# Clinical trial results:
# A Phase 3, Multicenter, Randomized, Double-blind, Placebo and Active Comparator- Controlled Study Evaluating the Efficacy and Safety of Guselkumab for the Treatment of Subjects with Moderate to Severe Plaque-type Psoriasis with Randomized Withdrawal and Retreatment

## Summary

| | |
|---|---|
| EudraCT number | 2014-000720-18 |
| Trial protocol | DE CZ PL ES |
| Global end of trial date | 01 July 2020 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 16 July 2021 |
| First version publication date | 16 July 2021 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | CNTO1959PSO3002 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02207244 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Janssen Pharmaceutical |
| Sponsor organisation address | 1400 McKean Rd., Spring House, United States, |
| Public contact | Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com |
| Scientific contact | Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com |

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 | 01 July 2020 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 01 July 2020 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The main objectives of this study were to evaluate the efficacy, safety, and tolerability of guselkumab in the treatment of subjects with moderate to severe plaque-type psoriasis.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. The safety and tolerability of guselkumab and adalimumab were monitored by collecting information on adverse events (AEs), including injection-site reactions (ISRs) and allergic reactions, clinical laboratory tests, physical examinations, vital signs, electrocardiograms (ECGs), concomitant medication review, and early detection of active tuberculosis (TB).

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 03 November 2014 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Australia: 51 |
| Country: Number of subjects enrolled | Canada: 130 |
| Country: Number of subjects enrolled | Czechia: 31 |
| Country: Number of subjects enrolled | Germany: 84 |
| Country: Number of subjects enrolled | Spain: 43 |
| Country: Number of subjects enrolled | Korea, Republic of: 98 |
| Country: Number of subjects enrolled | Poland: 265 |
| Country: Number of subjects enrolled | Russian Federation: 100 |
| Country: Number of subjects enrolled | United States: 190 |
| Worldwide total number of subjects | 992 |
| EEA total number of subjects | 423 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 | 0 |

| wk | |
|---|---|
| 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) | 949 |
| From 65 to 84 years | 43 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 1279 subjects were screened. Of these 1279, 992 subjects were randomized.

### Period 1

| | |
|---|---|
| Period 1 title | Placebo Controlled Period: Week 0 - 16 |
| 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** | Placebo (Week 0 - 16) |

Arm description:

Subjects received placebo matched to guselkumab subcutaneous (SC) injection at Weeks 0, 4, and 12 and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 to maintain the blind during placebo controlled period (PCP).

| | |
|---|---|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo (for guselkumab) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder and solvent for solution for injection in pre-filled syringe, Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Placebo matching to guselkumab was administered subcutaneously at Weeks 0, 4 and 12 in PCP.

| | |
|---|---|
| Investigational medicinal product name | Placebo (for adalimumab) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Placebo matching to adalimumab was administered subcutaneously (2 doses) at Week 0 followed by single subcutaneous dose thereafter through Week 15 in PCP.

| | |
|---|---|
| **Arm title** | Guselkumab 100 mg (Week 0 - 16) |

Arm description:

Subjects received guselkumab 100 milligram (mg) SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 during PCP.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | CNTO1959 |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously at Weeks 0, 4, and 12.

| **Arm title** | Adalimumab (Week 0 - 16) |
|---|---|

Arm description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 followed by adalimumab 40 mg (1 SC injection) at Week 1 and every other week thereafter through Week 15 and placebo matched to guselkumab SC injection at Weeks 0, 4, and 12 during PCP.

| Arm type | Active comparator |
|---|---|
| Investigational medicinal product name | Adalimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Adalimumab 80 mg was administered subcutaneously (2 doses) at Week 0 followed by single subcutaneous dose of adalimumab 40 mg at Week 1 and thereafter through Week 15.

| **Number of subjects in period 1** | Placebo (Week 0 - 16) | Guselkumab 100 mg (Week 0 - 16) | Adalimumab (Week 0 - 16) |
|---|---|---|---|
| Started | 248 | 496 | 248 |
| Completed | 233 | 478 | 237 |
| Not completed | 15 | 18 | 11 |
| Consent withdrawn by subject | 7 | 1 | - |
| Adverse event, non-fatal | 2 | 9 | 4 |
| Unspecified | - | 2 | 2 |
| Lost to follow-up | 1 | 3 | 2 |
| Protocol deviation | 1 | 3 | 1 |
| Lack of efficacy | 4 | - | 2 |

## Period 2

| Period 2 title | Placebo crossover and ACP: Week 16 - 28 |
|---|---|
| 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** | Placebo then Guselkumab 100 mg (Week 16 - 28) |

Arm description:

Subjects who started receiving placebo in the first period were crossed over to receive guselkumab 100 mg SC injection at Weeks 16 and 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21, and 23 during the active comparator controlled period (ACP).

| Arm type | Placebo |
|---|---|

| | |
|---|---|
| Investigational medicinal product name | Placebo (for adalimumab) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Placebo matching to adalimumab was administered subcutaneously at Weeks 17, 19, 21, 23, and q2w in active controlled period.

| | |
|---|---|
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | CNTO1959 |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously to subjects receiving matching placebo in PCP and crossed over to receive guselkumab in ACP.

| | |
|---|---|
| **Arm title** | Guselkumab 100 mg (Week 16 - 28) |

Arm description:

Subjects who started receiving guselkumab in the first period, received placebo matched to guselkumab SC injection at Week 16 followed by guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21 and 23.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | CNTO1959 |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously q8w in ACP to subjects initially receiving guselkumab 100 mg in PCP.

| | |
|---|---|
| **Arm title** | Adalimumab (Week 16 - 28) |

Arm description:

Subjects who received adalimumab in the first period, continued to receive adalimumab 40 mg (1 SC injection) every 2 weeks (q2w) from Week 17 through Week 23 and placebo matched to guselkumab SC injection at Weeks 16 and 20.

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Adalimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Adalimumab 40 mg was administered to subcutaneously q2w in ACP to subjects who were initially receiving adalimumab in PCP.

| Number of subjects in period 2 | Placebo then Guselkumab 100 mg (Week 16 - 28) | Guselkumab 100 mg (Week 16 - 28) | Adalimumab (Week 16 - 28) |
|---|---|---|---|
| Started | 233 | 478 | 237 |
| Completed | 227 | 470 | 228 |
| Not completed | 6 | 8 | 9 |
| Consent withdrawn by subject | 3 | 3 | 2 |
| Adverse event, non-fatal | - | 3 | 2 |
| Unspecified | 1 | - | - |
| Lost to follow-up | 1 | 2 | 2 |
| Protocol deviation | 1 | - | 1 |
| Lack of efficacy | - | - | 2 |

## Period 3

| | |
|---|---|
| Period 3 title | Withdrawal and Re-treatment: Week 28-72 |
| 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** | Placebo then Guselkumab 100 mg (Week 28 - 72) |

Arm description:

Subjects assigned to the placebo, then guselkumab arm through Week 28 were assessed for psoriasis area and severity index (PASI) 90 response at Week 28. Subjects who were PASI 90 non-responders received guselkumab 100 mg SC injection at Week 28 and then every 8 weeks (q8w) thereafter through Week 72 and placebo matched to guselkumab SC injection at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders at Week 28 received placebo matched to guselkumab SC injection at Week 28 and every 4 weeks (q4w) thereafter through Week 72 or until loss of greater than or equal to (>=) 50 percentage (%) in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab.

| | |
|---|---|
| Arm type | Placebo |
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | CNTO1959 |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously to PASI 90 non-responders at Week 28 and then q8w thereafter through Week 72.

| | |
|---|---|
| Investigational medicinal product name | Placebo (for guselkumab) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Placebo matching to guselkumab was administered subcutaneously to PASI 90 non-responders at Week 32 and then q8w through Week 72 whereas placebo matching to guselkumab was administered subcutaneously to PASI 90 responders at Week 28 and q4w thereafter through Week 72 or until loss of >=50% the improvement in PASI.

| **Arm title** | Guselkumab 100 mg (Week 28 - 72) |
|---|---|

Arm description:

Subjects assigned to the guselkumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders were re-randomized to either guselkumab or placebo. Subjects re-randomized to guselkumab, received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 32 and then q8w through Week 72. Subjects re-randomized to placebo, received placebo matched to guselkumab SC injection q4w through Week 72 or until loss of >=50% in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | CNTO1959 |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously to PASI 90 non-responders at Week 28 and q8w thereafter through Week 72 whereas PASI 90 responders were re-randomized to guselkumab through Week 72.

| **Arm title** | Adalimumab then Guselkumab 100 mg (Week 28 - 72) |
|---|---|

Arm description:

Subjects who were assigned to the adalimumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and 32 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 36 and 44. Subjects who were PASI 90 responders, received placebo matched to guselkumab SC injection q4w thereafter through Week 72 or until loss of >=50% in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were treated with guselkumab.

| Arm type | Active comparator |
|---|---|
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | CNTO1959 |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously to PASI 90 non-responders at Week 28 and 32 and q8w thereafter through Week 72.

| **Arm title** | Adalimumab (After ACP) |
|---|---|

Arm description:

Subjects who received adalimumab 80 mg at Week 0 and adalimumab 40 mg at Week 1 and every other week through Week 23 were assessed for PASI 90 response at Week 28. PASI 90 responders who did not crossover to guselkumab upon loss of >=50% in the improvement in PASI and did not continue any treatment at Week 28 are reported in this arm.

| Arm type | Active comparator |
|---|---|

| | |
|---|---|
| Investigational medicinal product name | Adalimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Adalimumab 40 mg was administered subcutaneously to subjects through Week 23.

| **Number of subjects in period 3** | Placebo then Guselkumab 100 mg (Week 28 - 72) | Guselkumab 100 mg (Week 28 - 72) | Adalimumab then Guselkumab 100 mg (Week 28 - 72) |
|---|---|---|---|
| Started | 227 | 470 | 220 |
| Nonresponders | 80 [1] | 95 [2] | 112 [3] |
| Responders at Week (Wk) 28 | 0 [4] | 375 [5] | 0 [6] |
| Responders at Wk 28, withdrawn treatment | 147 [7] | 0 [8] | 108 [9] |
| Completed | 213 | 443 | 211 |
| Not completed | 14 | 27 | 9 |
| Consent withdrawn by subject | 2 | 7 | 2 |
| Adverse event, non-fatal | 1 | 5 | 3 |
| Pregnancy | - | 2 | - |
| Unspecified | - | 2 | - |
| Subjects not retreated with guselkumab | 8 | - | - |
| Lost to follow-up | 2 | 7 | - |
| Lack of efficacy | 1 | 3 | 2 |
| Protocol deviation | - | 1 | 1 |
| Noncompliance | - | - | 1 |

| **Number of subjects in period 3** | Adalimumab (After ACP) |
|---|---|
| Started | 8 |
| Nonresponders | 0 |
| Responders at Week (Wk) 28 | 0 |
| Responders at Wk 28, withdrawn treatment | 0 |
| Completed | 0 |
| Not completed | 8 |
| Consent withdrawn by subject | 2 |
| Adverse event, non-fatal | 2 |
| Pregnancy | - |
| Unspecified | - |
| Subjects not retreated with guselkumab | - |
| Lost to follow-up | 2 |

| | |
|---|---|
| Lack of efficacy | 2 |
| Protocol deviation | - |
| Noncompliance | - |

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: There were only specified number of subjects in each arm of each milestone.

[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: There were only specified number of subjects in each arm of each milestone.

[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: There were only specified number of subjects in each arm of each milestone.

[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: There were only specified number of subjects in each arm of each milestone.

[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: There were only specified number of subjects in each arm of each milestone.

[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: There were only specified number of subjects in each arm of each milestone.

[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: There were only specified number of subjects in each arm of each milestone.

[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: There were only specified number of subjects in each arm of each milestone.

[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: There were only specified number of subjects in each arm of each milestone.

## Period 4

| | |
|---|---|
| Period 4 title | Open-label Guselkumab: Week 72-264 |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

## Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Guselkumab Combined |

Arm description:

All subjects who received guselkumab 100 mg subcutaneously q8w at Week 76 and thereafter through Week 252.

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

| | |
|---|---|
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | CNTO1959 |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously at Week 76 and then q8w through Week 252.

| **Arm title** | Adalimumab then Guselkumab 100 mg (Week 72 - 264) |
|---|---|

Arm description:

All subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | CNTO1959 |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously at Week 76 and then q8w through Week 252.

| **Number of subjects in period 4** | Guselkumab Combined | Adalimumab then Guselkumab 100 mg (Week 72 - 264) |
|---|---|---|
| Started | 656 | 211 |
| Completed | 554 | 173 |
| Not completed | 102 | 38 |
| Adverse event, serious fatal | 1 | 1 |
| Consent withdrawn by subject | 30 | 10 |
| Adverse event, non-fatal | 21 | 12 |
| Pregnancy | 2 | - |
| Unspecified | 19 | 8 |
| Lost to follow-up | 26 | 5 |
| Lack of efficacy | 3 | 2 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Placebo (Week 0 - 16) |
| Reporting group description: | |
| Subjects received placebo matched to guselkumab subcutaneous (SC) injection at Weeks 0, 4, and 12 and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 to maintain the blind during placebo controlled period (PCP). | |
| Reporting group title | Guselkumab 100 mg (Week 0 - 16) |
| Reporting group description: | |
| Subjects received guselkumab 100 milligram (mg) SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 during PCP. | |
| Reporting group title | Adalimumab (Week 0 - 16) |
| Reporting group description: | |
| Subjects received adalimumab 80 mg (2 SC injections) at Week 0 followed by adalimumab 40 mg (1 SC injection) at Week 1 and every other week thereafter through Week 15 and placebo matched to guselkumab SC injection at Weeks 0, 4, and 12 during PCP. | |

| Reporting group values | Placebo (Week 0 - 16) | Guselkumab 100 mg (Week 0 - 16) | Adalimumab (Week 0 - 16) |
|---|---|---|---|
| Number of subjects | 248 | 496 | 248 |
| Title for AgeCategorical | | | |
| Units: subjects | | | |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 239 | 473 | 237 |
| From 65 to 84 years | 9 | 23 | 11 |
| 85 years and over | 0 | 0 | 0 |
| Title for AgeContinuous | | | |
| Units: years | | | |
| arithmetic mean | 43.3 | 43.7 | 43.2 |
| standard deviation | ± 12.38 | ± 12.23 | ± 11.92 |
| Title for Gender | | | |
| Units: subjects | | | |
| Female | 75 | 147 | 78 |
| Male | 173 | 349 | 170 |

| Reporting group values | Total | | |
|---|---|---|---|
| Number of subjects | 992 | | |
| Title for AgeCategorical | | | |
| Units: subjects | | | |
| Children (2-11 years) | 0 | | |
| Adolescents (12-17 years) | 0 | | |
| Adults (18-64 years) | 949 | | |
| From 65 to 84 years | 43 | | |
| 85 years and over | 0 | | |
| Title for AgeContinuous | | | |
| Units: years | | | |
| arithmetic mean | | | |

| | | | |
|---|---|---|---|
| standard deviation | - | | |

| | | | |
|---|---|---|---|
| Title for Gender<br>Units: subjects | | | |
| Female | 300 | | |
| Male | 692 | | |

### End points reporting groups

| Reporting group title | Placebo (Week 0 - 16) |
|---|---|

Reporting group description:

Subjects received placebo matched to guselkumab subcutaneous (SC) injection at Weeks 0, 4, and 12 and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 to maintain the blind during placebo controlled period (PCP).

| Reporting group title | Guselkumab 100 mg (Week 0 - 16) |
|---|---|

Reporting group description:

Subjects received guselkumab 100 milligram (mg) SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 during PCP.

| Reporting group title | Adalimumab (Week 0 - 16) |
|---|---|

Reporting group description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 followed by adalimumab 40 mg (1 SC injection) at Week 1 and every other week thereafter through Week 15 and placebo matched to guselkumab SC injection at Weeks 0, 4, and 12 during PCP.

| Reporting group title | Placebo then Guselkumab 100 mg (Week 16 - 28) |
|---|---|

Reporting group description:

Subjects who started receiving placebo in the first period were crossed over to receive guselkumab 100 mg SC injection at Weeks 16 and 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21, and 23 during the active comparator controlled period (ACP).

| Reporting group title | Guselkumab 100 mg (Week 16 - 28) |
|---|---|

Reporting group description:

Subjects who started receiving guselkumab in the first period, received placebo matched to guselkumab SC injection at Week 16 followed by guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21 and 23.

| Reporting group title | Adalimumab (Week 16 - 28) |
|---|---|

Reporting group description:

Subjects who received adalimumab in the first period, continued to receive adalimumab 40 mg (1 SC injection) every 2 weeks (q2w) from Week 17 through Week 23 and placebo matched to guselkumab SC injection at Weeks 16 and 20.

| Reporting group title | Placebo then Guselkumab 100 mg (Week 28 - 72) |
|---|---|

Reporting group description:

Subjects assigned to the placebo, then guselkumab arm through Week 28 were assessed for psoriasis area and severity index (PASI) 90 response at Week 28. Subjects who were PASI 90 non-responders received guselkumab 100 mg SC injection at Week 28 and then every 8 weeks (q8w) thereafter through Week 72 and placebo matched to guselkumab SC injection at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders at Week 28 received placebo matched to guselkumab SC injection at Week 28 and every 4 weeks (q4w) thereafter through Week 72 or until loss of greater than or equal to (>=) 50 percentage (%) in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab.

| Reporting group title | Guselkumab 100 mg (Week 28 - 72) |
|---|---|

Reporting group description:

Subjects assigned to the guselkumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders were re-randomized to either guselkumab or placebo. Subjects re-randomized to guselkumab, received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 32 and then q8w through Week 72. Subjects re-randomized to placebo, received placebo matched to guselkumab SC injection q4w through Week 72 or until loss of >=50% in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab.

| Reporting group title | Adalimumab then Guselkumab 100 mg (Week 28 - 72) |
|---|---|

Reporting group description:

Subjects who were assigned to the adalimumab arm through Week 28 were assessed for PASI 90

response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and 32 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 36 and 44. Subjects who were PASI 90 responders, received placebo matched to guselkumab SC injection q4w thereafter through Week 72 or until loss of >=50% in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were treated with guselkumab.

| Reporting group title | Adalimumab (After ACP) |
|---|---|

Reporting group description:

Subjects who received adalimumab 80 mg at Week 0 and adalimumab 40 mg at Week 1 and every other week through Week 23 were assessed for PASI 90 response at Week 28. PASI 90 responders who did not crossover to guselkumab upon loss of >=50% in the improvement in PASI and did not continue any treatment at Week 28 are reported in this arm.

| Reporting group title | Guselkumab Combined |
|---|---|

Reporting group description:

All subjects who received guselkumab 100 mg subcutaneously q8w at Week 76 and thereafter through Week 252.

| Reporting group title | Adalimumab then Guselkumab 100 mg (Week 72 - 264) |
|---|---|

Reporting group description:

All subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252.

| Subject analysis set title | Guselkumab Combined |
|---|---|
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

All subjects who crossed over to receive guselkumab 100 mg subcutaneously at Week 16 from placebo group and subjects who were randomized to guselkumab 100 mg group at Week 0. Placebo crossover subjects were included in the guselkumab column after crossover to guselkumab.

| Subject analysis set title | Withdrawal Group (Through Week 72) |
|---|---|
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Subjects in withdrawal group received guselkumab 100 mg SC injection at Weeks 0, 4 and 12 and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, 5 and q2w through Week 15 to maintain the blind during PCP. Subjects received placebo matched to guselkumab SC injection at Week 16 then guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at q2w from Week 17 through Week 23. These subjects who were PASI 90 responders at Week 28 were randomized to receive placebo matched to guselkumab SC injection at Week 28 and q4w thereafter through Week 72 until loss of >=50% in the improvement in PASI.

| Subject analysis set title | Guselkumab Maintenance Group (Through Week 72) |
|---|---|
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Subjects of maintenance group received guselkumab 100 mg SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 then placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, 5, 7, and q2w through Week 15. Subjects received placebo matched to guselkumab SC injection at Week 16 then guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at q2w from Week 17 through Week 23. These subjects were PASI 90 responders who were randomized to receive guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 32, 40 and thereafter through Week 72.

| Subject analysis set title | Guselkumab 100 mg |
|---|---|
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Subjects received guselkumab 100 mg SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 then placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, 5 and q2w thereafter through Week 15. Subjects received placebo matched to guselkumab SC injection at Week 16 then guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21 and 23.

| Subject analysis set title | Adalimumab |
|---|---|
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 followed by adalimumab 40 mg (1 SC injection) at Weeks 1, 3, 5 and every other week thereafter through Week 15 and placebo matched to

guselkumab SC injection at Weeks 0, 4, and 12. Subjects who received adalimumab in the first period, continued to receive adalimumab 40 mg (1 SC injection) q2w from Week 17 through Week 23 and placebo matched to guselkumab SC injection at Weeks 16 and 20.

| | |
|---|---|
| Subject analysis set title | Adalimumab then Guselkumab 100 mg (Week 28 - 264) |
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Subjects who were assigned to the adalimumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and 32 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 36 and 44. Subjects who were PASI 90 responders, received placebo matched to guselkumab SC injection q4w thereafter through Week 72 or until loss of >=50% in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were treated with guselkumab. All subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252.

## Primary: Percentage of Subjects Who Achieved an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Placebo Group at Week 16

| | |
|---|---|
| End point title | Percentage of Subjects Who Achieved an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Placebo Group at Week 16[1] |

End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set included all subjects who were randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

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

End point timeframe:

Week 16

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

| End point values | Placebo (Week 0 - 16) | Guselkumab 100 mg (Week 0 - 16) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 248 | 495 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 8.5 | 84.1 | | |

## Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|---|
| Comparison groups | Placebo (Week 0 - 16) v Guselkumab 100 mg (Week 0 - 16) |
| Number of subjects included in analysis | 743 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel chi-square test |

## Primary: Percentage of Subjects Who Achieved Psoriasis Area and Severity Index (PASI) 90 Response in the Guselkumab Group Compared to the Placebo Group at Week 16

| End point title | Percentage of Subjects Who Achieved Psoriasis Area and Severity Index (PASI) 90 Response in the Guselkumab Group Compared to the Placebo Group at Week 16[2] |
|---|---|

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these area was assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Randomized analysis set included all subjects who were randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

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

End point timeframe:

Week 16

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

| End point values | Placebo (Week 0 - 16) | Guselkumab 100 mg (Week 0 - 16) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 248 | 496 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 2.4 | 70.0 | | |

### Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|---|
| Comparison groups | Placebo (Week 0 - 16) v Guselkumab 100 mg (Week 0 - 16) |
| Number of subjects included in analysis | 744 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel chi-square test |

## Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) in the Guselkumab Group Compared to the Adalimumab Group at Week 24

| End point title | Percentage of Subjects Who Achieved an IGA Score of Cleared (0) in the Guselkumab Group Compared to the Adalimumab Group at Week 24 |
|---|---|

End point description:

The IGA documents the investigator's assessment of the subject's' psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set included all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 24 or who did not come for evaluation at Week 24 were considered nonresponders) was used to impute missing values.

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

End point timeframe:

Week 24

| **End point values** | Guselkumab 100 mg | Adalimumab | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 496 | 248 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 51.8 | 31.5 | | |

**Statistical analyses**

| **Statistical analysis title** | Statistical Analysis 1 |
|---|---|
| Comparison groups | Guselkumab 100 mg v Adalimumab |
| Number of subjects included in analysis | 744 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel chi-square test |

## Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Week 24

| End point title | Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Week 24 |
|---|---|

End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set included all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 24 or who did not come for evaluation at Week 24 were considered nonresponders) was used to impute missing values.

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

End point timeframe:

Week 24

| End point values | Guselkumab 100 mg | Adalimumab | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 496 | 248 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 83.5 | 64.9 | | |

**Statistical analyses**

| Statistical analysis title | Statistical Analysis 1 |
|---|---|
| Comparison groups | Guselkumab 100 mg v Adalimumab |
| Number of subjects included in analysis | 744 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel chi-square test |

**Secondary: Percentage of Subjects Who Achieved PASI 90 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 24**

| End point title | Percentage of Subjects Who Achieved PASI 90 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 24 |
|---|---|

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Randomized analysis set. Nonresponder imputation (subjects who met treatment-failure criteria before Week 24 or who did not come for evaluation at Week 24 were considered nonresponders) was used to impute missing values.

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

End point timeframe:

Week 24

| End point values | Guselkumab 100 mg | Adalimumab | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 496 | 248 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 75.2 | 54.8 | | |

**Statistical analyses**

| Statistical analysis title | Statistical Analysis 1 |
|---|---|
| Comparison groups | Guselkumab 100 mg v Adalimumab |
| Number of subjects included in analysis | 744 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel chi-square test |

## Secondary: Cumulative Maintenance Rate of PASI 90 Response in the Placebo Group Compared to the Guselkumab Group Through Week 48 to Evaluate Loss of a PASI 90 Response

| End point title | Cumulative Maintenance Rate of PASI 90 Response in the Placebo Group Compared to the Guselkumab Group Through Week 48 to Evaluate Loss of a PASI 90 Response |
|---|---|

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Cumulative maintenance rate was defined as percentage of subjects who maintained their PASI 90 response through Week 48. Randomized analysis set who achieved a PASI 90 response at Week 28, were re-randomized to continue guselkumab or receive placebo and with at least one PASI assessment post Week 28.

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

End point timeframe:

Through Week 48

| End point values | Withdrawal Group (Through Week 72) | Guselkumab Maintenance Group (Through Week 72) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 181 | 193 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 35.4 | 81.8 | | |

### Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|---|

Statistical analysis description:

p value is based on the log-rank test stratified by investigator site (pooled).

| Comparison groups | Withdrawal Group (Through Week 72) v Guselkumab Maintenance Group (Through Week 72) |
|---|---|

| | |
|---|---|
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Logrank |

## Secondary: Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 16 in the Guselkumab Group Compared to the Placebo Group

| | |
|---|---|
| End point title | Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 16 in the Guselkumab Group Compared to the Placebo Group[3] |

End point description:

The DLQI is a 10-item questionnaire that measures the impact of skin disease on participant's quality of life (QoL). Each question was evaluated on a 4-point scale ranging from 0 (not at all) to 3 (very much); where higher scores indicate more impact on QoL. The DLQI total score ranges from 0 (not at all) to 30 (very much): 0-1 = no effect at all on the subject's life; 2-6 = small effect on the subject's life; 7-12 = moderate effect on the subject's life; 13-18 = very large effect on the subject's life; 19-30 = extremely large effect on the subject's life. Higher scores indicate more impact on QoL of subjects. Randomized analysis set included all subjects who were randomized at Week 0 and with a baseline DLQI score.

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

End point timeframe:

Baseline, Week 16

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

| **End point values** | Placebo (Week 0 - 16) | Guselkumab 100 mg (Week 0 - 16) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 248 | 495 | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.6 (± 6.85) | -11.23 (± 6.82) | | |

### Statistical analyses

| **Statistical analysis title** | Statistical Analysis 1 |
|---|---|

Statistical analysis description:

p value is based on analysis of variance (ANOVA) model stratified by investigator site (pooled).

| | |
|---|---|
| Comparison groups | Placebo (Week 0 - 16) v Guselkumab 100 mg (Week 0 - 16) |
| Number of subjects included in analysis | 743 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANOVA |

## Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Week 16

| End point title | Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Week 16[4] |
|---|---|

End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set included all subjects who were randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

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

End point timeframe:

Week 16

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Endpoint was planned to be analyzed for specified arms only.

| End point values | Guselkumab 100 mg (Week 0 - 16) | Adalimumab (Week 0 - 16) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 496 | 248 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 84.1 | 67.7 | | |

### Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|---|

Statistical analysis description:

p value is based on 1-sided Mantel Haenszel (MH) Z-test adjusted for investigator site (pooled).

| Comparison groups | Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16) |
|---|---|
| Number of subjects included in analysis | 744 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[5] |
| P-value | < 0.001 |
| Method | MH Z-test |
| Parameter estimate | Difference in Percentage |
| Point estimate | 16.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 10 |
| upper limit | 23.2 |

Notes:

[5] - non-inferiority margin= -10.0%

| Statistical analysis title | Statistical Analysis 2 |
|---|---|

| | |
|---|---|
| Statistical analysis description: | |
| p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled). | |
| Comparison groups | Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16) |
| Number of subjects included in analysis | 744 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel chi-square test |

## Secondary: Percentage of Subjects Who Achieved PASI 90 Response, in the Guselkumab Group Compared to the Adalimumab Group at Week 16

| | |
|---|---|
| End point title | Percentage of Subjects Who Achieved PASI 90 Response, in the Guselkumab Group Compared to the Adalimumab Group at Week 16[6] |

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Randomized analysis set included all subjects who were randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

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

End point timeframe:

Week 16

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Endpoint was planned to be analyzed for specified arms only.

| **End point values** | Guselkumab 100 mg (Week 0 - 16) | Adalimumab (Week 0 - 16) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 495 | 248 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 70.0 | 46.8 | | |

## Statistical analyses

| | |
|---|---|
| **Statistical analysis title** | Statistical Analysis 2 |
| Statistical analysis description: | |
| p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled). | |
| Comparison groups | Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16) |

| | |
|---|---|
| Number of subjects included in analysis | 743 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel chi-square test |

| **Statistical analysis title** | Statistical Analysis 1 |
|---|---|

Statistical analysis description:

p value is based on 1-sided MH Z-test adjusted for investigator site (pooled).

| | |
|---|---|
| Comparison groups | Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16) |
| Number of subjects included in analysis | 743 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[7] |
| P-value | < 0.001 |
| Method | MH Z-test |
| Parameter estimate | Difference in Percentage |
| Point estimate | 23.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 16 |
| upper limit | 30.4 |

Notes:

[7] - non-inferiority margin= -10.0%

## Secondary: Percentage of Subjects Who Achieved PASI 75 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 16

| End point title | Percentage of Subjects Who Achieved PASI 75 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 16[8] |
|---|---|

End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 75 response represents subjects who achieved at least a 75 percent improvement from baseline in the PASI score. Randomized analysis set. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

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

End point timeframe:

Week 16

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Endpoint was planned to be analyzed for specified arms only.

| End point values | Guselkumab 100 mg (Week 0 - 16) | Adalimumab (Week 0 - 16) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 496 | 248 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 86.3 | 68.5 | | |

**Statistical analyses**

| Statistical analysis title | Statistical Analysis 2 |
|---|---|
| Statistical analysis description: | |
| p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled). | |
| Comparison groups | Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16) |
| Number of subjects included in analysis | 744 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel chi-square test |

| Statistical analysis title | Statistical Analysis 1 |
|---|---|
| Statistical analysis description: | |
| p value is based on 1-sided MH Z-test adjusted for investigator site (pooled). | |
| Comparison groups | Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16) |
| Number of subjects included in analysis | 744 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[9] |
| P-value | < 0.001 |
| Method | MH Z-test |
| Parameter estimate | Difference in percentage |
| Point estimate | 17.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 11.4 |
| upper limit | 24.4 |

Notes:

[9] - non-inferiority margin= -10%

**Secondary: Percentage of Subjects who Achieved a Scalp-specific Investigator's Global Assessment (ss-IGA) Score of 0 or 1 and at Least a 2-Grade Improvement From Baseline at Week 16 in the Guselkumab Group Compared to the Placebo Group**

| End point title | Percentage of Subjects who Achieved a Scalp-specific Investigator's Global Assessment (ss-IGA) Score of 0 or 1 and at Least a 2-Grade Improvement From Baseline at Week 16 in the Guselkumab Group Compared to the Placebo Group[10] |
|---|---|

End point description:

The ss-IGA instrument is used to evaluate the disease severity of scalp psoriasis. The lesions were assessed in terms of the clinical signs of redness, thickness, and scaliness, which are scored on a 5-point scale ranging from 0 = absence of disease, 1 = very mild disease, 2 = mild disease, 3 = moderate disease, and 4 = severe disease. Population analyzed included only randomized subjects who had an ss-IGA score greater than or equal to (>=) 2 at baseline. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint.

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

End point timeframe:

Week 16

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

| **End point values** | Placebo (Week 0 - 16) | Guselkumab 100 mg (Week 0 - 16) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 202 | 408 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 10.9 | 80.6 | | |

**Statistical analyses**

| **Statistical analysis title** | Statistical Analysis 1 |
|---|---|

Statistical analysis description:

p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).

| Comparison groups | Placebo (Week 0 - 16) v Guselkumab 100 mg (Week 0 - 16) |
|---|---|
| Number of subjects included in analysis | 610 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel chi-square test |

## Secondary: Change From Baseline in Psoriasis Symptom and Sign Diary (PSSD) Symptom Score at Week 16 in the Guselkumab Group Compared to the Placebo Group

| End point title | Change From Baseline in Psoriasis Symptom and Sign Diary (PSSD) Symptom Score at Week 16 in the Guselkumab Group Compared to the Placebo Group[11] |
|---|---|

End point description:

The PSSD consisted of 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 (absent) to 10 (worst imaginable) numerical rating scales for severity. The average value is converted into 0-100 scoring, such that Symptom [or Sign] score=average value*10, where, 0=least severe and 100=most severe and higher score indicates more severe disease. PSSD analysis set included all subjects who had baseline PSSD scores as the average score of at least 4 days out of the 7 days prior to the Week 0 visit. This endpoint was planned to be compared only for groups Placebo and Guselkumab 100 mg.

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

End point timeframe:

Baseline and Week 16

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

| **End point values** | Placebo (Week 0 - 16) | Guselkumab 100 mg (Week 0 - 16) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 198 | 411 | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -8.3 (± 23.67) | -40.4 (± 26.52) | | |

**Statistical analyses**

| **Statistical analysis title** | Statistical Analysis 1 |
|---|---|

Statistical analysis description:

p value is based on ANOVA model stratified by investigator site (pooled).

| Comparison groups | Placebo (Week 0 - 16) v Guselkumab 100 mg (Week 0 - 16) |
|---|---|
| Number of subjects included in analysis | 609 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANOVA |

## Secondary: Percentage of Subjects who Achieved a PSSD Symptom Score of 0 in the Guselkumab Group Compared to the Adalimumab Group at Week 24

| End point title | Percentage of Subjects who Achieved a PSSD Symptom Score of 0 in the Guselkumab Group Compared to the Adalimumab Group at Week 24 |
|---|---|

End point description:

The PSSD consisted of 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 (absent) to 10 (worst imaginable) numerical rating scales for severity. The average value is converted into 0-100 scoring, such that Symptom [or Sign] score=average value*10, where, 0=least severe and 100=most severe and higher score indicates more severe disease. PSSD analysis set included all subjects who were randomized at Week 0 and had baseline PSSD score greater than 0. This endpoint was planned to be compared only for groups Placebo and Guselkumab 100 mg.

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

End point timeframe:

Week 24

| End point values | Guselkumab 100 mg | Adalimumab | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 410 | 200 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 35.1 | 22.5 | | |

### Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|---|

Statistical analysis description:

p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).

| | |
|---|---|
| Comparison groups | Guselkumab 100 mg v Adalimumab |
| Number of subjects included in analysis | 610 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel chi-square test |

## Secondary: Cumulative Maintenance Rate of PASI 90 Response in the Guselkumab Withdrawal Group Compared to the Guselkumab Maintenance Group Through Week 72 to Evaluate Loss of a PASI 90 Response

| End point title | Cumulative Maintenance Rate of PASI 90 Response in the Guselkumab Withdrawal Group Compared to the Guselkumab Maintenance Group Through Week 72 to Evaluate Loss of a PASI 90 Response |
|---|---|

End point description:

In PASI system, body is divided into 4 regions: head, trunk, upper and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score ranging from 0 to 6 and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score ranging from 0 to 72. Higher score=more severe disease. PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in PASI score. Cumulative maintenance rate was determined for subjects who were withdrawn from study medication and who maintained guselkumab every 8 weeks dosing schedule and was defined as percentage of subjects who maintained their PASI 90 response through Week 72. Population analyzed included PASI 90 responders at Week 28 and who were randomized at Week 28 and treated with guselkumab. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint.

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

End point timeframe:

Through Week 72

| End point values | Withdrawal Group (Through Week 72) | Guselkumab Maintenance Group (Through Week 72) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 181 | 193 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 11.5 | 86 | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Who Achieved PASI 90 Response at Week 252

| End point title | Percentage of Subjects Who Achieved PASI 90 Response at Week 252 |
|---|---|

End point description:

In PASI system, body is divided into 4 regions: head, trunk, upper and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score ranging from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score that can range from 0 to 72. Higher score= more severe disease. PASI 90 response signify subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

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

End point timeframe:

Week 252

| End point values | Guselkumab Combined | Adalimumab then Guselkumab 100 mg (Week 28 - 264) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 560 | 177 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 82.0 | 79.1 | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Who Achieved PASI 75 Response at Week 252

| End point title | Percentage of Subjects Who Achieved PASI 75 Response at Week 252 |
|---|---|

End point description:

In PASI system, body is divided into 4 regions: head, trunk, upper and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score ranging from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score that can range from 0 to 72. Higher score= more severe disease. PASI 75 response signify subjects who achieved at least a 75 percent improvement from baseline in the PASI score. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

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

End point timeframe:

Week 252

| **End point values** | Guselkumab Combined | Adalimumab then Guselkumab 100 mg (Week 28 - 264) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 560 | 177 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 93.4 | 92.7 | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) at Week 252

| End point title | Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) at Week 252 |
|---|---|

End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject’s psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

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

End point timeframe:

Week 252

| End point values | Guselkumab Combined | Adalimumab then Guselkumab 100 mg (Week 28 - 264) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 559 | 177 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 85.0 | 83.1 | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects with a DLQI Score of 0 or 1 at Week 252

| End point title | Percentage of Subjects with a DLQI Score of 0 or 1 at Week 252 |
|---|---|

End point description:

DLQI measures impact of skin disease on subject's QoL. Each question was evaluated on a 4-point scale ranging from 0 (not at all) to 3 (very much). DLQI total score ranges from 0 (not at all) to 30 (very much): 0-1=no effect on subject's life; 2-6=small effect; 7-12=moderate effect; 13-18=very large effect; 19-30=extremely large effect. DLQI was calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. Higher scores indicate more impact on subject's QoL. Population analyzed included subjects randomized at Week 0 and treated with guselkumab with baseline DLQI score >1. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

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

End point timeframe:

Week 252

| End point values | Guselkumab Combined | Adalimumab then Guselkumab 100 mg (Week 28 - 264) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 550 | 173 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 71.1 | 69.9 | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects who Achieved a PSSD Symptom Score of 0 at Week 252

| End point title | Percentage of Subjects who Achieved a PSSD Symptom Score |
|---|---|

| | |
|---|---|
| | of 0 at Week 252 |

End point description:

The PSSD consisted of 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 (absent) to 10 (worst imaginable) numerical rating scales for severity. The average value is converted into 0-100 scoring, such that Symptom score=average value*10, where, 0=least severe and 100=most severe and higher score indicates more severe disease. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab with baseline PSSD symptom score >0. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

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

End point timeframe:

Week 252

| **End point values** | Guselkumab Combined | Adalimumab then Guselkumab 100 mg (Week 28 - 264) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 460 | 145 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 42.0 | 36.6 | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects who Achieved a PSSD Sign Score of 0 at Week 252

| | |
|---|---|
| End point title | Percentage of Subjects who Achieved a PSSD Sign Score of 0 at Week 252 |

End point description:

The PSSD consisted of 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 (absent) to 10 (worst imaginable) numerical rating scales for severity. The average value is converted into 0-100 scoring, such that Sign score=average value*10, where, 0=least severe and 100=most severe and higher score indicates more severe disease. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab with baseline PSSD sign score >0. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

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

End point timeframe:

Week 252

| End point values | Guselkumab Combined | Adalimumab then Guselkumab 100 mg (Week 28 - 264) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 461 | 145 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | 31.0 | 24.1 | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Baseline (Week 0) up to Week 264

Adverse event reporting additional description:

All subjects who were randomized at Week 0, received >=1 dose of study agent (partial or complete). Subjects who discontinued treatment prematurely were followed for at least 12 weeks after last dose and who discontinued in the previous period and had safety follow-up continuing in the current period, were counted in both the periods.

| | |
|---|---|
| Assessment type | Non-systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 23.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Guselkumab 100 mg (Week 0 - 16) |

Reporting group description:

Subjects received guselkumab 100 milligram (mg) SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 during PCP.

| | |
|---|---|
| Reporting group title | Placebo (Week 0 - 16) |

Reporting group description:

Subjects received placebo matched to guselkumab SC injection at Weeks 0, 4, and 12 and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 to maintain the blind during placebo controlled period (PCP).

| | |
|---|---|
| Reporting group title | Placebo then Guselkumab 100 mg (Week 16 - 28) |

Reporting group description:

Subjects who started receiving placebo in the first period were crossed over to receive guselkumab 100 mg SC injection at Weeks 16 and 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21, and 23 during the active comparator controlled period (ACP).

| | |
|---|---|
| Reporting group title | Adalimumab (Week 0 - 16) |

Reporting group description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 followed by adalimumab 40 mg (1 SC injection) at Week 1 and every other week thereafter through Week 15 and placebo matched to guselkumab SC injection at Weeks 0, 4, and 12 during PCP.

| | |
|---|---|
| Reporting group title | Guselkumab 100 mg (Week 16 - 28) |

Reporting group description:

Subjects who started receiving guselkumab in the first period, received placebo matched to guselkumab SC injection at Week 16 followed by guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21 and 23.

| | |
|---|---|
| Reporting group title | Adalimumab (Week 16 - 28) |

Reporting group description:

Subjects who received adalimumab in the first period, continued to receive adalimumab 40 mg (1 SC injection) every 2 weeks (q2w) from Week 17 through Week 23 and placebo matched to guselkumab SC injection at Weeks 16 and 20.

| | |
|---|---|
| Reporting group title | Placebo then Guselkumab 100 mg (Week 28 - 264) |

Reporting group description:

Subjects assigned to the placebo, then guselkumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders received guselkumab 100 mg SC injection at Week 28 and then every 8 weeks (q8w) thereafter through Week 72 and placebo matched to guselkumab SC injection at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders at Week 28 received placebo matched to guselkumab SC injection at Week 28 and every 4 weeks (q4w) thereafter through Week 72 or until loss of greater than or equal to (>=) 50 percentage (%) in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab. Thereafter, subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252.

| Reporting group title | Guselkumab 100 mg (Week 28 - 264) |
|---|---|

Reporting group description:

Subjects assigned to the guselkumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders were re-randomized to either guselkumab or placebo. Subjects re-randomized to guselkumab, received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 32 and then q8w through Week 72. Subjects re-randomized to placebo, received placebo matched to guselkumab SC injection q4w through Week 72 or until loss of >=50% in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab. Thereafter, subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252.

| Reporting group title | Adalimumab Then Guselkumab 100 mg (Week 28 - 264) |
|---|---|

Reporting group description:

Subjects who were assigned to the adalimumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders received guselkumab 100 mg SC injection at Week 28 and 32 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Week 36 and q8w through Week 72. Subjects who were PASI 90 responders, received placebo matched to guselkumab SC injection q4w thereafter through Week 72 or until loss of >=50% in the improvement in PASI. If they lost response according to this definition, they were treated with guselkumab. Thereafter, subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252. The presentation of data from the adalimumab group from Week 28 to Week 264 is divided into 2 arms (adalimumab then guselkumab 100 mg (Week 28 - 264) and adalimumab (After ACP) in order to represent exposure to 2 different active study agents (adalimumab vs guselkumab).

| Reporting group title | Adalimumab (After ACP) |
|---|---|

Reporting group description:

Subjects who received adalimumab 80 mg at Week 0 and adalimumab 40 mg at Week 1 and every other week through Week 23 were assessed for PASI 90 response at Week 28. PASI 90 responders who did not crossover to guselkumab upon loss of >=50% in the improvement in PASI and did not continue any treatment at Week 28 are reported in this arm.

| **Serious adverse events** | Guselkumab 100 mg (Week 0 - 16) | Placebo (Week 0 - 16) | Placebo then Guselkumab 100 mg (Week 16 - 28) |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 8 / 494 (1.62%) | 3 / 248 (1.21%) | 5 / 233 (2.15%) |
| number of deaths (all causes) | 0 | 1 | 1 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| B-Cell Lymphoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Benign Neoplasm of Thyroid Gland | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Breast Cancer | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Bronchial Carcinoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Endometrial Cancer | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Ependymoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Fibroadenoma of Breast | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Inflammatory Pseudotumour | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Lipoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 1 / 233 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant Melanoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Osteochondroma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Pancreatic Carcinoma Stage Iv | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Prostate Cancer | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Rectal Cancer | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Sinonasal Papilloma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Uterine Leiomyoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Varicose Vein | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion Spontaneous | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Ectopic Pregnancy | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Sudden Death | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Immune system disorders | | | |
| Anaphylactic Reaction | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Drug Hypersensitivity | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 1 / 233 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Social circumstances | | | |
| Miscarriage of Partner | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Reproductive system and breast disorders | | | |
| Benign Prostatic Hyperplasia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Ovarian Cyst | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Prostatitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Uterine Haemorrhage | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Nasal Septum Deviation | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Pulmonary Embolism | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Pulmonary Fibrosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |

| | | | |
|---|---|---|---|
| Respiratory Failure | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Sinus Polyp | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Sleep Apnoea Syndrome | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 | | | |
| Device Dislocation | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Alcoholism | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Depression | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Suicide Attempt | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Investigations | | | |

| | | | |
|---|---|---|---|
| Alanine Aminotransferase Increased | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Injury, poisoning and procedural complications | | | |
| Chest Injury | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 1 / 233 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Craniocerebral Injury | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Eye Injury | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Femur Fracture | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Head Injury | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Joint Dislocation | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |

| | | | |
|---|---|---|---|
| Ligament Rupture | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Ligament Sprain | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Lower Limb Fracture | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Meniscus Injury | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Multiple Fractures | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 1 / 233 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Multiple Injuries | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Nerve Injury | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Radius Fracture | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Spinal Cord Injury Cervical | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Subdural Haematoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Subdural Haemorrhage | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 1 / 233 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ulnar Nerve Injury | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Wound | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 1 / 233 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Acute Myocardial Infarction | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Angina Pectoris | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Angina Unstable | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Atrial Fibrillation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Bradycardia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 Failure | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Coronary Artery Disease | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Myocardial Infarction | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Myocardial Ischaemia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 | | | |
| Cerebellar Stroke | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Diabetic Coma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Epilepsy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Myelitis Transverse | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Myelopathy | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Peripheral Nerve Lesion | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Peripheral Nerve Paresis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Syncope | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 1 / 233 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 1 / 233 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Eye disorders | | | |
| Retinal Vein Occlusion | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 | | | |
| Duodenal Perforation | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 Haemorrhage | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 248 (0.40%) | 0 / 233 (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 |
| Haemorrhoidal Haemorrhage | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Inguinal Hernia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Irritable Bowel Syndrome | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Mallory-Weiss Syndrome | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Pancreatitis Acute | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Submaxillary Gland Enlargement | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Umbilical Hernia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Upper Gastrointestinal Haemorrhage | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Hepatobiliary disorders | | | |
| Cholecystitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Cholecystitis Acute | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Cholecystitis Chronic | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 248 (0.40%) | 0 / 233 (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 |
| Cholelithiasis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Hepatic Steatosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 Colic | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Ureterolithiasis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Urinary Retention | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Intervertebral Disc Protrusion | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Muscular Weakness | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Musculoskeletal Chest Pain | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Musculoskeletal Pain | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 248 (0.40%) | 0 / 233 (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 |
| Osteoarthritis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Osteonecrosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Psoriatic Arthropathy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Rotator Cuff Syndrome | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Synovitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Appendicitis Perforated | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Chronic Sinusitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Chronic Tonsillitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Disseminated Tuberculosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Hiv Infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Influenza | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Injection Site Abscess | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Peritonsillar Abscess | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Pilonidal Cyst | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Retroperitoneal Abscess | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Soft Tissue Infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Tuberculosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Urosepsis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Vestibular Neuronitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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 |
| Wound Infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 1 / 233 (0.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Obesity | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (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** | Adalimumab (Week 0 - 16) | Guselkumab 100 mg (Week 16 - 28) | Adalimumab (Week 16 - 28) |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 248 (2.42%) | 10 / 481 (2.08%) | 3 / 240 (1.25%) |
| number of deaths (all causes) | 3 | 0 | 3 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| B-Cell Lymphoma | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Benign Neoplasm of Thyroid Gland | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Breast Cancer | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Bronchial Carcinoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Endometrial Cancer | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Ependymoma | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Fibroadenoma of Breast | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Inflammatory Pseudotumour | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Lipoma | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Malignant Melanoma | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Osteochondroma | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Pancreatic Carcinoma Stage Iv | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Prostate Cancer | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 1 / 481 (0.21%) | 0 / 240 (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 |
| Rectal Cancer | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Sinonasal Papilloma | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Uterine Leiomyoma | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Varicose Vein | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Pregnancy, puerperium and perinatal conditions | | | |

| | | | |
|---|---|---|---|
| Abortion Spontaneous | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Ectopic Pregnancy | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Sudden Death | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Immune system disorders | | | |
| Anaphylactic Reaction | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Drug Hypersensitivity | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Social circumstances | | | |
| Miscarriage of Partner | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Reproductive system and breast disorders | | | |
| Benign Prostatic Hyperplasia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Ovarian Cyst | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 1 / 481 (0.21%) | 0 / 240 (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 |
| Prostatitis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Uterine Haemorrhage | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Nasal Septum Deviation | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Pulmonary Embolism | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Pulmonary Fibrosis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Respiratory Failure | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Sinus Polyp | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Sleep Apnoea Syndrome | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 | | | |
| Device Dislocation | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Alcoholism | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Depression | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Suicide Attempt | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Investigations | | | |
| Alanine Aminotransferase Increased | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 | | | |
| Chest Injury | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Concussion | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Craniocerebral Injury | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Eye Injury | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Femur Fracture | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Head Injury | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Joint Dislocation | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Ligament Rupture | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Ligament Sprain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Lower Limb Fracture | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Meniscus Injury | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Multiple Fractures | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Multiple Injuries | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Nerve Injury | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Radius Fracture | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Spinal Cord Injury Cervical | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Subdural Haematoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Subdural Haemorrhage | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Ulnar Nerve Injury | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Wound | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 | | | |
| Acute Myocardial Infarction | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 1 / 481 (0.21%) | 0 / 240 (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 |
| Angina Pectoris | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Angina Unstable | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Atrial Fibrillation | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Bradycardia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 Failure | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 1 / 481 (0.21%) | 0 / 240 (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 |
| Coronary Artery Disease | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Myocardial Infarction | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | 1 / 481 (0.21%) | 0 / 240 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial Ischaemia | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 | | | |
| Cerebellar Stroke | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Diabetic Coma | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 1 / 240 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myelitis Transverse | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Myelopathy | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Peripheral Nerve Lesion | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Peripheral Nerve Paresis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Syncope | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Thrombocytopenia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 1 / 481 (0.21%) | 0 / 240 (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 |
| Eye disorders | | | |
| Retinal Vein Occlusion | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 | | | |
| Duodenal Perforation | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Gastritis | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Gastrointestinal Haemorrhage | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Haemorrhoidal Haemorrhage | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Irritable Bowel Syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Mallory-Weiss Syndrome | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 1 / 481 (0.21%) | 0 / 240 (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 |
| Pancreatitis Acute | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Submaxillary Gland Enlargement | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Umbilical Hernia | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Upper Gastrointestinal Haemorrhage | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Hepatobiliary disorders | | | |
| Cholecystitis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Cholecystitis Acute | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Cholecystitis Chronic | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Cholelithiasis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Hepatic Steatosis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 1 / 481 (0.21%) | 0 / 240 (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 |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 Colic | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Ureterolithiasis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Urinary Retention | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|---|---|---|
| Arthralgia | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Intervertebral Disc Protrusion | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Muscular Weakness | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Musculoskeletal Chest Pain | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Musculoskeletal Pain | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Osteoarthritis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Osteonecrosis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Psoriatic Arthropathy | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | 0 / 481 (0.00%) | 1 / 240 (0.42%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rotator Cuff Syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Synovitis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Appendicitis Perforated | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 1 / 481 (0.21%) | 0 / 240 (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 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Chronic Sinusitis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Chronic Tonsillitis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Cystitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Disseminated Tuberculosis | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Hiv Infection | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Influenza | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Injection Site Abscess | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Peritonsillar Abscess | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Pilonidal Cyst | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Retroperitoneal Abscess | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Soft Tissue Infection | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 1 / 481 (0.21%) | 0 / 240 (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 |
| Tuberculosis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 1 / 240 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Urosepsis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Vestibular Neuronitis | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Wound Infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 |
| Metabolism and nutrition disorders | | | |
| Obesity | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 0 / 240 (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 then Guselkumab 100 mg (Week 28 - 264) | Guselkumab 100 mg (Week 28 - 264) | Adalimumab Then Guselkumab 100 mg (Week 28 - 264) |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 36 / 229 (15.72%) | 66 / 473 (13.95%) | 36 / 220 (16.36%) |
| number of deaths (all causes) | 1 | 0 | 3 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| B-Cell Lymphoma | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Benign Neoplasm of Thyroid Gland | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Breast Cancer | | | |
| subjects affected / exposed | 2 / 229 (0.87%) | 0 / 473 (0.00%) | 0 / 220 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial Carcinoma | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Endometrial Cancer | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Ependymoma | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Fibroadenoma of Breast | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Inflammatory Pseudotumour | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Lipoma | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Malignant Melanoma | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Osteochondroma | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Pancreatic Carcinoma Stage Iv | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Prostate Cancer | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Rectal Cancer | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinonasal Papilloma | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Uterine Leiomyoma | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Hypertension | | | |
| subjects affected / exposed | 2 / 229 (0.87%) | 0 / 473 (0.00%) | 0 / 220 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Varicose Vein | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion Spontaneous | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Ectopic Pregnancy | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Sudden Death | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Immune system disorders | | | |
| Anaphylactic Reaction | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Drug Hypersensitivity | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Social circumstances | | | |
| Miscarriage of Partner | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Reproductive system and breast disorders | | | |
| Benign Prostatic Hyperplasia | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Ovarian Cyst | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Prostatitis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine Haemorrhage | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Nasal Septum Deviation | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 2 / 473 (0.42%) | 0 / 220 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary Embolism | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Pulmonary Fibrosis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Failure | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Sinus Polyp | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Sleep Apnoea Syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Psychiatric disorders | | | |
| Device Dislocation | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Alcoholism | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Suicide Attempt | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Investigations | | | |
| Alanine Aminotransferase Increased | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 | | | |
| Chest Injury | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |

| | | | |
|---|---|---|---|
| Concussion | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Craniocerebral Injury | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Eye Injury | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur Fracture | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Head Injury | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Joint Dislocation | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Ligament Rupture | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Ligament Sprain | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Lower Limb Fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Meniscus Injury | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Multiple Fractures | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Multiple Injuries | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nerve Injury | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Radius Fracture | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Spinal Cord Injury Cervical | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Subdural Haematoma | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subdural Haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Ulnar Nerve Injury | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Wound | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 | | | |
| Acute Myocardial Infarction | | | |
| subjects affected / exposed | 2 / 229 (0.87%) | 4 / 473 (0.85%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 4 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Angina Pectoris | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 1 / 473 (0.21%) | 0 / 220 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Angina Unstable | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial Fibrillation | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bradycardia | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac Failure | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Coronary Artery Disease | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Myocardial Infarction | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 2 / 220 (0.91%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Myocardial Ischaemia | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Nervous system disorders | | | |
| Cerebellar Stroke | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Diabetic Coma | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Myelitis Transverse | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Myelopathy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Peripheral Nerve Lesion | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Peripheral Nerve Paresis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Syncope | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| **Blood and lymphatic system disorders** | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 1 / 473 (0.21%) | 0 / 220 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| **Eye disorders** | | | |

| | | | |
|---|---|---|---|
| Retinal Vein Occlusion | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Gastrointestinal disorders | | | |
| Duodenal Perforation | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Gastrointestinal Haemorrhage | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Haemorrhoidal Haemorrhage | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 2 / 473 (0.42%) | 0 / 220 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Irritable Bowel Syndrome | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Mallory-Weiss Syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis Acute | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Submaxillary Gland Enlargement | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Umbilical Hernia | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper Gastrointestinal Haemorrhage | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Hepatobiliary disorders | | | |
| Cholecystitis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholecystitis Acute | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 2 / 220 (0.91%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholecystitis Chronic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 229 (0.00%) | 2 / 473 (0.42%) | 0 / 220 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholelithiasis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 2 / 220 (0.91%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic Steatosis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal Colic | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Ureterolithiasis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Urinary Retention | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Intervertebral Disc Protrusion | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Muscular Weakness | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Musculoskeletal Chest Pain | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Musculoskeletal Pain | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Osteoarthritis | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 2 / 473 (0.42%) | 3 / 220 (1.36%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteonecrosis | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Psoriatic Arthropathy | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 3 / 473 (0.63%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rotator Cuff Syndrome | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Synovitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Appendicitis | | | |
| subjects affected / exposed | 2 / 229 (0.87%) | 4 / 473 (0.85%) | 0 / 220 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis Perforated | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 4 / 473 (0.85%) | 0 / 220 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 3 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chronic Sinusitis | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Chronic Tonsillitis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Disseminated Tuberculosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Diverticulitis | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Hiv Infection | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Influenza | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Injection Site Abscess | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Peritonsillar Abscess | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Pilonidal Cyst | | | |
| subjects affected / exposed | 1 / 229 (0.44%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Pneumonia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 229 (0.87%) | 2 / 473 (0.42%) | 2 / 220 (0.91%) |
| occurrences causally related to treatment / all | 1 / 2 | 1 / 2 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Retroperitoneal Abscess | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 1 / 220 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Soft Tissue Infection | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Tuberculosis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Urosepsis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Vestibular Neuronitis | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |
| Wound Infection | | | |
| subjects affected / exposed | 0 / 229 (0.00%) | 0 / 473 (0.00%) | 0 / 220 (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 |
| Metabolism and nutrition disorders | | | |
| Obesity | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 229 (0.00%) | 1 / 473 (0.21%) | 0 / 220 (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 |

| **Serious adverse events** | Adalimumab (After ACP) | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| B-Cell Lymphoma | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Benign Neoplasm of Thyroid Gland | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Breast Cancer | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchial Carcinoma | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Endometrial Cancer | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ependymoma | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | | |
|---|---|---|---|---|
| Fibroadenoma of Breast | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Inflammatory Pseudotumour | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lipoma | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Malignant Melanoma | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Osteochondroma | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pancreatic Carcinoma Stage Iv | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Prostate Cancer | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rectal Cancer | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sinonasal Papilloma | | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Uterine Leiomyoma | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Varicose Vein | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion Spontaneous | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ectopic Pregnancy | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Non-Cardiac Chest Pain | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sudden Death | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Immune system disorders | | | | |
| Anaphylactic Reaction | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Drug Hypersensitivity | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Social circumstances | | | | |
| Miscarriage of Partner | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Reproductive system and breast disorders | | | | |
| Benign Prostatic Hyperplasia | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ovarian Cyst | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Prostatitis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|---|---|---|---|
| Uterine Haemorrhage | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory, thoracic and mediastinal disorders | | | | |
| Nasal Septum Deviation | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary Embolism | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary Fibrosis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory Failure | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sinus Polyp | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sleep Apnoea Syndrome | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Psychiatric disorders | | | | |
| Device Dislocation | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|---|---|---|---|
| Alcoholism | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Anxiety | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Depression | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Suicide Attempt | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Investigations | | | | |
| Alanine Aminotransferase Increased | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Injury, poisoning and procedural complications | | | | |
| Chest Injury | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Concussion | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Craniocerebral Injury | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|---|---|---|---|
| Eye Injury | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Femur Fracture | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Head Injury | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Joint Dislocation | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ligament Rupture | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ligament Sprain | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lower Limb Fracture | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Meniscus Injury | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Multiple Fractures | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Multiple Injuries | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nerve Injury | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Radius Fracture | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Spinal Cord Injury Cervical | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Subdural Haematoma | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Subdural Haemorrhage | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ulnar Nerve Injury | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Wound | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac disorders | | | | |
| Acute Myocardial Infarction | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Angina Pectoris | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Angina Unstable | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Atrial Fibrillation | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bradycardia | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac Failure | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Coronary Artery Disease | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Myocardial Infarction | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Myocardial Ischaemia | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nervous system disorders | | | | |
| Cerebellar Stroke | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Diabetic Coma | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Epilepsy | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Myelitis Transverse | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Myelopathy | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Paraesthesia | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Peripheral Nerve Lesion | | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Peripheral Nerve Paresis | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Presyncope | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Syncope | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| Retinal Vein Occlusion | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Duodenal Perforation | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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|---|---|---|---|---|
| Gastritis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal Haemorrhage | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haemorrhoidal Haemorrhage | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haemorrhoids | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Inguinal Hernia | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Irritable Bowel Syndrome | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Mallory-Weiss Syndrome | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pancreatitis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pancreatitis Acute | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Submaxillary Gland Enlargement | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Umbilical Hernia | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Upper Gastrointestinal Haemorrhage | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatobiliary disorders | | | | |
| Cholecystitis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cholecystitis Acute | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cholecystitis Chronic | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cholelithiasis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatic Steatosis | | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal Colic | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urinary Retention | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Intervertebral Disc Protrusion | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Muscular Weakness | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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|---|---|---|---|---|
| Musculoskeletal Chest Pain | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Musculoskeletal Pain | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Osteoarthritis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Osteonecrosis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Psoriatic Arthropathy | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rotator Cuff Syndrome | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Synovitis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infections and infestations | | | | |
| Appendicitis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Appendicitis Perforated | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchitis | | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cellulitis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Chronic Sinusitis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Chronic Tonsillitis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cystitis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Disseminated Tuberculosis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Diverticulitis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Erysipelas | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hiv Infection | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Influenza | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Injection Site Abscess | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Peritonsillar Abscess | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pilonidal Cyst | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Retroperitoneal Abscess | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Soft Tissue Infection | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tuberculosis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Upper Respiratory Tract Infection | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Urosepsis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Vestibular Neuronitis | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Wound Infection | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Metabolism and nutrition disorders | | | | |
| Obesity | | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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

| **Non-serious adverse events** | Guselkumab 100 mg (Week 0 - 16) | Placebo (Week 0 - 16) | Placebo then Guselkumab 100 mg (Week 16 - 28) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 125 / 494 (25.30%) | 60 / 248 (24.19%) | 33 / 233 (14.16%) |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 10 / 494 (2.02%) | 4 / 248 (1.61%) | 1 / 233 (0.43%) |
| occurrences (all) | 11 | 4 | 1 |
| Cardiac disorders | | | |
| Cardiac Failure Congestive | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 248 (0.00%) | 0 / 233 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 25 / 494 (5.06%) | 7 / 248 (2.82%) | 5 / 233 (2.15%) |
| occurrences (all) | 27 | 7 | 5 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 11 / 494 (2.23%) | 2 / 248 (0.81%) | 0 / 233 (0.00%) |
| occurrences (all) | 12 | 2 | 0 |
| Gastrooesophageal Reflux Disease | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 248 (0.00%) | 0 / 233 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 8 / 494 (1.62%) | 4 / 248 (1.61%) | 1 / 233 (0.43%) |
| occurrences (all) | 8 | 4 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis Contact | | | |
| subjects affected / exposed | 4 / 494 (0.81%) | 2 / 248 (0.81%) | 0 / 233 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| Psoriasis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 3 / 248 (1.21%) | 0 / 233 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 11 / 494 (2.23%) | 6 / 248 (2.42%) | 0 / 233 (0.00%) |
| occurrences (all) | 12 | 6 | 0 |
| Back Pain | | | |
| subjects affected / exposed | 4 / 494 (0.81%) | 6 / 248 (2.42%) | 0 / 233 (0.00%) |
| occurrences (all) | 4 | 6 | 0 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 3 / 494 (0.61%) | 3 / 248 (1.21%) | 6 / 233 (2.58%) |
| occurrences (all) | 3 | 3 | 7 |
| Gastroenteritis | | | |
| subjects affected / exposed | 4 / 494 (0.81%) | 1 / 248 (0.40%) | 0 / 233 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 35 / 494 (7.09%) | 16 / 248 (6.45%) | 12 / 233 (5.15%) |
| occurrences (all) | 36 | 17 | 12 |
| Pharyngitis | | | |
| subjects affected / exposed | 7 / 494 (1.42%) | 2 / 248 (0.81%) | 2 / 233 (0.86%) |
| occurrences (all) | 7 | 2 | 2 |
| Sinusitis | | | |
| subjects affected / exposed | 3 / 494 (0.61%) | 3 / 248 (1.21%) | 1 / 233 (0.43%) |
| occurrences (all) | 3 | 3 | 1 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 16 / 494 (3.24%) | 10 / 248 (4.03%) | 5 / 233 (2.15%) |
| occurrences (all) | 17 | 11 | 5 |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 6 / 494 (1.21%) | 1 / 248 (0.40%) | 1 / 233 (0.43%) |
| occurrences (all) | 7 | 1 | 1 |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 2 / 494 (0.40%) | 1 / 248 (0.40%) | 0 / 233 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |

| **Non-serious adverse events** | Adalimumab (Week 0 - 16) | Guselkumab 100 mg (Week 16 - 28) | Adalimumab (Week 16 - 28) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 51 / 248 (20.56%) | 63 / 481 (13.10%) | 45 / 240 (18.75%) |

| | | | |
|---|---|---|---|
| Vascular disorders<br>Hypertension<br>subjects affected / exposed<br>occurrences (all) | 6 / 248 (2.42%)<br>6 | 4 / 481 (0.83%)<br>4 | 1 / 240 (0.42%)<br>1 |
| Cardiac disorders<br>Cardiac Failure Congestive<br>subjects affected / exposed<br>occurrences (all) | 0 / 248 (0.00%)<br>0 | 0 / 481 (0.00%)<br>0 | 0 / 240 (0.00%)<br>0 |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all) | 5 / 248 (2.02%)<br>6 | 6 / 481 (1.25%)<br>6 | 4 / 240 (1.67%)<br>4 |
| Gastrointestinal disorders<br>Diarrhoea<br>subjects affected / exposed<br>occurrences (all)<br><br>Gastrooesophageal Reflux Disease<br>subjects affected / exposed<br>occurrences (all) | 4 / 248 (1.61%)<br>4<br><br>1 / 248 (0.40%)<br>1 | 3 / 481 (0.62%)<br>3<br><br>1 / 481 (0.21%)<br>1 | 3 / 240 (1.25%)<br>3<br><br>2 / 240 (0.83%)<br>2 |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all) | 1 / 248 (0.40%)<br>1 | 2 / 481 (0.42%)<br>2 | 2 / 240 (0.83%)<br>2 |
| Skin and subcutaneous tissue disorders<br>Dermatitis Contact<br>subjects affected / exposed<br>occurrences (all)<br><br>Psoriasis<br>subjects affected / exposed<br>occurrences (all) | 1 / 248 (0.40%)<br>1<br><br>5 / 248 (2.02%)<br>6 | 2 / 481 (0.42%)<br>2<br><br>1 / 481 (0.21%)<br>1 | 0 / 240 (0.00%)<br>0<br><br>1 / 240 (0.42%)<br>1 |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all)<br><br>Back Pain<br>subjects affected / exposed<br>occurrences (all) | 2 / 248 (0.81%)<br>2<br><br>0 / 248 (0.00%)<br>0 | 8 / 481 (1.66%)<br>8<br><br>6 / 481 (1.25%)<br>7 | 6 / 240 (2.50%)<br>7<br><br>0 / 240 (0.00%)<br>0 |

| | | | |
|---|---|---|---|
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 5 / 248 (2.02%) | 3 / 481 (0.62%) | 3 / 240 (1.25%) |
| occurrences (all) | 6 | 3 | 3 |
| Gastroenteritis | | | |
| subjects affected / exposed | 5 / 248 (2.02%) | 1 / 481 (0.21%) | 0 / 240 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 20 / 248 (8.06%) | 18 / 481 (3.74%) | 16 / 240 (6.67%) |
| occurrences (all) | 20 | 19 | 17 |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | 5 / 481 (1.04%) | 2 / 240 (0.83%) |
| occurrences (all) | 1 | 5 | 2 |
| Sinusitis | | | |
| subjects affected / exposed | 2 / 248 (0.81%) | 3 / 481 (0.62%) | 2 / 240 (0.83%) |
| occurrences (all) | 3 | 3 | 2 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 4 / 248 (1.61%) | 12 / 481 (2.49%) | 6 / 240 (2.50%) |
| occurrences (all) | 5 | 13 | 7 |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 0 / 248 (0.00%) | 0 / 481 (0.00%) | 1 / 240 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | 0 / 481 (0.00%) | 2 / 240 (0.83%) |
| occurrences (all) | 1 | 0 | 2 |

| **Non-serious adverse events** | Placebo then Guselkumab 100 mg (Week 28 - 264) | Guselkumab 100 mg (Week 28 - 264) | Adalimumab Then Guselkumab 100 mg (Week 28 - 264) |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 144 / 229 (62.88%) | 297 / 473 (62.79%) | 159 / 220 (72.27%) |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 27 / 229 (11.79%) | 43 / 473 (9.09%) | 20 / 220 (9.09%) |
| occurrences (all) | 30 | 51 | 23 |
| Cardiac disorders | | | |

| | | | |
|---|---|---|---|
| Cardiac Failure Congestive<br>subjects affected / exposed<br>occurrences (all) | 0 / 229 (0.00%)<br>0 | 0 / 473 (0.00%)<br>0 | 0 / 220 (0.00%)<br>0 |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all) | 9 / 229 (3.93%)<br>18 | 31 / 473 (6.55%)<br>44 | 17 / 220 (7.73%)<br>25 |
| Gastrointestinal disorders<br>Diarrhoea<br>subjects affected / exposed<br>occurrences (all) | 11 / 229 (4.80%)<br>13 | 15 / 473 (3.17%)<br>16 | 12 / 220 (5.45%)<br>14 |
| Gastrooesophageal Reflux Disease<br>subjects affected / exposed<br>occurrences (all) | 2 / 229 (0.87%)<br>2 | 12 / 473 (2.54%)<br>13 | 4 / 220 (1.82%)<br>7 |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all) | 10 / 229 (4.37%)<br>12 | 16 / 473 (3.38%)<br>22 | 13 / 220 (5.91%)<br>16 |
| Skin and subcutaneous tissue disorders<br>Dermatitis Contact<br>subjects affected / exposed<br>occurrences (all) | 2 / 229 (0.87%)<br>2 | 11 / 473 (2.33%)<br>14 | 6 / 220 (2.73%)<br>6 |
| Psoriasis<br>subjects affected / exposed<br>occurrences (all) | 3 / 229 (1.31%)<br>3 | 8 / 473 (1.69%)<br>10 | 9 / 220 (4.09%)<br>9 |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 17 / 229 (7.42%)<br>36 | 46 / 473 (9.73%)<br>56 | 22 / 220 (10.00%)<br>32 |
| Back Pain<br>subjects affected / exposed<br>occurrences (all) | 18 / 229 (7.86%)<br>26 | 25 / 473 (5.29%)<br>32 | 16 / 220 (7.27%)<br>16 |
| Infections and infestations<br>Bronchitis<br>subjects affected / exposed<br>occurrences (all) | 15 / 229 (6.55%)<br>16 | 23 / 473 (4.86%)<br>28 | 21 / 220 (9.55%)<br>23 |
| Gastroenteritis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 11 / 229 (4.80%) | 16 / 473 (3.38%) | 11 / 220 (5.00%) |
| occurrences (all) | 12 | 18 | 13 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 67 / 229 (29.26%) | 142 / 473 (30.02%) | 81 / 220 (36.82%) |
| occurrences (all) | 160 | 296 | 175 |
| Pharyngitis | | | |
| subjects affected / exposed | 18 / 229 (7.86%) | 32 / 473 (6.77%) | 5 / 220 (2.27%) |
| occurrences (all) | 23 | 43 | 9 |
| Sinusitis | | | |
| subjects affected / exposed | 16 / 229 (6.99%) | 23 / 473 (4.86%) | 11 / 220 (5.00%) |
| occurrences (all) | 20 | 32 | 16 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 39 / 229 (17.03%) | 111 / 473 (23.47%) | 49 / 220 (22.27%) |
| occurrences (all) | 68 | 213 | 110 |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 7 / 229 (3.06%) | 19 / 473 (4.02%) | 12 / 220 (5.45%) |
| occurrences (all) | 13 | 26 | 15 |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 4 / 229 (1.75%) | 9 / 473 (1.90%) | 3 / 220 (1.36%) |
| occurrences (all) | 5 | 13 | 3 |

| **Non-serious adverse events** | Adalimumab (After ACP) | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 4 / 11 (36.36%) | | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cardiac disorders | | | |
| Cardiac Failure Congestive | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | |
| occurrences (all) | 1 | | |
| Nervous system disorders | | | |
| Headache | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrooesophageal Reflux Disease | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | |
| occurrences (all) | 1 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | |
| occurrences (all) | 1 | | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis Contact | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | |
| occurrences (all) | 1 | | |
| Psoriasis | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | |
| occurrences (all) | 1 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences (all) | 0 | | |
| Back Pain | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | |
| occurrences (all) | 1 | | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasopharyngitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences (all) | 0 | | |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | |
| occurrences (all) | 1 | | |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 0 / 11 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 11 (9.09%) | | |
| occurrences (all) | 2 | | |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 12 February 2015 | Amendment 1 included the following major changes: assessments describing antibodies to study agent were added at Week 16 and Week 44; A physical examination and weight measurement were moved to Week 100 from Week 108, and added at Week 148; The inclusion criteria were clarified to indicate that barrier methods should be used with a spermicidal agent if spermicidal agents were available in their locale; The exclusion criterion for major surgery was clarified. The text describing serious adverse event (SAE) reporting for hospitalization was edited to address a potential contradiction with this exclusion criterion; and an exclusion criterion was added to exclude sponsor employees from participation in the study. |
| 25 June 2015 | Amendnment 2 included the following change: to restrict the use of concomitant medications for psoriasis through Week 76 instead of through Week 48. |
| 04 April 2017 | Amendment 3 included the following major changes: to extend the duration of long-term extensions by 2 years thereby changing the final study visit (end of study) from Week 160 to Week 264; Updated all references to end of study and last study visit throughout the protocol; Updated to capture that, after Week 148, study drug administration information was no longer captured electronically in an eDiary, but were documented in source documents and the electronic case report form (eCRF); and minor errors were noted. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

All subjects were on guselkumab after Week 76; therefore, there was no concurrent control group within the study after Week 76.

Notes: