) | 0 | 0 | 1 |
| localised infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 7 / 52 (13.46%) | 5 / 51 (9.80%) | 6 / 51 (11.76%) |
| occurrences (all) | 8 | 7 | 8 |
| oral herpes | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|----------------|----------------|----------------|
| otitis externa | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 2 / 51 (3.92%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pulpitis dental | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 1 / 51 (1.96%) | 1 / 51 (1.96%) |
| occurrences (all) | 0 | 1 | 1 |
| skin infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 52 (1.92%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| tinea pedis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 52 (3.85%) | 6 / 51 (11.76%) | 3 / 51 (5.88%) |
| occurrences (all) | 2 | 6 | 3 |
| urethritis chlamydial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| viral upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 1 / 51 (1.96%) |
| occurrences (all) | 0 | 0 | 1 |
| vulvovaginal candidiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[9] | 0 / 10 (0.00%) | 0 / 12 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| wound infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypercholesterolaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypertriglyceridaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| obesity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 52 (0.00%) | 0 / 51 (0.00%) | 0 / 51 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | Induction: 300 mg Mirikizumab Q8W | Maintenance: 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN | Maintenance: 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN |
|--|--------------------------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 19 / 51 (37.25%) | 13 / 15 (86.67%) | 20 / 30 (66.67%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| skin papilloma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Vascular disorders | | | |
| hypertension | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 51 (5.88%) | 0 / 15 (0.00%) | 3 / 30 (10.00%) |
| occurrences (all) | 3 | 0 | 3 |
| Surgical and medical procedures | | | |
| cataract operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinus operation | | | |
| alternative dictionary used: | | | |

| | | | |
|---|----------------|----------------|----------------|
| MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| tooth extraction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General disorders and administration site conditions | | | |
| fatigue | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| injection site pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 51 (3.92%) | 1 / 15 (6.67%) | 1 / 30 (3.33%) |
| occurrences (all) | 9 | 9 | 6 |
| injection site reaction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| pyrexia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| dysmenorrhoea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[1] | 0 / 15 (0.00%) | 0 / 4 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| menorrhagia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[2] | 0 / 15 (0.00%) | 0 / 4 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ovarian cyst | | | |

| | | | |
|--|--------------------------------|--------------------------------|---------------------------------|
| <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[3]</p> <p>occurrences (all)</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>prostatomegaly</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[4]</p> <p>occurrences (all)</p> | <p>0 / 36 (0.00%)</p> <p>0</p> | <p>0 / 11 (0.00%)</p> <p>0</p> | <p>0 / 20 (0.00%)</p> <p>0</p> |
| <p>scrotal pain</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[5]</p> <p>occurrences (all)</p> | <p>0 / 36 (0.00%)</p> <p>0</p> | <p>0 / 11 (0.00%)</p> <p>0</p> | <p>0 / 20 (0.00%)</p> <p>0</p> |
| <p>vaginal haemorrhage</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> | <p>1 / 10 (10.00%)</p> <p>1</p> |
| <p>vulvovaginal pruritus</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p> | <p>1 / 15 (6.67%)</p> <p>1</p> | <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>asthma</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 51 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 30 (0.00%)</p> <p>0</p> |
| <p>cough</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 51 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>2 / 30 (6.67%)</p> <p>2</p> |
| <p>dyspnoea</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 51 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 30 (0.00%)</p> <p>0</p> |
| <p>oropharyngeal pain</p> <p>alternative dictionary used: MedDRA 22.0</p> | | | |

| | | | |
|---|---------------------|----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 2 / 15 (13.33%) 2 | 1 / 30 (3.33%) 1 |
| rhinitis allergic alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 1 / 15 (6.67%) 1 | 1 / 30 (3.33%) 1 |
| sinus congestion alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 1 / 15 (6.67%) 1 | 1 / 30 (3.33%) 1 |
| upper respiratory tract congestion alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| Psychiatric disorders anxiety alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 51 (1.96%) 1 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 1 / 15 (6.67%) 7 | 0 / 30 (0.00%) 0 |
| aspartate aminotransferase increased alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 1 / 15 (6.67%) 5 | 0 / 30 (0.00%) 0 |
| blood creatine phosphokinase increased alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| electrocardiogram qt prolonged alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| weight increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Injury, poisoning and procedural complications | | | |
| facial bones fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| humerus fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| limb injury | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| maternal exposure during pregnancy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[8] | 1 / 15 (6.67%) | 0 / 4 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |
| muscle strain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 1 |
| procedural pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 1 | 2 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|--|--|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>skin laceration</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>tooth fracture</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 51 (0.00%)</p> <p>0</p> <p>0 / 51 (0.00%)</p> <p>0</p> <p>1 / 51 (1.96%)</p> <p>1</p> | <p>0 / 15 (0.00%)</p> <p>0</p> <p>0 / 15 (0.00%)</p> <p>0</p> <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 30 (0.00%)</p> <p>0</p> <p>0 / 30 (0.00%)</p> <p>0</p> <p>0 / 30 (0.00%)</p> <p>0</p> |
| <p>Cardiac disorders</p> <p>atrial fibrillation</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>myocardial infarction</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 51 (0.00%)</p> <p>0</p> <p>0 / 51 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 30 (0.00%)</p> <p>0</p> <p>0 / 30 (0.00%)</p> <p>0</p> |
| <p>Nervous system disorders</p> <p>headache</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 51 (1.96%)</p> <p>1</p> | <p>1 / 15 (6.67%)</p> <p>1</p> | <p>2 / 30 (6.67%)</p> <p>5</p> |
| <p>Blood and lymphatic system disorders</p> <p>anaemia</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 51 (0.00%)</p> <p>0</p> | <p>1 / 15 (6.67%)</p> <p>1</p> | <p>0 / 30 (0.00%)</p> <p>0</p> |
| <p>Ear and labyrinth disorders</p> <p>vertigo</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 51 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 30 (0.00%)</p> <p>0</p> |
| <p>Eye disorders</p> | | | |

| | | | |
|---|---------------------|----------------------|---------------------|
| cataract alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 1 / 15 (6.67%) 1 | 1 / 30 (3.33%) 2 |
| Gastrointestinal disorders | | | |
| abdominal pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 1 / 15 (6.67%) 1 | 0 / 30 (0.00%) 0 |
| abdominal tenderness alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| diarrhoea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 3 / 51 (5.88%) 3 | 2 / 15 (13.33%) 2 | 0 / 30 (0.00%) 0 |
| duodenal ulcer alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 1 / 15 (6.67%) 1 | 0 / 30 (0.00%) 0 |
| gastritis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 1 / 15 (6.67%) 1 | 0 / 30 (0.00%) 0 |
| gastrooesophageal reflux disease alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| irritable bowel syndrome alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| large intestine polyp alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|--|---|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>nausea</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>periodontal disease</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>toothache</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>vomiting</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 51 (0.00%)</p> <p>0</p> <p>1 / 51 (1.96%)</p> <p>1</p> <p>0 / 51 (0.00%)</p> <p>0</p> <p>1 / 51 (1.96%)</p> <p>1</p> <p>0 / 51 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> <p>0 / 15 (0.00%)</p> <p>0</p> <p>0 / 15 (0.00%)</p> <p>0</p> <p>1 / 15 (6.67%)</p> <p>1</p> <p>0 / 15 (0.00%)</p> <p>0</p> <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 30 (0.00%)</p> <p>0</p> <p>1 / 30 (3.33%)</p> <p>1</p> <p>0 / 30 (0.00%)</p> <p>0</p> <p>0 / 30 (0.00%)</p> <p>0</p> <p>0 / 30 (0.00%)</p> <p>0</p> |
| <p>Hepatobiliary disorders</p> <p>cholelithiasis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>hyperplastic cholecystopathy</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 51 (0.00%)</p> <p>0</p> <p>0 / 51 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 30 (0.00%)</p> <p>0</p> <p>0 / 30 (0.00%)</p> <p>0</p> |
| <p>Skin and subcutaneous tissue disorders</p> <p>dermatitis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>onycholysis</p> <p>alternative dictionary used: MedDRA 22.0</p> | <p>0 / 51 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 30 (0.00%)</p> <p>0</p> |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pruritus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| psoriasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| stasis dermatitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urticaria | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Renal and urinary disorders | | | |
| haematuria | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pollakiuria | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| proteinuria | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| arthralgia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| arthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| back pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 1 | 1 |
| exostosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| joint swelling | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle spasms | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle tightness | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| musculoskeletal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pain in extremity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---------------------|---------------------|---------------------|
| psoriatic arthropathy alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| tenosynovitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| Infections and infestations appendicitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| body tinea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| bronchitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 1 / 30 (3.33%) 1 |
| conjunctivitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 1 / 30 (3.33%) 2 |
| ear infection alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| erythema migrans alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 51 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 30 (0.00%) 0 |
| gastroenteritis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastrointestinal infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| helicobacter infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hepatitis a | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hepatitis e | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| influenza | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 1 |
| localised infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 8 / 51 (15.69%) | 3 / 15 (20.00%) | 3 / 30 (10.00%) |
| occurrences (all) | 10 | 8 | 3 |
| oral herpes | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|----------------|----------------|----------------|
| otitis externa | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 1 / 15 (6.67%) | 1 / 30 (3.33%) |
| occurrences (all) | 1 | 1 | 1 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pulpitis dental | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 1 | 1 |
| skin infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tinea pedis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| tooth infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 1 |
| upper respiratory tract infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 51 (3.92%) | 2 / 15 (13.33%) | 5 / 30 (16.67%) |
| occurrences (all) | 3 | 2 | 6 |
| urethritis chlamydial alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| urinary tract infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| viral upper respiratory tract infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 1 |
| vulvovaginal candidiasis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[9] | 0 / 15 (0.00%) | 0 / 4 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| wound infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| diabetes mellitus alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 1 / 30 (3.33%) |
| occurrences (all) | 0 | 0 | 1 |
| hypercholesterolaemia alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypertriglyceridaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 15 (6.67%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| obesity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 0 / 30 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 0 / 15 (0.00%) | 2 / 30 (6.67%) |
| occurrences (all) | 0 | 0 | 2 |

| Non-serious adverse events | Maintenance: 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN | Maintenance: Placebo to 300 mg Mirikizumab Q8W | Maintenance: 30 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W |
|---|---|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 23 / 34 (67.65%) | 38 / 50 (76.00%) | 28 / 34 (82.35%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| skin papilloma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 2 / 34 (5.88%) |
| occurrences (all) | 0 | 1 | 2 |
| Vascular disorders | | | |
| hypertension | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 34 (8.82%) | 4 / 50 (8.00%) | 3 / 34 (8.82%) |
| occurrences (all) | 4 | 4 | 3 |
| Surgical and medical procedures | | | |
| cataract operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinus operation | | | |
| alternative dictionary used: | | | |

| | | | |
|---|----------------|-----------------|----------------|
| MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth extraction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 1 / 34 (2.94%) |
| occurrences (all) | 0 | 1 | 1 |
| General disorders and administration site conditions | | | |
| fatigue | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 1 / 34 (2.94%) |
| occurrences (all) | 0 | 1 | 1 |
| injection site pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 34 (2.94%) | 4 / 50 (8.00%) | 3 / 34 (8.82%) |
| occurrences (all) | 3 | 92 | 67 |
| injection site reaction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 2 / 50 (4.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 6 | 0 |
| pyrexia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 2 / 50 (4.00%) | 2 / 34 (5.88%) |
| occurrences (all) | 0 | 2 | 2 |
| Reproductive system and breast disorders | | | |
| dysmenorrhoea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[1] | 0 / 8 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| menorrhagia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[2] | 0 / 8 (0.00%) | 1 / 10 (10.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ovarian cyst | | | |

| | | | |
|--|--------------------------------|---------------------------------|---------------------------------|
| <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[3]</p> <p>occurrences (all)</p> | <p>0 / 8 (0.00%)</p> <p>0</p> | <p>1 / 10 (10.00%)</p> <p>1</p> | <p>0 / 8 (0.00%)</p> <p>0</p> |
| <p>prostatomegaly</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[4]</p> <p>occurrences (all)</p> | <p>0 / 26 (0.00%)</p> <p>0</p> | <p>0 / 40 (0.00%)</p> <p>0</p> | <p>0 / 26 (0.00%)</p> <p>0</p> |
| <p>scrotal pain</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[5]</p> <p>occurrences (all)</p> | <p>0 / 26 (0.00%)</p> <p>0</p> | <p>0 / 40 (0.00%)</p> <p>0</p> | <p>0 / 26 (0.00%)</p> <p>0</p> |
| <p>vaginal haemorrhage</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p> | <p>0 / 8 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> | <p>0 / 8 (0.00%)</p> <p>0</p> |
| <p>vulvovaginal pruritus</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p> | <p>0 / 8 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> | <p>0 / 8 (0.00%)</p> <p>0</p> |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>asthma</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>2 / 34 (5.88%)</p> <p>2</p> |
| <p>cough</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>2 / 34 (5.88%)</p> <p>2</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>5 / 34 (14.71%)</p> <p>8</p> |
| <p>dyspnoea</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>1 / 34 (2.94%)</p> <p>1</p> |
| <p>oropharyngeal pain</p> <p>alternative dictionary used: MedDRA 22.0</p> | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 1 / 34 (2.94%) | 3 / 50 (6.00%) | 2 / 34 (5.88%) |
| occurrences (all) | 1 | 3 | 2 |
| rhinitis allergic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 1 / 34 (2.94%) |
| occurrences (all) | 0 | 1 | 1 |
| sinus congestion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 34 (5.88%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| upper respiratory tract congestion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| anxiety | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 34 (5.88%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 34 (2.94%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| blood creatine phosphokinase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 2 / 34 (5.88%) |
| occurrences (all) | 0 | 2 | 5 |
| electrocardiogram qt prolonged | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| weight increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 1 / 34 (2.94%) |
| occurrences (all) | 0 | 0 | 1 |
| Injury, poisoning and procedural complications | | | |
| facial bones fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| humerus fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| limb injury | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 3 / 50 (6.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| maternal exposure during pregnancy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[8] | 0 / 8 (0.00%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle strain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 2 / 50 (4.00%) | 2 / 34 (5.88%) |
| occurrences (all) | 0 | 2 | 2 |
| procedural pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 34 (2.94%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|--|--|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>skin laceration</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>tooth fracture</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> <p>1 / 34 (2.94%)</p> <p>1</p> <p>0 / 34 (0.00%)</p> <p>0</p> | <p>1 / 50 (2.00%)</p> <p>1</p> <p>2 / 50 (4.00%)</p> <p>2</p> <p>0 / 50 (0.00%)</p> <p>0</p> | <p>0 / 34 (0.00%)</p> <p>0</p> <p>1 / 34 (2.94%)</p> <p>1</p> <p>3 / 34 (8.82%)</p> <p>4</p> |
| <p>Cardiac disorders</p> <p>atrial fibrillation</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>myocardial infarction</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> <p>0 / 50 (0.00%)</p> <p>0</p> | <p>0 / 34 (0.00%)</p> <p>0</p> <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>Nervous system disorders</p> <p>headache</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>3 / 34 (8.82%)</p> <p>3</p> | <p>3 / 50 (6.00%)</p> <p>4</p> | <p>2 / 34 (5.88%)</p> <p>4</p> |
| <p>Blood and lymphatic system disorders</p> <p>anaemia</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>Ear and labyrinth disorders</p> <p>vertigo</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 34 (2.94%)</p> <p>1</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>Eye disorders</p> | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| cataract alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 1 / 50 (2.00%) 1 | 1 / 34 (2.94%) 2 |
| Gastrointestinal disorders | | | |
| abdominal pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 1 / 50 (2.00%) 2 | 0 / 34 (0.00%) 0 |
| abdominal tenderness alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 0 / 50 (0.00%) 0 | 0 / 34 (0.00%) 0 |
| diarrhoea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 34 (2.94%) 1 | 2 / 50 (4.00%) 2 | 1 / 34 (2.94%) 1 |
| duodenal ulcer alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 0 / 50 (0.00%) 0 | 0 / 34 (0.00%) 0 |
| gastritis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 2 / 50 (4.00%) 3 | 1 / 34 (2.94%) 1 |
| gastrooesophageal reflux disease alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 1 / 50 (2.00%) 1 | 1 / 34 (2.94%) 1 |
| irritable bowel syndrome alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 0 / 50 (0.00%) 0 | 0 / 34 (0.00%) 0 |
| large intestine polyp alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|--------------------------------|--------------------------------|--------------------------------|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>1 / 34 (2.94%)</p> <p>1</p> |
| <p>nausea</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>2 / 34 (5.88%)</p> <p>2</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>1 / 34 (2.94%)</p> <p>1</p> |
| <p>periodontal disease</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>1 / 34 (2.94%)</p> <p>1</p> |
| <p>toothache</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>2 / 34 (5.88%)</p> <p>3</p> |
| <p>vomiting</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>1 / 50 (2.00%)</p> <p>1</p> | <p>1 / 34 (2.94%)</p> <p>1</p> |
| <p>Hepatobiliary disorders</p> <p>cholelithiasis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>hyperplastic cholecystopathy</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>Skin and subcutaneous tissue disorders</p> <p>dermatitis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>2 / 34 (5.88%)</p> <p>2</p> |
| <p>onycholysis</p> <p>alternative dictionary used: MedDRA 22.0</p> | | | |

| | | | |
|--|--------------------------------|--------------------------------|--------------------------------|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>pruritus</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>3 / 50 (6.00%)</p> <p>3</p> | <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>psoriasis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>stasis dermatitis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>urticaria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>1 / 34 (2.94%)</p> <p>1</p> |
| <p>Renal and urinary disorders</p> <p>haematuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>2 / 34 (5.88%)</p> <p>2</p> | <p>1 / 50 (2.00%)</p> <p>1</p> | <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>pollakiuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>proteinuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 34 (0.00%)</p> <p>0</p> | <p>0 / 50 (0.00%)</p> <p>0</p> | <p>0 / 34 (0.00%)</p> <p>0</p> |
| <p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 22.0</p> | | | |

| | | | |
|---|----------------|----------------|-----------------|
| subjects affected / exposed | 3 / 34 (8.82%) | 1 / 50 (2.00%) | 2 / 34 (5.88%) |
| occurrences (all) | 3 | 4 | 2 |
| arthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| back pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 3 / 50 (6.00%) | 8 / 34 (23.53%) |
| occurrences (all) | 0 | 3 | 10 |
| exostosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| joint swelling | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 34 (5.88%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| muscle spasms | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle tightness | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| musculoskeletal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 34 (5.88%) | 1 / 50 (2.00%) | 2 / 34 (5.88%) |
| occurrences (all) | 2 | 1 | 2 |
| pain in extremity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---------------------|---------------------|---------------------|
| psoriatic arthropathy alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 2 / 50 (4.00%) 3 | 1 / 34 (2.94%) 1 |
| tenosynovitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 34 (2.94%) 1 | 0 / 50 (0.00%) 0 | 0 / 34 (0.00%) 0 |
| Infections and infestations appendicitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 0 / 50 (0.00%) 0 | 0 / 34 (0.00%) 0 |
| body tinea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 3 / 34 (8.82%) 3 | 0 / 50 (0.00%) 0 | 0 / 34 (0.00%) 0 |
| bronchitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 0 / 50 (0.00%) 0 | 1 / 34 (2.94%) 1 |
| conjunctivitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 0 / 50 (0.00%) 0 | 2 / 34 (5.88%) 2 |
| ear infection alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 0 / 50 (0.00%) 0 | 0 / 34 (0.00%) 0 |
| erythema migrans alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 34 (0.00%) 0 | 0 / 50 (0.00%) 0 | 0 / 34 (0.00%) 0 |
| gastroenteritis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|------------------|------------------|
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 1 / 34 (2.94%) |
| occurrences (all) | 0 | 0 | 1 |
| gastrointestinal infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| helicobacter infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis a | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis e | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| influenza | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 34 (5.88%) | 3 / 50 (6.00%) | 2 / 34 (5.88%) |
| occurrences (all) | 2 | 3 | 2 |
| localised infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 7 / 34 (20.59%) | 15 / 50 (30.00%) | 12 / 34 (35.29%) |
| occurrences (all) | 10 | 26 | 25 |
| oral herpes | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 34 (2.94%) | 2 / 50 (4.00%) | 1 / 34 (2.94%) |
| occurrences (all) | 1 | 2 | 1 |

| | | | |
|---|----------------|----------------|----------------|
| otitis externa | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| pharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 2 / 50 (4.00%) | 3 / 34 (8.82%) |
| occurrences (all) | 0 | 2 | 3 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pulpitis dental | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 34 (2.94%) | 1 / 50 (2.00%) | 1 / 34 (2.94%) |
| occurrences (all) | 2 | 1 | 1 |
| skin infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tinea pedis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 34 (2.94%) | 0 / 50 (0.00%) | 2 / 34 (5.88%) |
| occurrences (all) | 1 | 0 | 2 |
| tooth infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 34 (5.88%) | 8 / 50 (16.00%) | 3 / 34 (8.82%) |
| occurrences (all) | 2 | 9 | 7 |
| urethritis chlamydial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 34 (8.82%) | 4 / 50 (8.00%) | 1 / 34 (2.94%) |
| occurrences (all) | 3 | 5 | 1 |
| viral upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vulvovaginal candidiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[9] | 1 / 8 (12.50%) | 0 / 10 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| wound infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 34 (5.88%) | 1 / 50 (2.00%) | 1 / 34 (2.94%) |
| occurrences (all) | 2 | 1 | 1 |
| hypercholesterolaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 1 / 34 (2.94%) |
| occurrences (all) | 0 | 1 | 1 |
| hypertriglyceridaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 1 / 50 (2.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| obesity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 34 (2.94%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 34 (0.00%) | 0 / 50 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | Maintenance: 100 mg Mirikizumab Q8W to 300 mg MirikizumabQ8W | Maintenance: 300 mg Mirikizumab Q8W | 300 mg Mirikizumab Q8W-Rescue |
|---|--|-------------------------------------|-------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 18 / 21 (85.71%) | 13 / 15 (86.67%) | 9 / 10 (90.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| skin papilloma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| hypertension | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 5 / 21 (23.81%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| Surgical and medical procedures | | | |
| cataract operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| sinus operation | | | |
| alternative dictionary used: | | | |

| | | | |
|---|----------------|----------------|-----------------|
| MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth extraction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General disorders and administration site conditions | | | |
| fatigue | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| injection site pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 21 (9.52%) | 0 / 15 (0.00%) | 2 / 10 (20.00%) |
| occurrences (all) | 31 | 0 | 39 |
| injection site reaction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 21 (9.52%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| pyrexia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| dysmenorrhoea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[1] | 0 / 6 (0.00%) | 1 / 6 (16.67%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| menorrhagia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[2] | 0 / 6 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ovarian cyst | | | |

| | | | |
|--|--------------------------------|--------------------------------|--------------------------------|
| <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[3]</p> <p>occurrences (all)</p> | <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>prostatomegaly</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[4]</p> <p>occurrences (all)</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>1 / 9 (11.11%)</p> <p>1</p> | <p>0 / 8 (0.00%)</p> <p>0</p> |
| <p>scrotal pain</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[5]</p> <p>occurrences (all)</p> | <p>1 / 15 (6.67%)</p> <p>1</p> | <p>0 / 9 (0.00%)</p> <p>0</p> | <p>0 / 8 (0.00%)</p> <p>0</p> |
| <p>vaginal haemorrhage</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p> | <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>vulvovaginal pruritus</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p> | <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>asthma</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 21 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>cough</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 21 (4.76%)</p> <p>1</p> | <p>1 / 15 (6.67%)</p> <p>1</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>dyspnoea</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>2 / 21 (9.52%)</p> <p>2</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>oropharyngeal pain</p> <p>alternative dictionary used: MedDRA 22.0</p> | | | |

| | | | |
|---|----------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 2 / 21 (9.52%) 2 | 0 / 15 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| rhinitis allergic alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 0 / 15 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| sinus congestion alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 15 (6.67%) 1 | 0 / 10 (0.00%) 0 |
| upper respiratory tract congestion alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 15 (6.67%) 1 | 0 / 10 (0.00%) 0 |
| Psychiatric disorders anxiety alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 0 / 15 (0.00%) 0 | 1 / 10 (10.00%) 1 |
| Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| aspartate aminotransferase increased alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| blood creatine phosphokinase increased alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 3 / 21 (14.29%) 5 | 0 / 15 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| electrocardiogram qt prolonged alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| weight increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| facial bones fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| humerus fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| limb injury | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| maternal exposure during pregnancy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[8] | 0 / 6 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle strain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| procedural pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|--|--|--|
| <p>subjects affected / exposed</p> <p>0 / 21 (0.00%)</p> <p>1 / 15 (6.67%)</p> <p>0 / 10 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p> <p>0</p> | | | |
| <p>skin laceration</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>0 / 21 (0.00%)</p> <p>1 / 15 (6.67%)</p> <p>0 / 10 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p> <p>0</p> | | | |
| <p>tooth fracture</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>0 / 21 (0.00%)</p> <p>1 / 15 (6.67%)</p> <p>0 / 10 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p> <p>0</p> | | | |
| <p>Cardiac disorders</p> <p>atrial fibrillation</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>0 / 21 (0.00%)</p> <p>1 / 15 (6.67%)</p> <p>0 / 10 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>2</p> <p>0</p> | | | |
| <p>myocardial infarction</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>0 / 21 (0.00%)</p> <p>1 / 15 (6.67%)</p> <p>0 / 10 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p> <p>0</p> | | | |
| <p>Nervous system disorders</p> <p>headache</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>2 / 21 (9.52%)</p> <p>0 / 15 (0.00%)</p> <p>0 / 10 (0.00%)</p> <p>occurrences (all)</p> <p>2</p> <p>0</p> <p>0</p> | | | |
| <p>Blood and lymphatic system disorders</p> <p>anaemia</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>0 / 21 (0.00%)</p> <p>0 / 15 (0.00%)</p> <p>0 / 10 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>0</p> <p>0</p> | | | |
| <p>Ear and labyrinth disorders</p> <p>vertigo</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>0 / 21 (0.00%)</p> <p>2 / 15 (13.33%)</p> <p>0 / 10 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>2</p> <p>0</p> | | | |
| <p>Eye disorders</p> | | | |

| | | | |
|---|---------------------|----------------------|---------------------|
| cataract alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 15 (6.67%) 2 | 0 / 10 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| abdominal pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 0 / 15 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| abdominal tenderness alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 15 (6.67%) 1 | 0 / 10 (0.00%) 0 |
| diarrhoea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 2 / 15 (13.33%) 3 | 0 / 10 (0.00%) 0 |
| duodenal ulcer alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| gastritis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| gastrooesophageal reflux disease alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 1 / 15 (6.67%) 1 | 0 / 10 (0.00%) 0 |
| irritable bowel syndrome alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 15 (6.67%) 1 | 0 / 10 (0.00%) 0 |
| large intestine polyp alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|---|--|---|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>nausea</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>periodontal disease</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>toothache</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>vomiting</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 21 (0.00%)</p> <p>0</p> <p>1 / 21 (4.76%)</p> <p>1</p> <p>0 / 21 (0.00%)</p> <p>0</p> <p>0 / 21 (0.00%)</p> <p>0</p> <p>0 / 21 (0.00%)</p> <p>0</p> <p>0 / 21 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> <p>1 / 15 (6.67%)</p> <p>1</p> <p>0 / 15 (0.00%)</p> <p>0</p> <p>0 / 15 (0.00%)</p> <p>0</p> <p>1 / 15 (6.67%)</p> <p>1</p> | <p>1 / 10 (10.00%)</p> <p>1</p> <p>0 / 10 (0.00%)</p> <p>0</p> <p>0 / 10 (0.00%)</p> <p>0</p> <p>0 / 10 (0.00%)</p> <p>0</p> <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>Hepatobiliary disorders</p> <p>cholelithiasis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>hyperplastic cholecystopathy</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 21 (0.00%)</p> <p>0</p> <p>0 / 21 (0.00%)</p> <p>0</p> | <p>1 / 15 (6.67%)</p> <p>2</p> <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> <p>1 / 10 (10.00%)</p> <p>1</p> |
| <p>Skin and subcutaneous tissue disorders</p> <p>dermatitis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>onycholysis</p> <p>alternative dictionary used: MedDRA 22.0</p> | <p>0 / 21 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |

| | | | |
|--|--------------------------------|--------------------------------|---------------------------------|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 21 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>pruritus</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 21 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>psoriasis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 21 (0.00%)</p> <p>0</p> | <p>1 / 15 (6.67%)</p> <p>2</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>stasis dermatitis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 21 (0.00%)</p> <p>0</p> | <p>1 / 15 (6.67%)</p> <p>1</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>urticaria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 21 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>1 / 10 (10.00%)</p> <p>1</p> |
| <p>Renal and urinary disorders</p> <p>haematuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 21 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>pollakiuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 21 (0.00%)</p> <p>0</p> | <p>1 / 15 (6.67%)</p> <p>1</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>proteinuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 21 (0.00%)</p> <p>0</p> | <p>0 / 15 (0.00%)</p> <p>0</p> | <p>0 / 10 (0.00%)</p> <p>0</p> |
| <p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 22.0</p> | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 3 / 21 (14.29%) | 1 / 15 (6.67%) | 1 / 10 (10.00%) |
| occurrences (all) | 4 | 1 | 1 |
| arthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| back pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 21 (14.29%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| exostosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| joint swelling | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle spasms | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| muscle tightness | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| musculoskeletal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pain in extremity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 21 (9.52%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |

| | | | |
|---|---------------------|----------------------|---------------------|
| psoriatic arthropathy alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 1 / 15 (6.67%) 1 | 0 / 10 (0.00%) 0 |
| tenosynovitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 15 (6.67%) 1 | 0 / 10 (0.00%) 0 |
| Infections and infestations appendicitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 15 (6.67%) 1 | 0 / 10 (0.00%) 0 |
| body tinea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 15 (6.67%) 1 | 0 / 10 (0.00%) 0 |
| bronchitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 2 / 21 (9.52%) 2 | 3 / 15 (20.00%) 4 | 0 / 10 (0.00%) 0 |
| conjunctivitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| ear infection alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 15 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| erythema migrans alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 15 (6.67%) 1 | 0 / 10 (0.00%) 0 |
| gastroenteritis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 3 / 21 (14.29%) | 1 / 15 (6.67%) | 1 / 10 (10.00%) |
| occurrences (all) | 3 | 1 | 1 |
| gastrointestinal infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| helicobacter infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis a | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis e | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| influenza | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| localised infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 5 / 21 (23.81%) | 5 / 15 (33.33%) | 2 / 10 (20.00%) |
| occurrences (all) | 13 | 12 | 3 |
| oral herpes | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| otitis externa | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 1 | 2 |
| pharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 21 (14.29%) | 2 / 15 (13.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| pulpitis dental | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 15 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| tinea pedis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 21 (4.76%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| upper respiratory tract infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 5 / 21 (23.81%) | 1 / 15 (6.67%) | 1 / 10 (10.00%) |
| occurrences (all) | 6 | 2 | 1 |
| urethritis chlamydial alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urinary tract infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 2 / 15 (13.33%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| viral upper respiratory tract infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 15 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |
| vulvovaginal candidiasis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[9] | 0 / 6 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| wound infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Metabolism and nutrition disorders | | | |
| diabetes mellitus alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypercholesterolaemia alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 15 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |
| hypertriglyceridaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| obesity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 15 (6.67%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 15 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | 30 mg Mirikizumab Q8W to 30 mg Mirikizumab PRN- Follow-up | 100 mg Mirikizumab Q8W to 100 mg Mirikizumab PRN- Follow-up | 300 mg Mirikizumab Q8W to 300 mg Mirikizumab PRN- Follow-up |
|--|--|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 4 (25.00%) | 0 / 3 (0.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| skin papilloma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 4 (25.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vascular disorders | | | |
| hypertension | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Surgical and medical procedures | | | |
| cataract operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinus operation | | | |
| alternative dictionary used: | | | |

| | | | |
|---|---------------|---------------|---------------|
| MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth extraction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| fatigue | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| injection site pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| injection site reaction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pyrexia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| dysmenorrhoea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[1] | 0 / 2 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| menorrhagia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[2] | 0 / 2 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ovarian cyst | | | |

| | | | |
|---|---|---|---|
| <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[3]</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 1 (0.00%)</p> <p>0</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>prostatomegaly</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[4]</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>scrotal pain</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[5]</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>vaginal haemorrhage</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 1 (0.00%)</p> <p>0</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>vulvovaginal pruritus</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 1 (0.00%)</p> <p>0</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>asthma</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>cough</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>dyspnoea</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>oropharyngeal pain</p> <p>alternative dictionary used: MedDRA 22.0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> |

| | | | |
|---|--------------------|--------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| rhinitis allergic alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| sinus congestion alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| upper respiratory tract congestion alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Psychiatric disorders anxiety alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| aspartate aminotransferase increased alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| blood creatine phosphokinase increased alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| electrocardiogram qt prolonged alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| weight increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| facial bones fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| humerus fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| limb injury | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| maternal exposure during pregnancy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[8] | 0 / 2 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle strain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| procedural pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|---|---|---|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>skin laceration</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>tooth fracture</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> |
| <p>Cardiac disorders</p> <p>atrial fibrillation</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>myocardial infarction</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> |
| <p>Nervous system disorders</p> <p>headache</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> |
| <p>Blood and lymphatic system disorders</p> <p>anaemia</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> |
| <p>Ear and labyrinth disorders</p> <p>vertigo</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> |
| <p>Eye disorders</p> | | | |

| | | | |
|---|--------------------|--------------------|--------------------|
| cataract alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| abdominal pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| abdominal tenderness alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| diarrhoea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| duodenal ulcer alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| gastritis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| gastrooesophageal reflux disease alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| irritable bowel syndrome alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| large intestine polyp alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|---|---|---|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>nausea</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>periodontal disease</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>toothache</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>vomiting</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> |
| <p>Hepatobiliary disorders</p> <p>cholelithiasis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>hyperplastic cholecystopathy</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> |
| <p>Skin and subcutaneous tissue disorders</p> <p>dermatitis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>onycholysis</p> <p>alternative dictionary used: MedDRA 22.0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> |

| | | | |
|--|---|---|---|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pruritus</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>psoriasis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>stasis dermatitis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>urticaria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> |
| <p>Renal and urinary disorders</p> <p>haematuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pollakiuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>proteinuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> | <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> |
| <p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 22.0</p> | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| arthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| back pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| exostosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| joint swelling | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle spasms | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle tightness | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| musculoskeletal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pain in extremity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|--------------------|--------------------|--------------------|
| psoriatic arthropathy alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| tenosynovitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Infections and infestations appendicitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| body tinea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| bronchitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| conjunctivitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| ear infection alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| erythema migrans alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| gastroenteritis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastrointestinal infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| helicobacter infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis a | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis e | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| influenza | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| localised infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oral herpes | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---------------|---------------|---------------|
| otitis externa | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pulpitis dental | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tinea pedis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urethritis chlamydial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| viral upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vulvovaginal candidiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[9] | 0 / 2 (0.00%) | 0 / 1 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| wound infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypercholesterolaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypertriglyceridaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| obesity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 4 (0.00%) | 0 / 3 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | Placebo to 300 mg Mirikizumab Q8W- Follow-up | 30 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W- Follow-up | 100 mg Mirikizumab Q8W to 300 mg Mirikizumab Q8W- Follow-up |
|--|--|---|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 6 (33.33%) | 1 / 2 (50.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| skin papilloma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| hypertension | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Surgical and medical procedures | | | |
| cataract operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinus operation | | | |
| alternative dictionary used: | | | |

| | | | |
|---|---------------|---------------|---------------|
| MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth extraction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| fatigue | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| injection site pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| injection site reaction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pyrexia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| dysmenorrhoea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[1] | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| menorrhagia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[2] | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ovarian cyst | | | |

| | | | |
|--|-------------------------------|-------------------------------|-------------------------------|
| <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[3]</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>prostatomegaly</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[4]</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>scrotal pain</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[5]</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>vaginal haemorrhage</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>vulvovaginal pruritus</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 1 (0.00%)</p> <p>0</p> |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>asthma</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>cough</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>dyspnoea</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>oropharyngeal pain</p> <p>alternative dictionary used: MedDRA 22.0</p> | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| rhinitis allergic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinus congestion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| upper respiratory tract congestion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| anxiety | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| blood creatine phosphokinase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| electrocardiogram qt prolonged | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| weight increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| facial bones fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| humerus fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| limb injury | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| maternal exposure during pregnancy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[8] | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle strain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| procedural pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|--------------------|--------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| skin laceration alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| tooth fracture alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Cardiac disorders atrial fibrillation alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| myocardial infarction alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Nervous system disorders headache alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Ear and labyrinth disorders vertigo alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Eye disorders | | | |

| | | | |
|---|--------------------|--------------------|--------------------|
| cataract alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| abdominal pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| abdominal tenderness alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| diarrhoea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| duodenal ulcer alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| gastritis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| gastrooesophageal reflux disease alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| irritable bowel syndrome alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| large intestine polyp alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|---|---|---|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>nausea</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>periodontal disease</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>toothache</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>vomiting</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>Hepatobiliary disorders</p> <p>cholelithiasis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>hyperplastic cholecystopathy</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>Skin and subcutaneous tissue disorders</p> <p>dermatitis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>onycholysis</p> <p>alternative dictionary used: MedDRA 22.0</p> | <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> |

| | | | |
|--|---|---|---|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pruritus</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>psoriasis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>stasis dermatitis</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>urticaria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>Renal and urinary disorders</p> <p>haematuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pollakiuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>proteinuria</p> <p>alternative dictionary used: MedDRA 22.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> | <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> | <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> <p>0 / 2 (0.00%)</p> <p>0</p> |
| <p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 22.0</p> | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| arthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| back pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| exostosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| joint swelling | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle spasms | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle tightness | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| musculoskeletal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pain in extremity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|--------------------|---------------------|--------------------|
| psoriatic arthropathy alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| tenosynovitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| Infections and infestations appendicitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| body tinea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| bronchitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| conjunctivitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| ear infection alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 1 / 6 (16.67%) 1 | 0 / 2 (0.00%) 0 |
| erythema migrans alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 6 (0.00%) 0 | 0 / 2 (0.00%) 0 |
| gastroenteritis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|---------------|---------------|----------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastrointestinal infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| helicobacter infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis a | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis e | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| influenza | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| localised infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oral herpes | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---------------|----------------|---------------|
| otitis externa | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 6 (16.67%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pulpitis dental | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tinea pedis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| upper respiratory tract infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urethritis chlamydial alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urinary tract infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| viral upper respiratory tract infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vulvovaginal candidiasis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[9] | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| wound infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| diabetes mellitus alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypercholesterolaemia alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|---------------|---------------|---------------|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypertriglyceridaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| obesity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 6 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported