



Clinical trial results:

A Phase 3 Multicenter, Randomized, Placebo-controlled, Double blind Study to Evaluate the Safety and Efficacy of Golimumab Maintenance Therapy, Administered Subcutaneously, in Subjects with Moderately to Severely Active Ulcerative Colitis

Due to the EudraCT – Results system being out of service between 31 July 2015 and 12 January 2016, these results have been published in compliance with revised timelines.

Summary

| | |
|--------------------------|--|
| EudraCT number | 2006-003399-37 |
| Trial protocol | DE HU AT BE FR LT LV NL DK SE BG SK CZ |
| Global end of trial date | 12 February 2015 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 04 June 2016 |
| First version publication date | 04 June 2016 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | C0524T18 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00488631 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Janssen Research & Development, LLC |
| Sponsor organisation address | Turnhoutseweg 30, Beerse, Belgium, B-2340 |
| Public contact | Janssen Research and Development, Clinical Registry Group-JB BV, ClinicalTrialsEU@its.jnj.com |
| Scientific contact | Janssen Research and Development, Clinical Registry Group-JB BV, 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 | 12 February 2015 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 12 February 2015 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the efficacy and safety of maintenance regimens of CNTO 148 (golimumab) in maintaining clinical response through Week 54.

Protection of trial subjects:

The safety assessments included vital signs, physical examinations (including skin examinations), clinical laboratory tests, adverse events (AEs), antinuclear antibodies (ANAs) and anti-double-stranded deoxyribonucleic acid (dsDNA) antibodies, tuberculosis (TB) evaluations, and pregnancy testing.

Background therapy:

Subjects could have been receiving concomitant treatment with 5-ASAs, corticosteroids, and /or immunomodulators {(ie. 6-MP, azathioprine (AZA), or methotrexate (MTX)} on entry into the maintenance study.

Evidence for comparator:

No

| | |
|---|-------------------|
| Actual start date of recruitment | 28 September 2007 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety, Efficacy |
| Long term follow-up duration | 3 Years |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Australia: 64 |
| Country: Number of subjects enrolled | Austria: 25 |
| Country: Number of subjects enrolled | Belgium: 9 |
| Country: Number of subjects enrolled | Bulgaria: 57 |
| Country: Number of subjects enrolled | Canada: 55 |
| Country: Number of subjects enrolled | Czech Republic: 10 |
| Country: Number of subjects enrolled | Denmark: 20 |
| Country: Number of subjects enrolled | France: 24 |
| Country: Number of subjects enrolled | Germany: 59 |
| Country: Number of subjects enrolled | Hungary: 106 |
| Country: Number of subjects enrolled | India: 80 |
| Country: Number of subjects enrolled | Israel: 39 |
| Country: Number of subjects enrolled | Japan: 62 |
| Country: Number of subjects enrolled | Latvia: 1 |
| Country: Number of subjects enrolled | Netherlands: 13 |

| | |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | New Zealand: 22 |
| Country: Number of subjects enrolled | Poland: 142 |
| Country: Number of subjects enrolled | Romania: 20 |
| Country: Number of subjects enrolled | Russian Federation: 20 |
| Country: Number of subjects enrolled | Serbia: 35 |
| Country: Number of subjects enrolled | Slovakia: 52 |
| Country: Number of subjects enrolled | South Africa: 9 |
| Country: Number of subjects enrolled | Sweden: 2 |
| Country: Number of subjects enrolled | Ukraine: 34 |
| Country: Number of subjects enrolled | United States: 268 |
| Worldwide total number of subjects | 1228 |
| EEA total number of subjects | 540 |

Notes:

Subjects enrolled per age group

| | |
|---|------|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 1178 |
| From 65 to 84 years | 50 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The study was conducted from 28 September 2007 to 12 February 2015.

Pre-assignment

Screening details:

A total of 1,228 subjects were enrolled in study among these subjects 464 subjects received randomized treatment and 764 received nonrandomized treatment

Period 1

| | |
|------------------------------|---------------------------------|
| Period 1 title | Double blind period (Week 0-54) |
| 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 | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance |

Arm description:

Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to placebo subcutaneous injection matching to golimumab administered every 4 weeks through Week 52 in the maintenance study. Subjects with loss of clinical response had their dose increased to golimumab 100 milligram (mg) subcutaneous injection administered every 4 weeks through Week 52.

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

Dosage and administration details:

Subjects received placebo subcutaneous injection matching to golimumab administered every 4 weeks through Week 52 in the maintenance study.

| | |
|--|------------------------|
| Investigational medicinal product name | Golimumab 100 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52 after dose adjustment following loss of clinical response.

| | |
|------------------|---------------------------------------|
| Arm title | GLM-I-Rsp-Golimumab 50 mg Maintenance |
|------------------|---------------------------------------|

Arm description:

Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to golimumab 50 mg subcutaneous injection administered every 4 weeks through Week 52 in maintenance study. Subjects with loss of clinical response will be re-randomized to receive golimumab 50 mg or 100 mg subcutaneous injections every 4 weeks through Week 52.

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

| | |
|--|------------------------|
| Investigational medicinal product name | Golimumab 50 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects receive golimumab 50 mg subcutaneous injection administered every 4 weeks through Week 52.

| | |
|--|------------------------------|
| Investigational medicinal product name | Golimumab 100 milligram (mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52 after dose adjustment following loss of clinical response.

| | |
|------------------|--|
| Arm title | GLM-I-Rsp-Golimumab 100 mg Maintenance |
|------------------|--|

Arm description:

Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52 in maintenance study C0524T18. Subjects with loss of clinical response will be re-randomized to receive golimumab 100 mg or 200 mg subcutaneous injections every 4 weeks through Week 52 (prior to protocol amendment 3).

| | |
|--|------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Golimumab 100 milligram (mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52.

| | |
|--|------------------------|
| Investigational medicinal product name | Golimumab 200 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 200 mg every 4 weeks through Week 52 after dose adjustment following loss of clinical response. Following amendment 3, Subjects remaining on golimumab 200 mg had their dose decreased to golimumab 100 mg subcutaneous injection administered every 4 weeks.

| | |
|------------------|--|
| Arm title | Placebo induction responders (PBO-I-Rsp)-Placebo Maintenance |
|------------------|--|

Arm description:

Subjects in clinical response to placebo at Week 6 of induction study (C0524T16 or C0524T17) and received placebo subcutaneous injection matching to golimumab administered every 4 weeks through Week 52 in maintenance study. These subjects were not randomized. Subjects with loss of clinical response will have their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52.

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

Dosage and administration details:

Subjects received placebo subcutaneous injection matching to golimumab administered every 4 weeks through Week 52.

| | |
|--|------------------------------|
| Investigational medicinal product name | Golimumab 100 milligram (mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52 after dose increase following loss of clinical response.

| | |
|------------------|---|
| Arm title | PBO-I-nonRsp-Golimumab 100 mg Maintenance |
|------------------|---|

Arm description:

Subjects not in clinical response to placebo at Week 6 induction study (C0524T16 or C0524T17) and received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52; not randomized.

| | |
|--|------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Golimumab 100 milligram (mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52.

| | |
|------------------|---|
| Arm title | GLM-I-nonRsp-Golimumab 100 mg Maintenance |
|------------------|---|

Arm description:

Subjects not in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52; not randomized.

| | |
|--|------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Golimumab 100 milligram (mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52.

| Number of subjects in period 1 | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance | GLM-I-Rsp-Golimumab 50 mg Maintenance | GLM-I-Rsp-Golimumab 100 mg Maintenance |
|----------------------------------|--|---------------------------------------|--|
| | | | |
| Started | 156 | 154 | 154 |
| Completed | 113 | 111 | 109 |
| Not completed | 43 | 43 | 45 |
| Adverse event, serious fatal | - | - | - |
| Other | 6 | 12 | 10 |
| Adverse event, serious non-fatal | 17 | 12 | 12 |

| | | | |
|-------------------|----|----|----|
| Lost to follow-up | 1 | 2 | 1 |
| Lack of efficacy | 19 | 17 | 22 |

| Number of subjects in period 1 | Placebo induction responders (PBO-I-Rsp)-Placebo Maintenance | PBO-I-nonRsp-Golimumab 100 mg Maintenance | GLM-I-nonRsp-Golimumab 100 mg Maintenance |
|----------------------------------|--|---|---|
| | | | |
| Started | 129 | 230 | 405 |
| Completed | 88 | 127 | 189 |
| Not completed | 41 | 103 | 216 |
| Adverse event, serious fatal | - | - | 1 |
| Other | 11 | 14 | 34 |
| Adverse event, serious non-fatal | 12 | 30 | 50 |
| Lost to follow-up | - | 3 | 7 |
| Lack of efficacy | 18 | 56 | 124 |

Period 2

| | |
|------------------------------|-------------------------------|
| Period 2 title | Study Extension (Week 54-228) |
| Is this the baseline period? | No |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Blinding implementation details:

Blinded up to the DBL for week 54 and resulting analyses were completed.

Arms

| | |
|------------------------------|-------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Placebo Extension |

Arm description:

Subjects entered the study extension at Week 54 receiving placebo subcutaneous injection administered every 4 weeks until study unblinding and discontinuation of subjects remaining on placebo; those whose UC disease worsened (in the opinion of the investigator) had their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks in the study extension.

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

Dosage and administration details:

Subjects received placebo subcutaneous injection administered every 4 weeks in study extension

| | |
|------------------|---------------------------|
| Arm title | Golimumab 50 mg Extension |
|------------------|---------------------------|

Arm description:

Subjects entered the study extension at Week 54 receiving golimumab 50 mg subcutaneous injection administered every 4 weeks; those whose UC disease worsened (in the opinion of the investigator) had their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks.

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

| | |
|--|------------------------|
| Investigational medicinal product name | Golimumab 50 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects receive golimumab 50 mg subcutaneous injection administered every 4 weeks in study extension or until dose increase following an increase in UC disease activity.

| | |
|------------------|----------------------------|
| Arm title | Golimumab 100 mg Extension |
|------------------|----------------------------|

Arm description:

Subjects entered the study extension at Week 54 receiving golimumab 100 mg subcutaneous injection administered every 4 weeks; prior to Amendment 3, those whose UC disease worsened (in the opinion of the investigator) had their dose increased to golimumab 200 mg subcutaneous injection administered every 4 weeks.

| | |
|--|------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Golimumab 100 milligram (mg) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 100 mg subcutaneous injection administered every 4 weeks in the study extension.

| | |
|------------------|----------------------------|
| Arm title | Golimumab 200 mg Extension |
|------------------|----------------------------|

Arm description:

Subjects entered the study extension at Week 54 receiving golimumab 200 mg subcutaneous injection administered every 4 weeks. With Amendment 3 subjects remaining on golimumab 200 mg had their dose decreased to golimumab 100 mg subcutaneous injection administered every 4 weeks.

| | |
|--|------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Golimumab 200 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 200 mg subcutaneous injection administered every 4 weeks in the study extension or until the dose was decreased to golimumab 100 mg.

| Number of subjects in period 2^[1] | Placebo Extension | Golimumab 50 mg Extension | Golimumab 100 mg Extension |
|---|-------------------|---------------------------|----------------------------|
| Started | 96 | 93 | 470 |
| Completed | 16 | 66 | 288 |
| Not completed | 80 | 27 | 182 |
| Adverse event, serious fatal | - | - | 1 |
| Other | 63 | 14 | 87 |
| Adverse event, serious non-fatal | 10 | 8 | 54 |
| Lost to follow-up | 2 | - | 6 |
| Lack of efficacy | 5 | 5 | 34 |

| Number of subjects in period 2^[1] | Golimumab 200 mg Extension |
|---|-----------------------------------|
| Started | 7 |
| Completed | 4 |
| Not completed | 3 |
| Adverse event, serious fatal | - |
| Other | - |
| Adverse event, serious non-fatal | - |
| Lost to follow-up | - |
| Lack of efficacy | 3 |

Notes:

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

Justification: Please note that the subjects enrolled in the study extension period is not the same as of Double bling period. Study extension period is extension of Double blind period with different number of subjects.

Baseline characteristics

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance |
|-----------------------|--|

Reporting group description:

Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to placebo subcutaneous injection matching to golimumab administered every 4 weeks through Week 52 in the maintenance study. Subjects with loss of clinical response had their dose increased to golimumab 100 milligram (mg) subcutaneous injection administered every 4 weeks through Week 52.

| | |
|-----------------------|---------------------------------------|
| Reporting group title | GLM-I-Rsp-Golimumab 50 mg Maintenance |
|-----------------------|---------------------------------------|

Reporting group description:

Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to golimumab 50 mg subcutaneous injection administered every 4 weeks through Week 52 in maintenance study. Subjects with loss of clinical response will be re-randomized to receive golimumab 50 mg or 100 mg subcutaneous injections every 4 weeks through Week 52.

| | |
|-----------------------|--|
| Reporting group title | GLM-I-Rsp-Golimumab 100 mg Maintenance |
|-----------------------|--|

Reporting group description:

Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52 in maintenance study C0524T18. Subjects with loss of clinical response will be re-randomized to receive golimumab 100 mg or 200 mg subcutaneous injections every 4 weeks through Week 52 (prior to protocol amendment 3).

| | |
|-----------------------|--|
| Reporting group title | Placebo induction responders (PBO-I-Rsp)-Placebo Maintenance |
|-----------------------|--|

Reporting group description:

Subjects in clinical response to placebo at Week 6 of induction study (C0524T16 or C0524T17) and received placebo subcutaneous injection matching to golimumab administered every 4 weeks through Week 52 in maintenance study. These subjects were not randomized. Subjects with loss of clinical response will have their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52.

| | |
|-----------------------|---|
| Reporting group title | PBO-I-nonRsp-Golimumab 100 mg Maintenance |
|-----------------------|---|

Reporting group description:

Subjects not in clinical response to placebo at Week 6 induction study (C0524T16 or C0524T17) and received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52; not randomized.

| | |
|-----------------------|---|
| Reporting group title | GLM-I-nonRsp-Golimumab 100 mg Maintenance |
|-----------------------|---|

Reporting group description:

Subjects not in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52; not randomized.

| Reporting group values | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance | GLM-I-Rsp-Golimumab 50 mg Maintenance | GLM-I-Rsp-Golimumab 100 mg Maintenance |
|---|--|---------------------------------------|--|
| Number of subjects | 156 | 154 | 154 |
| Title for AgeCategorical Units: subjects | | | |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 147 | 148 | 152 |
| From 65 to 84 years | 9 | 6 | 2 |
| 85 years and over | 0 | 0 | 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Title for AgeContinuous Units: years arithmetic mean standard deviation | 40.2 ± 14.05 | 41.4 ± 13.84 | 39.1 ± 13.11 |
| Title for Gender Units: subjects | | | |
| Female | 81 | 77 | 65 |
| Male | 75 | 77 | 89 |

| Reporting group values | Placebo induction responders (PBO-I- Rsp)-Placebo Maintenance | PBO-I-nonRsp- Golimumab 100 mg Maintenance | GLM-I-nonRsp- Golimumab 100 mg Maintenance |
|--|--|--|--|
| Number of subjects | 129 | 230 | 405 |
| Title for AgeCategorical Units: subjects | | | |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 125 | 221 | 385 |
| From 65 to 84 years | 4 | 9 | 20 |
| 85 years and over | 0 | 0 | 0 |
| Title for AgeContinuous Units: years arithmetic mean standard deviation | 38 ± 13.27 | 40.3 ± 12.67 | 41.2 ± 13.6 |
| Title for Gender Units: subjects | | | |
| Female | 68 | 99 | 138 |
| Male | 61 | 131 | 267 |

| Reporting group values | Total | | |
|--|-------|--|--|
| Number of subjects | 1228 | | |
| Title for AgeCategorical Units: subjects | | | |
| Children (2-11 years) | 0 | | |
| Adolescents (12-17 years) | 0 | | |
| Adults (18-64 years) | 1178 | | |
| From 65 to 84 years | 50 | | |
| 85 years and over | 0 | | |
| Title for AgeContinuous Units: years arithmetic mean standard deviation | - | | |
| Title for Gender Units: subjects | | | |
| Female | 528 | | |
| Male | 700 | | |

End points

End points reporting groups

| | |
|---|--|
| Reporting group title | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance |
| Reporting group description: Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to placebo subcutaneous injection matching to golimumab administered every 4 weeks through Week 52 in the maintenance study. Subjects with loss of clinical response had their dose increased to golimumab 100 milligram (mg) subcutaneous injection administered every 4 weeks through Week 52. | |
| Reporting group title | GLM-I-Rsp-Golimumab 50 mg Maintenance |
| Reporting group description: Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to golimumab 50 mg subcutaneous injection administered every 4 weeks through Week 52 in maintenance study. Subjects with loss of clinical response will be re-randomized to receive golimumab 50 mg or 100 mg subcutaneous injections every 4 weeks through Week 52. | |
| Reporting group title | GLM-I-Rsp-Golimumab 100 mg Maintenance |
| Reporting group description: Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52 in maintenance study C0524T18. Subjects with loss of clinical response will be re-randomized to receive golimumab 100 mg or 200 mg subcutaneous injections every 4 weeks through Week 52 (prior to protocol amendment 3). | |
| Reporting group title | Placebo induction responders (PBO-I-Rsp)-Placebo Maintenance |
| Reporting group description: Subjects in clinical response to placebo at Week 6 of induction study (C0524T16 or C0524T17) and received placebo subcutaneous injection matching to golimumab administered every 4 weeks through Week 52 in maintenance study. These subjects were not randomized. Subjects with loss of clinical response will have their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52. | |
| Reporting group title | PBO-I-nonRsp-Golimumab 100 mg Maintenance |
| Reporting group description: Subjects not in clinical response to placebo at Week 6 induction study (C0524T16 or C0524T17) and received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52; not randomized. | |
| Reporting group title | GLM-I-nonRsp-Golimumab 100 mg Maintenance |
| Reporting group description: Subjects not in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52; not randomized. | |
| Reporting group title | Placebo Extension |
| Reporting group description: Subjects entered the study extension at Week 54 receiving placebo subcutaneous injection administered every 4 weeks until study unblinding and discontinuation of subjects remaining on placebo; those whose UC disease worsened (in the opinion of the investigator) had their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks in the study extension. | |
| Reporting group title | Golimumab 50 mg Extension |
| Reporting group description: Subjects entered the study extension at Week 54 receiving golimumab 50 mg subcutaneous injection administered every 4 weeks; those whose UC disease worsened (in the opinion of the investigator) had their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks. | |
| Reporting group title | Golimumab 100 mg Extension |
| Reporting group description: Subjects entered the study extension at Week 54 receiving golimumab 100 mg subcutaneous injection administered every 4 weeks; prior to Amendment 3, those whose UC disease worsened (in the opinion of the investigator) had their dose increased to golimumab 200 mg subcutaneous injection administered every 4 weeks. | |
| Reporting group title | Golimumab 200 mg Extension |

Reporting group description:

Subjects entered the study extension at Week 54 receiving golimumab 200 mg subcutaneous injection administered every 4 weeks. With Amendment 3 subjects remaining on golimumab 200 mg had their dose decreased to golimumab 100 mg subcutaneous injection administered every 4 weeks.

Primary: Number of Subjects in Clinical Response Through Week 54

| | |
|-----------------|--|
| End point title | Number of Subjects in Clinical Response Through Week 54 ^[1] |
|-----------------|--|

End point description:

Clinical response is defined as decrease from induction baseline in Mayo score by greater than or equal to (\geq) 30 percent and ≥ 3 , with either decrease from induction baseline in rectal bleeding sub score of ≥ 1 or rectal bleeding sub score of 0 or 1. Subjects who lost clinical response prior to Week 54 were considered not to meet the endpoint. Mayo score is sum of 4 sub scores (i.e, stool frequency, rectal bleeding, endoscopic findings, physician's global assessment); each rated on scale from 0 to 3, with higher scores indicating more severe disease. Total Mayo score value ranges from 0 to 12. 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

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

End point timeframe:

Induction Baseline, Week 0 through Week 54

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: Primary analysis population included randomly assigned participants in clinical response to golimumab induction at Week 0 of the maintenance study.

| End point values | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance | GLM-I-Rsp-Golimumab 50 mg Maintenance | GLM-I-Rsp-Golimumab 100 mg Maintenance | |
|-----------------------------|--|---------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 154 | 151 | 151 | |
| Units: Subjects | | | | |
| number (not applicable) | 48 | 71 | 75 | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance v GLM-I-Rsp-Golimumab 50 mg Maintenance |
| Number of subjects included in analysis | 305 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.01 |
| Method | Cochran-Mantel-Haenszel |

| | |
|----------------------------|---|
| Statistical analysis title | Statistical Analysis 2 |
| Comparison groups | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance v GLM-I-Rsp-Golimumab 100 mg Maintenance |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 305 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Number of Subjects With Clinical Remission at Both Week 30 and Week 54

| | |
|-----------------|---|
| End point title | Number of Subjects With Clinical Remission at Both Week 30 and Week 54 ^[2] |
|-----------------|---|

End point description:

Clinical remission is defined as a Mayo score of less than or equal to 2, with no individual sub-score greater than 1. The Mayo score is sum of 4 sub-scores (that is (i.e.) stool frequency, rectal bleeding, endoscopic findings, and physician's global assessment); each rated on a scale from 0 to 3, with higher scores indicating more severe disease. The total Mayo score value ranges from 0 to 12. The number of subjects in clinical remission at both the weeks that is Week 30 as well as Week 54 will be reported. 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

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

End point timeframe:

Week 30 and Week 54

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: Primary analysis population included randomly assigned participants in clinical response to golimumab induction at Week 0 of the maintenance study.

| End point values | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance | GLM-I-Rsp-Golimumab 50 mg Maintenance | GLM-I-Rsp-Golimumab 100 mg Maintenance | |
|-----------------------------|--|---------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 154 | 151 | 151 | |
| Units: Subjects | | | | |
| number (not applicable) | 24 | 35 | 42 | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance v GLM-I-Rsp-Golimumab 50 mg Maintenance |
| Number of subjects included in analysis | 305 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.122 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 2 |
| Comparison groups | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance v GLM-I-Rsp-Golimumab 100 mg Maintenance |
| Number of subjects included in analysis | 305 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.004 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Number of Subjects With Mucosal Healing at Both Week 30 and Week 54

| | |
|-----------------|--|
| End point title | Number of Subjects With Mucosal Healing at Both Week 30 and Week 54 ^[3] |
|-----------------|--|

End point description:

Mucosal healing is determined from the endoscopy sub-score of the Mayo score. Mucosal healing is defined as an endoscopy sub-score of 0 or 1. Higher score indicates higher severity of disease. Endoscopy sub-score ranges from 0 (normal or inactive disease) to 3 (severe disease; spontaneous bleeding and ulceration). The number of subjects with mucosal healing at both the weeks that is Week 30 as well as Week 54 will be reported. 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

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

End point timeframe:

Week 30 and Week 54

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: Primary analysis population included randomly assigned participants in clinical response to golimumab induction at Week 0 of the maintenance study.

| End point values | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance | GLM-I-Rsp-Golimumab 50 mg Maintenance | GLM-I-Rsp-Golimumab 100 mg Maintenance | |
|-----------------------------|--|---------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 154 | 151 | 151 | |
| Units: Subjects | | | | |
| number (not applicable) | 41 | 63 | 64 | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance v GLM-I-Rsp-Golimumab 50 mg Maintenance |
| Number of subjects included in analysis | 305 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.011 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 2 |
| Comparison groups | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance v GLM-I-Rsp-Golimumab 100 mg Maintenance |
| Number of subjects included in analysis | 305 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.002 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Number of subjects With Clinical Remission at Both Week 30 and 54 Among Subjects With Clinical Remission at Week 0 of Maintenance Study

| | |
|-----------------|--|
| End point title | Number of subjects With Clinical Remission at Both Week 30 and 54 Among Subjects With Clinical Remission at Week 0 of Maintenance Study ^[4] |
|-----------------|--|

End point description:

Clinical remission is defined as a Mayo score of less than or equal to 2, with no individual sub-score greater than 1. The Mayo score is sum of 4 sub-scores (i.e., stool frequency, rectal bleeding, endoscopic findings, and physician's global assessment); each rated on a scale from 0 to 3, with higher scores indicating more severe disease. The total Mayo score value ranges from 0 to 12. The number of subjects in clinical remission at both the weeks that is Week 30 as well as Week 54 will be reported. 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

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

End point timeframe:

Week 30 and Week 54

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: Primary analysis population included randomly assigned participants in clinical response to golimumab induction at Week 0 of the maintenance study.

| End point values | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance | GLM-I-Rsp-Golimumab 50 mg Maintenance | GLM-I-Rsp-Golimumab 100 mg Maintenance | |
|-----------------------------|--|---------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 54 | 52 | 54 | |
| Units: Subjects | | | | |
| number (not applicable) | 13 | 19 | 21 | |

Statistical analyses

| | |
|-----------------------------------|--|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance v GLM-I-Rsp-Golimumab 50 mg Maintenance |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 106 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.365 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 2 |
| Comparison groups | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance v GLM-I-Rsp-Golimumab 100 mg Maintenance |
| Number of subjects included in analysis | 108 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.098 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Number of Subjects With Clinical Remission at Week 54 and Not Receiving Concomitant Corticosteroids Among Subjects on Corticosteroids at Week 0 of Maintenance Study

| | |
|-----------------|---|
| End point title | Number of Subjects With Clinical Remission at Week 54 and Not Receiving Concomitant Corticosteroids Among Subjects on Corticosteroids at Week 0 of Maintenance Study ^[5] |
|-----------------|---|

End point description:

Clinical remission is defined as a Mayo score of less than or equal to 2, with no individual sub-score greater than 1. The Mayo score is sum of 4 sub-scores (i.e., stool frequency, rectal bleeding, endoscopic findings, and physician's global assessment); each rated on a scale from 0 to 3, with higher scores indicating more severe disease. The total Mayo score value ranges from 0 to 12. 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

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

End point timeframe:

Week 54

Notes:

[5] - 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: Primary analysis population included randomly assigned participants in clinical response to golimumab induction at Week 0 of the maintenance study.

| End point values | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance | GLM-I-Rsp-Golimumab 50 mg Maintenance | GLM-I-Rsp-Golimumab 100 mg Maintenance | |
|-----------------------------|--|---------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 87 | 78 | 82 | |
| Units: Subjects | | | | |
| number (not applicable) | 16 | 22 | 19 | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance v GLM-I-Rsp-Golimumab 50 mg Maintenance |
| Number of subjects included in analysis | 165 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.279 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 2 |
| Comparison groups | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance v GLM-I-Rsp-Golimumab 100 mg Maintenance |
| Number of subjects included in analysis | 169 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.423 |
| Method | Cochran-Mantel-Haenszel |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to week 228

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 17.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance |
|-----------------------|--|

Reporting group description:

Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to placebo subcutaneous injection matching to golimumab administered every 4 weeks through Week 52 in the maintenance study. Adverse events are presented through Week 54. Subjects with loss of clinical response had their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52. For subjects with dose adjustment, adverse events are presented from Week 0 up to the time of dose adjustment.

| | |
|-----------------------|---------------------------------------|
| Reporting group title | GLM-I-Rsp-Golimumab 50 mg Maintenance |
|-----------------------|---------------------------------------|

Reporting group description:

Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to golimumab 50 mg subcutaneous injection administered every 4 weeks through Week 52 in maintenance study. Adverse events are presented through Week 54. Subjects with loss of clinical response will be re-randomized to receive golimumab 50 mg or 100 mg subcutaneous injections every 4 weeks through Week 52. For subjects with dose adjustment, adverse events are presented from Week 0 up to the time of dose adjustment.

| | |
|-----------------------|--|
| Reporting group title | GLM-I-Rsp-Golimumab 100 mg Maintenance |
|-----------------------|--|

Reporting group description:

Subjects in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and randomized to golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52 in maintenance study C0524T18. Adverse events are presented through Week 54. Subjects with loss of clinical response will be re-randomized to receive golimumab 100 mg or 200 mg subcutaneous injections every 4 weeks through Week 52 (prior to amendment 3). For subjects with dose adjustment, adverse events are presented from Week 0 up to the time of dose increase.

| | |
|-----------------------|---|
| Reporting group title | GLM-I-Rsp-Placebo Maintenance to Golimumab 100 mg |
|-----------------------|---|

Reporting group description:

Subjects in clinical response to golimumab at Week 6 of an induction study (C0524T16 or C0524T17) and randomized to placebo in the maintenance study, and who had their dose increased to golimumab 100 mg on loss of clinical response (from the time of dose adjustment onward). Adverse events are presented from the time of dose adjustment onward up to Week 54.

| | |
|-----------------------|---|
| Reporting group title | GLM-I-Rsp-Golimumab 50 mg Maintenance to Golimumab 100 mg |
|-----------------------|---|

Reporting group description:

Subjects in clinical response to golimumab at Week 6 of an induction study (C0524T16 or C0524T17) and randomized to golimumab 50 mg in the maintenance study, who had their dose increased to golimumab 100 mg on loss of clinical response. Adverse events are presented from the time of dose adjustment onward up to Week 54.

| | |
|-----------------------|--|
| Reporting group title | GLM-I-Rsp-Golimumab 100 mg Maintenance to Golimumab 200 mg |
|-----------------------|--|

Reporting group description:

Subject in clinical response to golimumab at Week 6 of an induction study (C0524T16 or C0524T17) and randomized to golimumab 100 mg in the maintenance study, who had their dose increased to golimumab 200 mg on loss of clinical response (prior to amendment 3). Adverse events are presented from the time of dose adjustment onward up to Week 54.

| | |
|-----------------------|--|
| Reporting group title | Placebo induction responders (PBO-I-Rsp)-Placebo Maintenance |
|-----------------------|--|

Reporting group description:

Subjects in clinical response to placebo at Week 6 of induction study (C0524T16 or C0524T17) and

received placebo subcutaneous injection matching to golimumab administered every 4 weeks through Week 52 in maintenance study; not randomized. Adverse events are presented through Week 54. Subjects with loss of clinical response will have their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52. For subjects with dose adjustment, adverse events are presented from Week 0 up to the time of dose adjustment.

| | |
|-----------------------|---|
| Reporting group title | PBO-I-nonRsp-Golimumab 100 mg Maintenance |
|-----------------------|---|

Reporting group description:

Subjects not in clinical response to placebo at Week 6 induction study (C0524T16 or C0524T17) and received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52 in maintenance study; not randomized. Adverse events are presented through Week 54.

| | |
|-----------------------|---|
| Reporting group title | GLM-I-nonRsp-Golimumab 100 mg Maintenance |
|-----------------------|---|

Reporting group description:

Subjects not in clinical response to golimumab at Week 6 of induction study (C0524T16 or C0524T17) and received golimumab 100 mg subcutaneous injection administered every 4 weeks through Week 52 in maintenance study; not randomized. Adverse events are presented through Week 54.

| | |
|-----------------------|---|
| Reporting group title | PBO-I-Rsp-Placebo Maintenance to Golimumab 100 mg |
|-----------------------|---|

Reporting group description:

Subjects in clinical response to placebo at Week 6 of an induction study (C0524T16 or C0524T17) and received placebo on entry into maintenance, and had their dose increased to golimumab 100 mg on loss of clinical response for subjects who dose adjusted to golimumab 100 mg; not randomized. Adverse events are presented from the time of dose adjustment onward up to Week 54.

| | |
|-----------------------|-------------------|
| Reporting group title | Placebo Extension |
|-----------------------|-------------------|

Reporting group description:

Subjects entered the study extension at Week 54 receiving placebo subcutaneous injection administered every 4 weeks until study unblinding and discontinuation of subjects remaining on placebo; those whose UC disease worsened had their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks in the study extension. Adverse events are presented from Week 54 up to Week 228 or the time of dose adjustment for subjects who increased dose.

| | |
|-----------------------|---------------------------|
| Reporting group title | Golimumab 50 mg Extension |
|-----------------------|---------------------------|

Reporting group description:

Subjects entered the study extension at Week 54 receiving golimumab 50 mg subcutaneous injection administered every 4 weeks; those whose UC disease worsened had their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks. Adverse events are presented from Week 54 up to Week 228 or the time of dose adjustment for subjects who increased dose.

| | |
|-----------------------|----------------------------|
| Reporting group title | Golimumab 100 mg Extension |
|-----------------------|----------------------------|

Reporting group description:

Subjects entered the study extension at Week 54 receiving golimumab 100 mg subcutaneous injection administered every 4 weeks; prior to Amendment 3, those whose UC disease worsened had their dose increased to golimumab 200 mg subcutaneous injection administered every 4 weeks. Adverse events are presented from Week 54 up to Week 228 or the time of dose adjustment for subjects who increased dose.

| | |
|-----------------------|----------------------------|
| Reporting group title | Golimumab 200 mg Extension |
|-----------------------|----------------------------|

Reporting group description:

Subjects entered the study extension at Week 54 receiving golimumab 200 mg subcutaneous injection administered every 4 weeks. With Amendment 3, subjects remaining on golimumab 200 mg had their dose decreased to golimumab 100 mg subcutaneous injection administered every 4 weeks. Adverse events are presented from Week 54 up to week 228.

| | |
|-----------------------|-------------------------------------|
| Reporting group title | Placebo - Golimumab 50 mg Extension |
|-----------------------|-------------------------------------|

Reporting group description:

A single subject entered the study extension receiving placebo subcutaneous injection administered every 4 weeks; and on worsening of UC disease had their dose increased to golimumab 50 mg subcutaneous injection administered every 4 weeks in the study extension. Adverse events are presented from the time of dose adjustment.

| | |
|-----------------------|------------------------------------|
| Reporting group title | Placebo-Golimumab 100 mg Extension |
|-----------------------|------------------------------------|

Reporting group description:

Subjects entered the study extension receiving placebo subcutaneous injection administered every 4 weeks and had their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks upon worsening of UC disease in the study extension. Adverse events are presented from the time of dose adjustment.

| | |
|-----------------------|-------------------------------------|
| Reporting group title | Golimumab 50 mg to 100 mg Extension |
|-----------------------|-------------------------------------|

Reporting group description:

Subjects entered the study extension at Week 54 receiving golimumab 50 mg and had their dose increased to golimumab 100 mg subcutaneous injection administered every 4 weeks upon worsening of UC disease in the study extension. Adverse events are presented from the time of dose adjustment.

| | |
|-----------------------|--------------------------------------|
| Reporting group title | Golimumab 100 mg to 200 mg Extension |
|-----------------------|--------------------------------------|

Reporting group description:

Subjects entered the study extension receiving golimumab 100 mg subcutaneous injection administered every 4 weeks and had their dose increased to golimumab 200 mg subcutaneous injection administered every 4 weeks upon worsening of UC disease. Adverse events are presented from the time of dose adjustment

| Serious adverse events | Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance | GLM-I-Rsp-Golimumab 50 mg Maintenance | GLM-I-Rsp-Golimumab 100 mg Maintenance |
|---|--|---------------------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 12 / 156 (7.69%) | 13 / 154 (8.44%) | 22 / 154 (14.29%) |
| number of deaths (all causes) | 0 | 1 | 2 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adrenal Adenoma | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Basal Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Adenoma | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Cancer Metastatic | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gallbladder Cancer | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hodgkin's Disease | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Huerthle Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ovarian Cancer | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Epithelial Cancer | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Adenocarcinoma | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Metastatic | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| T-Cell Lymphoma | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | | | |
| Aortic Aneurysm Rupture | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Deep Vein Thrombosis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Thrombophlebitis Superficial | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Chest Pain | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-Cardiac Chest Pain | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Polyserositis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Reproductive system and breast disorders | | | |
| Benign Prostatic Hyperplasia | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Cervical Dysplasia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Polyp | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 Prolapse | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal Prolapse | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Interstitial Lung Disease | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Infiltration | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural Effusion | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | | | |
| Depression | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Depression Suicidal | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Depressive Symptom | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mental Disorder | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Substance Abuse | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Liver Function Test Abnormal | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | | | |
| Accidental Overdose | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Accidental Poisoning | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ankle Fracture | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Incisional Hernia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intentional Overdose | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Laceration | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Penetrating Abdominal Trauma | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post Procedural Complication | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seroma | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spondylopathy Traumatic | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tendon Rupture | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thoracic Vertebral Fracture | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Pseudoaneurysm | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrist Fracture | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Coronary Artery Disease | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericarditis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Carotid Artery Stenosis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Convulsion | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Demyelination | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Facial Paresis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Loss of Consciousness | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Sclerosis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Root Compression | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sciatica | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient Ischaemic Attack | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anaemia of Chronic Disease | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aplastic Anaemia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemolytic Anaemia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Iron Deficiency Anaemia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Thrombocytosis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | | | |
| Blindness | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cataract | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Macular Fibrosis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | | | |
| Abdominal Hernia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal Pain | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Anal Fissure | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Colitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 3 / 156 (1.92%) | 3 / 154 (1.95%) | 6 / 154 (3.90%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | 0 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Dysplasia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Crohn's Disease | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Frequent Bowel Movements | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrooesophageal Reflux Disease | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large Intestinal Stenosis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large Intestine Polyp | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| 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 | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small Intestinal Obstruction | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Volvulus of Small Bowel | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | | | |
| Bile Duct Stone | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| 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 | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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-Induced Liver Injury | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Drug Eruption | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypersensitivity Vasculitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lichen Sclerosus | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyoderma Gangrenosum | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Bladder Neck Obstruction | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Pelvi-Ureteric Obstruction | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Renal Colic | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Failure Acute | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Autoimmune Thyroiditis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Back Pain | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bursitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| 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 Pain | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Osteoarthritis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Osteonecrosis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seronegative Arthritis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | | | |
| Abscess Intestinal | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Anal Abscess | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 3 / 154 (1.95%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacterial Sepsis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Brain Abscess | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Cytomegalovirus Infection | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Disseminated Tuberculosis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (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 |
| Encephalitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia Pyelonephritis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Extrapulmonary Tuberculosis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis Rotavirus | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Hepatitis A | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes Zoster | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Infected Cyst | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infectious Colitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lobar Pneumonia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis Viral | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis Externa | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Pelvic Sepsis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Legionella | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Postoperative Abscess | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Tuberculosis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Tract Infection Viral | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic Shock | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Bacteraemia | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Infection | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Streptococcal Sepsis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subcutaneous Abscess | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tick-Borne Viral Encephalitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 Tract Infection | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral Infection | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | | | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 1 / 154 (0.65%) | 0 / 154 (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 |
| Diabetes Mellitus | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| 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 | GLM-I-Rsp-Placebo Maintenance to Golimumab 100 mg | GLM-I-Rsp- Golimumab 50 mg Maintenance to Golimumab 100 mg | GLM-I-Rsp- Golimumab 100 mg Maintenance to Golimumab 200 mg |
|---|---|---|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 8 / 76 (10.53%) | 6 / 25 (24.00%) | 1 / 14 (7.14%) |
| number of deaths (all causes) | 1 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adrenal Adenoma | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Basal Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Adenoma | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gallbladder Cancer | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hodgkin's Disease | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Huerthle Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Cancer | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Epithelial Cancer | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Metastatic | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| T-Cell Lymphoma | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| Aortic Aneurysm Rupture | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Deep Vein Thrombosis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombophlebitis Superficial | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| Chest Pain | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-Cardiac Chest Pain | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polyserositis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cervical Dysplasia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Polyp | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Prolapse | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal Prolapse | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Interstitial Lung Disease | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Infiltration | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural Effusion | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| Depression | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Suicidal | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Depressive Symptom | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mental Disorder | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Substance Abuse | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| Liver Function Test Abnormal | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| Accidental Overdose | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Accidental Poisoning | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ankle Fracture | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Incisional Hernia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Intentional Overdose | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Laceration | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Penetrating Abdominal Trauma | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post Procedural Complication | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seroma | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spondylopathy Traumatic | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tendon Rupture | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thoracic Vertebral Fracture | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Pseudoaneurysm | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrist Fracture | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericarditis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| Carotid Artery Stenosis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Convulsion | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Demyelination | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Facial Paresis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Loss of Consciousness | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Sclerosis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Root Compression | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient Ischaemic Attack | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 1 / 25 (4.00%) | 0 / 14 (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 |
| Anaemia of Chronic Disease | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aplastic Anaemia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemolytic Anaemia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Iron Deficiency Anaemia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytosis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| Blindness | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cataract | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Macular Fibrosis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| Abdominal Hernia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal Pain | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|-----------------|----------------|
| Anal Fissure | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 6 / 76 (7.89%) | 3 / 25 (12.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Dysplasia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Crohn's Disease | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Frequent Bowel Movements | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 1 / 25 (4.00%) | 0 / 14 (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 |
| Gastrooesophageal Reflux Disease | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 0 / 14 (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 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large Intestinal Stenosis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large Intestine Polyp | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small Intestinal Obstruction | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Volvulus of Small Bowel | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| Bile Duct Stone | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholestasis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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-Induced Liver Injury | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Eruption | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypersensitivity Vasculitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lichen Sclerosus | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyoderma Gangrenosum | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |
| Bladder Neck Obstruction | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvi-Ureteric Obstruction | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Failure Acute | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Autoimmune Thyroiditis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Back Pain | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bursitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seronegative Arthritis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | | | |

| | | | |
|---|----------------|----------------|----------------|
| Abscess Intestinal | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal Abscess | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 1 / 25 (4.00%) | 0 / 14 (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 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacterial Sepsis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Brain Abscess | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytomegalovirus Infection | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Encephalitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia Pyelonephritis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Extrapulmonary Tuberculosis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis Rotavirus | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis A | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes Zoster | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infected Cyst | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infectious Colitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lobar Pneumonia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis Viral | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis Externa | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvic Sepsis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 0 / 14 (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 Legionella | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Postoperative Abscess | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Tuberculosis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Tract Infection Viral | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic Shock | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Bacteraemia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Infection | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal Sepsis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subcutaneous Abscess | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tick-Borne Viral Encephalitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 Tract Infection | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral Infection | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 1 / 25 (4.00%) | 0 / 14 (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 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diabetes Mellitus | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| 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 induction responders (PBO-I-Rsp)-Placebo Maintenance | PBO-I-nonRsp-Golimumab 100 mg Maintenance | GLM-I-nonRsp-Golimumab 100 mg Maintenance |
|--|--|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 7 / 129 (5.43%) | 34 / 230 (14.78%) | 63 / 405 (15.56%) |
| number of deaths (all causes) | 0 | 1 | 4 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adrenal Adenoma | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Basal Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | 1 / 129 (0.78%) | 0 / 230 (0.00%) | 0 / 405 (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 |
| Colon Adenoma | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gallbladder Cancer | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hodgkin's Disease | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Huerthle Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Cancer | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Epithelial Cancer | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 Metastatic | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| T-Cell Lymphoma | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| Aortic Aneurysm Rupture | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Deep Vein Thrombosis | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 129 (0.78%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombophlebitis Superficial | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| 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 | 1 / 129 (0.78%) | 0 / 230 (0.00%) | 0 / 405 (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 |
| Pregnancy | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| General disorders and administration site conditions | | | |
| Chest Pain | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Non-Cardiac Chest Pain | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polyserositis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Pyrexia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cervical Dysplasia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Polyp | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Prolapse | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal Prolapse | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Interstitial Lung Disease | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Infiltration | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural Effusion | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 1 / 230 (0.43%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Failure | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| Depression | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Suicidal | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Depressive Symptom | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mental Disorder | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Substance Abuse | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| Liver Function Test Abnormal | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Injury, poisoning and procedural complications | | | |
| Accidental Overdose | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Accidental Poisoning | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Ankle Fracture | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Contusion | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 0 / 230 (0.00%) | 0 / 405 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Incisional Hernia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intentional Overdose | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Laceration | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 0 / 230 (0.00%) | 0 / 405 (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 |
| Meniscus Injury | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Penetrating Abdominal Trauma | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 0 / 230 (0.00%) | 0 / 405 (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 |
| Post Procedural Complication | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 2 / 405 (0.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seroma | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spondylopathy Traumatic | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tendon Rupture | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thoracic Vertebral Fracture | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Pseudoaneurysm | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrist Fracture | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 2 / 405 (0.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial Fibrillation | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericarditis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| Carotid Artery Stenosis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Convulsion | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Demyelination | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Facial Paresis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Loss of Consciousness | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Sclerosis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Root Compression | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Transient Ischaemic Attack | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anaemia of Chronic Disease | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aplastic Anaemia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Haemolytic Anaemia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Iron Deficiency Anaemia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytosis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| Blindness | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cataract | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Macular Fibrosis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| Abdominal Hernia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|------------------|-------------------|
| Abdominal Pain | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal Fissure | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Colitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 3 / 129 (2.33%) | 13 / 230 (5.65%) | 43 / 405 (10.62%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 13 | 1 / 47 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Dysplasia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Crohn's Disease | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Frequent Bowel Movements | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrooesophageal Reflux Disease | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ileus | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large Intestinal Stenosis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large Intestine Polyp | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nausea | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 Acute | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small Intestinal Obstruction | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Volvulus of Small Bowel | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| Bile Duct Stone | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| 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 Chronic | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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-Induced Liver Injury | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Eruption | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypersensitivity Vasculitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lichen Sclerosus | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyoderma Gangrenosum | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| Bladder Neck Obstruction | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvi-Ureteric Obstruction | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal Failure Acute | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| Autoimmune Thyroiditis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Back Pain | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Bursitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Seronegative Arthritis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abscess Intestinal | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal Abscess | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Bacterial Sepsis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Brain Abscess | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Conjunctivitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytomegalovirus Infection | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 2 / 405 (0.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| Encephalitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia Pyelonephritis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Extrapulmonary Tuberculosis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis Rotavirus | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis A | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes Zoster | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infected Cyst | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infectious Colitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lobar Pneumonia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis Viral | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis Externa | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvic Sepsis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Pneumonia Legionella | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Postoperative Abscess | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary Tuberculosis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Tract Infection Viral | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic Shock | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Bacteraemia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Infection | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal Sepsis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subcutaneous Abscess | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (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 |
| Tick-Borne Viral Encephalitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 Tract Infection | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral Infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| 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 | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diabetes Mellitus | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | PBO-I-Rsp-Placebo Maintenance to Golimumab 100 mg | Placebo Extension | Golimumab 50 mg Extension |
|--|---|-------------------|------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 7 / 56 (12.50%) | 8 / 96 (8.33%) | 11 / 93 (11.83%) |
| number of deaths (all causes) | 0 | 1 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adrenal Adenoma | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Basal Cell Carcinoma | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Adenoma | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gallbladder Cancer | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hodgkin's Disease | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Huerthle Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Cancer | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Epithelial Cancer | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostate Cancer | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Metastatic | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| T-Cell Lymphoma | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| 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 | | | |
| Aortic Aneurysm Rupture | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Deep Vein Thrombosis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombophlebitis Superficial | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| Chest Pain | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-Cardiac Chest Pain | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Polyserositis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cervical Dysplasia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Polyp | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Prolapse | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal Prolapse | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| Aspiration | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Interstitial Lung Disease | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Infiltration | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural Effusion | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| Depression | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| 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 Suicidal | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Depressive Symptom | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mental Disorder | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Substance Abuse | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| Liver Function Test Abnormal | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| Accidental Overdose | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Accidental Poisoning | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ankle Fracture | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Contusion | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Incisional Hernia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intentional Overdose | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Laceration | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Penetrating Abdominal Trauma | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post Procedural Complication | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seroma | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spondylopathy Traumatic | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tendon Rupture | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 1 / 96 (1.04%) | 0 / 93 (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 |
| Thoracic Vertebral Fracture | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 1 / 96 (1.04%) | 0 / 93 (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 |
| Vascular Pseudoaneurysm | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrist Fracture | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 1 / 96 (1.04%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Coronary Artery Disease | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | 0 / 56 (0.00%) | 2 / 96 (2.08%) | 0 / 93 (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 |
| Pericarditis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| Carotid Artery Stenosis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Convulsion | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Demyelination | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Facial Paresis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Loss of Consciousness | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| 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 Sclerosis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Root Compression | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient Ischaemic Attack | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 1 / 96 (1.04%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 1 / 96 (1.04%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anaemia of Chronic Disease | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | | |
|----------------------------|---|----------------|----------------|----------------|
| Aplastic Anaemia | subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| | occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| | deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemolytic Anaemia | subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| | occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| | deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Iron Deficiency Anaemia | subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| | occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| | deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphadenopathy | subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| | occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| | deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytosis | subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| | 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 | | | | |
| Blindness | subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| | occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| | deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cataract | subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| | occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| | deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Macular Fibrosis | subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| | 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 | | | | |

| | | | |
|---|----------------|----------------|----------------|
| Abdominal Hernia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal Pain | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal Fissure | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 4 / 56 (7.14%) | 1 / 96 (1.04%) | 2 / 93 (2.15%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Dysplasia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Crohn's Disease | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterocolitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Frequent Bowel Movements | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrooesophageal Reflux Disease | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large Intestinal Stenosis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large Intestine Polyp | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small Intestinal Obstruction | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Volvulus of Small Bowel | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| Bile Duct Stone | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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-Induced Liver Injury | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Eruption | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 0 / 96 (0.00%) | 0 / 93 (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 |
| Hypersensitivity Vasculitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lichen Sclerosus | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyoderma Gangrenosum | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| Bladder Neck Obstruction | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 1 / 96 (1.04%) | 0 / 93 (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 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvi-Ureteric Obstruction | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Failure Acute | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Autoimmune Thyroiditis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Back Pain | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bursitis | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 0 / 96 (0.00%) | 0 / 93 (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 |
| Intervertebral Disc Protrusion | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Osteonecrosis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seronegative Arthritis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| Abscess Intestinal | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal Abscess | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacterial Sepsis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Brain Abscess | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | 1 / 56 (1.79%) | 0 / 96 (0.00%) | 0 / 93 (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 |
| Clostridium Difficile Infection | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytomegalovirus Infection | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Encephalitis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia Pyelonephritis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Extrapulmonary Tuberculosis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis Rotavirus | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis A | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes Zoster | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infected Cyst | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infectious Colitis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lobar Pneumonia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis Viral | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis Externa | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvic Sepsis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 / 56 (0.00%) | 1 / 96 (1.04%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Pneumonia Legionella | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Postoperative Abscess | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Tuberculosis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Tract Infection Viral | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic Shock | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Bacteraemia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Infection | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal Sepsis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subcutaneous Abscess | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tick-Borne Viral Encephalitis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 Tract Infection | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral Infection | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diabetes Mellitus | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| 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 | Golimumab 100 mg Extension | Golimumab 200 mg Extension | Placebo - Golimumab 50 mg Extension |
|---|----------------------------|----------------------------|-------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 91 / 469 (19.40%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| number of deaths (all causes) | 7 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adrenal Adenoma | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Basal Cell Carcinoma | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Breast Cancer | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Adenoma | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Colon Cancer Metastatic | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Gallbladder Cancer | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Hodgkin's Disease | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Huerthle Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Adenocarcinoma | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 Cancer | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 Epithelial Cancer | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 Metastatic | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| Renal Cancer Metastatic | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| T-Cell Lymphoma | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Uterine Leiomyoma | | | |

| | | | |
|--|-----------------|---------------|---------------|
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Aortic Aneurysm Rupture | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Deep Vein Thrombosis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombophlebitis Superficial | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion Spontaneous | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Pregnancy | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Chest Pain | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 3 / 469 (0.64%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-Cardiac Chest Pain | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Polyserositis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Reproductive system and breast disorders | | | |
| Benign Prostatic Hyperplasia | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cervical Dysplasia | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Uterine Polyp | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 Prolapse | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Vaginal Prolapse | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Aspiration | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Interstitial Lung Disease | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 4 / 4 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Infiltration | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural Effusion | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Pneumonitis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Pulmonary Embolism | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Respiratory Failure | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 | | | |

| | | | |
|---|-----------------|---------------|---------------|
| Depression | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Depression Suicidal | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Depressive Symptom | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Mental Disorder | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Substance Abuse | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Liver Function Test Abnormal | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Accidental Overdose | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Accidental Poisoning | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|---------------|---------------|
| Ankle Fracture | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Incisional Hernia | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intentional Overdose | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Laceration | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Penetrating Abdominal Trauma | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post Procedural Complication | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seroma | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Spondylopathy Traumatic | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Tendon Rupture | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thoracic Vertebral Fracture | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 Pseudoaneurysm | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Wrist Fracture | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 Pectoris | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Myocardial Infarction | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Pericarditis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Nervous system disorders | | | |
| Carotid Artery Stenosis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Convulsion | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Demyelination | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Facial Paresis | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Loss of Consciousness | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 Sclerosis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 Root Compression | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sciatica | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Syncope | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient Ischaemic Attack | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |

| | | | |
|---|-----------------|---------------|---------------|
| Anaemia of Chronic Disease | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aplastic Anaemia | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Haemolytic Anaemia | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Iron Deficiency Anaemia | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytosis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 disorders | | | |
| Blindness | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Cataract | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Macular Fibrosis | | | |

| | | | |
|---|------------------|---------------|---------------|
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 disorders | | | |
| Abdominal Hernia | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal Pain | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Anal Fissure | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 18 / 469 (3.84%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 2 / 21 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Dysplasia | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Crohn's Disease | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Diarrhoea | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Frequent Bowel Movements | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrooesophageal Reflux Disease | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Ileus | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large Intestinal Stenosis | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Large Intestine Polyp | | | |
| subjects affected / exposed | 3 / 469 (0.64%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nausea | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small Intestinal Obstruction | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Volvulus of Small Bowel | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Hepatobiliary disorders | | | |
| Bile Duct Stone | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Cholestasis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Drug-Induced Liver Injury | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 Eruption | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypersensitivity Vasculitis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Lichen Sclerosus | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyoderma Gangrenosum | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Rash | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Renal and urinary disorders | | | |
| Bladder Neck Obstruction | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Pelvi-Ureteric Obstruction | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Renal Failure Acute | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Autoimmune Thyroiditis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Back Pain | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bursitis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Musculoskeletal Pain | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Osteonecrosis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seronegative Arthritis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Abscess Intestinal | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal Abscess | | | |
| subjects affected / exposed | 3 / 469 (0.64%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Bacterial Sepsis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Brain Abscess | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (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 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytomegalovirus Infection | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Encephalitis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Escherichia Pyelonephritis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Extrapulmonary Tuberculosis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Gastroenteritis | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis Rotavirus | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis A | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Herpes Zoster | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Infected Cyst | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infectious Colitis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lobar Pneumonia | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis Viral | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis Externa | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvic Sepsis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Pilonidal Cyst | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 | 6 / 469 (1.28%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 2 / 6 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia Legionella | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Postoperative Abscess | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 Tuberculosis | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Respiratory Tract Infection Viral | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| Septic Shock | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Bacteraemia | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Infection | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal Sepsis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subcutaneous Abscess | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Tick-Borne Viral Encephalitis | | | |

| | | | |
|---|-----------------|---------------|---------------|
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral Infection | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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 | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diabetes Mellitus | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (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 |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| 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-Golimumab 100 mg Extension | Golimumab 50 mg to 100 mg Extension | Golimumab 100 mg to 200 mg Extension |
|---|------------------------------------|-------------------------------------|--------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 7 / 28 (25.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |

| | | | |
|---|----------------|----------------|----------------|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adrenal Adenoma | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Basal Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Breast Cancer | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Adenoma | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gallbladder Cancer | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hodgkin's Disease | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Huerthle Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Lung Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ovarian Cancer | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ovarian Epithelial Cancer | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostate Cancer | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| T-Cell Lymphoma | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine Leiomyoma | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Aortic Aneurysm Rupture | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Deep Vein Thrombosis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombophlebitis Superficial | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion Spontaneous | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Chest Pain | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-Cardiac Chest Pain | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polyserositis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Benign Prostatic Hyperplasia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cervical Dysplasia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine Polyp | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine Prolapse | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal Prolapse | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Interstitial Lung Disease | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Infiltration | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural Effusion | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary Embolism | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Failure | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |

| | | | |
|---|----------------|----------------|----------------|
| Depression | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Depression Suicidal | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Depressive Symptom | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mental Disorder | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Substance Abuse | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Liver Function Test Abnormal | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental Overdose | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Accidental Poisoning | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Ankle Fracture | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Incisional Hernia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intentional Overdose | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Laceration | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meniscus Injury | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Penetrating Abdominal Trauma | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post Procedural Complication | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seroma | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spondylopathy Traumatic | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tendon Rupture | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thoracic Vertebral Fracture | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular Pseudoaneurysm | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrist Fracture | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Acute Myocardial Infarction | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Angina Pectoris | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial Fibrillation | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac Failure | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Coronary Artery Disease | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial Infarction | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericarditis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Carotid Artery Stenosis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Convulsion | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Demyelination | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Facial Paresis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Loss of Consciousness | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Multiple Sclerosis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nerve Root Compression | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient Ischaemic Attack | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Anaemia of Chronic Disease | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aplastic Anaemia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemolytic Anaemia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Iron Deficiency Anaemia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytosis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Blindness | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cataract | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Macular Fibrosis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal Hernia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal Pain | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal Fissure | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon Dysplasia | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Crohn's Disease | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Frequent Bowel Movements | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrooesophageal Reflux Disease | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemorrhoidal Haemorrhage | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large Intestinal Stenosis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large Intestine Polyp | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis Acute | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small Intestinal Obstruction | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Volvulus of Small Bowel | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Bile Duct Stone | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholecystitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholecystitis Chronic | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Drug-Induced Liver Injury | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Drug Eruption | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypersensitivity Vasculitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lichen Sclerosus | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyoderma Gangrenosum | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Bladder Neck Obstruction | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvi-Ureteric Obstruction | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal Colic | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal Failure Acute | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Autoimmune Thyroiditis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Back Pain | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bursitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intervertebral Disc Protrusion | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal Pain | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|----------------|----------------|----------------|
| Osteoarthritis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteonecrosis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seronegative Arthritis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abscess Intestinal | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal Abscess | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacterial Sepsis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Brain Abscess | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytomegalovirus Infection | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 0 / 10 (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 |
| Disseminated Tuberculosis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Encephalitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia Pyelonephritis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Extrapulmonary Tuberculosis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis Rotavirus | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis A | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes Zoster | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 0 / 10 (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 |
| Infected Cyst | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infectious Colitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lobar Pneumonia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis Viral | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis Externa | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvic Sepsis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pilonidal Cyst | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia Legionella | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Postoperative Abscess | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary Tuberculosis | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Tract Infection Viral | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic Shock | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Bacteraemia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Infection | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal Sepsis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subcutaneous Abscess | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tick-Borne Viral Encephalitis | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral Infection | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diabetes Mellitus | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | Golimumab Induction Responders (GLM-I- Rsp)-Placebo Maintenance | GLM-I-Rsp- Golimumab 50 mg Maintenance | GLM-I-Rsp- Golimumab 100 mg Maintenance |
|--|--|---|--|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 88 / 156 (56.41%) | 102 / 154 (66.23%) | 94 / 154 (61.04%) |
| Vascular disorders | | | |
| Hot Flush | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 1 / 154 (0.65%) | 0 / 154 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 4 / 156 (2.56%) | 1 / 154 (0.65%) | 1 / 154 (0.65%) |
| occurrences (all) | 4 | 1 | 1 |
| Phlebitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Chest Pain | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 2 / 154 (1.30%) |
| occurrences (all) | 0 | 0 | 2 |
| Fatigue | | | |
| subjects affected / exposed | 4 / 156 (2.56%) | 4 / 154 (2.60%) | 6 / 154 (3.90%) |
| occurrences (all) | 5 | 4 | 6 |
| Feeling Cold | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza Like Illness | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 2 / 154 (1.30%) | 1 / 154 (0.65%) |
| occurrences (all) | 1 | 2 | 1 |
| Injection Site Erythema | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 1 / 154 (0.65%) | 4 / 154 (2.60%) |
| occurrences (all) | 5 | 16 | 15 |
| Injection Site Induration | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences (all) | 0 | 0 | 2 |
| Injection Site Oedema | | | |

| | | | |
|--|----------------------|-----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Injection Site Rash subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 1 / 154 (0.65%) 1 | 2 / 154 (1.30%) 3 |
| Oedema Peripheral subjects affected / exposed occurrences (all) | 1 / 156 (0.64%) 1 | 3 / 154 (1.95%) 3 | 4 / 154 (2.60%) 4 |
| Pain subjects affected / exposed occurrences (all) | 1 / 156 (0.64%) 1 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 7 / 156 (4.49%) 7 | 6 / 154 (3.90%) 14 | 3 / 154 (1.95%) 3 |
| Immune system disorders Drug Hypersensitivity subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Seasonal Allergy subjects affected / exposed occurrences (all) | 3 / 156 (1.92%) 3 | 2 / 154 (1.30%) 2 | 1 / 154 (0.65%) 1 |
| Reproductive system and breast disorders Cervix Haemorrhage Uterine subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 5 / 156 (3.21%) 6 | 5 / 154 (3.25%) 5 | 8 / 154 (5.19%) 9 |
| Dyspnoea subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 1 / 154 (0.65%) 1 | 1 / 154 (0.65%) 1 |
| Nasal Congestion subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Oropharyngeal Pain | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 1 / 156 (0.64%) 1 | 3 / 154 (1.95%) 3 | 6 / 154 (3.90%) 7 |
| Upper Respiratory Tract Congestion subjects affected / exposed occurrences (all) | 2 / 156 (1.28%) 2 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 2 / 154 (1.30%) | 2 / 154 (1.30%) |
| occurrences (all) | 1 | 2 | 2 |
| Depression | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 3 / 154 (1.95%) | 3 / 154 (1.95%) |
| occurrences (all) | 1 | 3 | 3 |
| Insomnia | | | |
| subjects affected / exposed | 2 / 156 (1.28%) | 1 / 154 (0.65%) | 2 / 154 (1.30%) |
| occurrences (all) | 2 | 1 | 3 |
| Investigations | | | |
| Alanine Aminotransferase Increased | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 3 / 154 (1.95%) | 3 / 154 (1.95%) |
| occurrences (all) | 1 | 4 | 3 |
| Aspartate Aminotransferase Increased | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 5 / 154 (3.25%) | 2 / 154 (1.30%) |
| occurrences (all) | 1 | 5 | 2 |
| Blood Calcium Increased | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood Creatinine Increased | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences (all) | 0 | 0 | 3 |
| Blood Parathyroid Hormone Increased | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoglobin Decreased | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 1 / 154 (0.65%) | 0 / 154 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Neutrophil Count Increased | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vitamin D Decreased | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White Blood Cell Count Increased | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 2 / 154 (1.30%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal Bite | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod Bite | | | |
| subjects affected / exposed | 2 / 156 (1.28%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences (all) | 2 | 0 | 1 |
| Bite | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand Fracture | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Joint Dislocation | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 2 / 154 (1.30%) |
| occurrences (all) | 0 | 0 | 2 |
| Ligament Sprain | | | |
| subjects affected / exposed | 2 / 156 (1.28%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Limb Fracture | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toxicity to Various Agents | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |

| | | | |
|--|------------------------|------------------------|------------------------|
| Demyelination subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 14 / 156 (8.97%) 25 | 13 / 154 (8.44%) 29 | 12 / 154 (7.79%) 57 |
| Hyperaesthesia subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Migraine subjects affected / exposed occurrences (all) | 1 / 156 (0.64%) 1 | 3 / 154 (1.95%) 6 | 0 / 154 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 1 / 156 (0.64%) 1 | 4 / 154 (2.60%) 7 | 5 / 154 (3.25%) 6 |
| Eosinophilia subjects affected / exposed occurrences (all) | 1 / 156 (0.64%) 1 | 1 / 154 (0.65%) 1 | 0 / 154 (0.00%) 0 |
| Leukopenia subjects affected / exposed occurrences (all) | 2 / 156 (1.28%) 2 | 2 / 154 (1.30%) 2 | 5 / 154 (3.25%) 5 |
| Ear and labyrinth disorders | | | |
| Ear Pain subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 1 / 154 (0.65%) 1 | 0 / 154 (0.00%) 0 |
| Eye disorders | | | |
| Dry Eye subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Eye Irritation subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 1 / 154 (0.65%) 1 | 0 / 154 (0.00%) 0 |
| Myopia subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Ocular Hyperaemia | | | |

| | | | |
|-----------------------------|-------------------|-------------------|-------------------|
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences (all) | 1 | 0 | 1 |
| Vision Blurred | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal Discomfort | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 2 / 154 (1.30%) |
| occurrences (all) | 0 | 0 | 2 |
| Abdominal Pain | | | |
| subjects affected / exposed | 4 / 156 (2.56%) | 10 / 154 (6.49%) | 11 / 154 (7.14%) |
| occurrences (all) | 4 | 11 | 14 |
| Abdominal Pain Upper | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 4 / 154 (2.60%) | 1 / 154 (0.65%) |
| occurrences (all) | 1 | 4 | 1 |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 29 / 156 (18.59%) | 25 / 154 (16.23%) | 18 / 154 (11.69%) |
| occurrences (all) | 30 | 27 | 19 |
| Constipation | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 2 / 154 (1.30%) | 3 / 154 (1.95%) |
| occurrences (all) | 1 | 2 | 3 |
| Dental Caries | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 7 / 156 (4.49%) | 4 / 154 (2.60%) | 5 / 154 (3.25%) |
| occurrences (all) | 8 | 4 | 6 |
| Dyspepsia | | | |
| subjects affected / exposed | 2 / 156 (1.28%) | 3 / 154 (1.95%) | 2 / 154 (1.30%) |
| occurrences (all) | 2 | 3 | 3 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 2 / 156 (1.28%) | 1 / 154 (0.65%) | 5 / 154 (3.25%) |
| occurrences (all) | 2 | 2 | 5 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Haemorrhoids | | | |
| subjects affected / exposed | 2 / 156 (1.28%) | 3 / 154 (1.95%) | 3 / 154 (1.95%) |
| occurrences (all) | 4 | 4 | 3 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 1 / 154 (0.65%) |
| occurrences (all) | 0 | 1 | 1 |
| Nausea | | | |
| subjects affected / exposed | 3 / 156 (1.92%) | 7 / 154 (4.55%) | 7 / 154 (4.55%) |
| occurrences (all) | 4 | 9 | 8 |
| Vomiting | | | |
| subjects affected / exposed | 5 / 156 (3.21%) | 2 / 154 (1.30%) | 3 / 154 (1.95%) |
| occurrences (all) | 6 | 2 | 3 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 2 / 156 (1.28%) | 2 / 154 (1.30%) | 1 / 154 (0.65%) |
| occurrences (all) | 2 | 2 | 1 |
| Alopecia | | | |
| subjects affected / exposed | 3 / 156 (1.92%) | 0 / 154 (0.00%) | 4 / 154 (2.60%) |
| occurrences (all) | 4 | 0 | 5 |
| Blister | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Dermal Cyst | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 4 / 156 (2.56%) | 1 / 154 (0.65%) | 1 / 154 (0.65%) |
| occurrences (all) | 4 | 1 | 1 |
| Drug Eruption | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema | | | |
| subjects affected / exposed | 3 / 156 (1.92%) | 1 / 154 (0.65%) | 1 / 154 (0.65%) |
| occurrences (all) | 4 | 1 | 1 |
| Rash | | | |

| | | | |
|---|------------------------|------------------------|-----------------------|
| subjects affected / exposed occurrences (all) | 3 / 156 (1.92%) 3 | 9 / 154 (5.84%) 12 | 6 / 154 (3.90%) 8 |
| Rash Erythematous subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Renal and urinary disorders | | | |
| Dysuria subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 1 / 154 (0.65%) 1 |
| Micturition Urgency subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Pollakiuria subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Renal Colic subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 1 / 154 (0.65%) 1 | 1 / 154 (0.65%) 1 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia subjects affected / exposed occurrences (all) | 11 / 156 (7.05%) 12 | 11 / 154 (7.14%) 13 | 9 / 154 (5.84%) 12 |
| Back Pain subjects affected / exposed occurrences (all) | 4 / 156 (2.56%) 15 | 3 / 154 (1.95%) 3 | 7 / 154 (4.55%) 7 |
| Muscle Spasms subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 1 / 154 (0.65%) 1 |
| Pain in Extremity subjects affected / exposed occurrences (all) | 4 / 156 (2.56%) 4 | 3 / 154 (1.95%) 3 | 1 / 154 (0.65%) 1 |
| Rotator Cuff Syndrome subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Spinal Osteoarthritis | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Infections and infestations | | | |
| Acute Tonsillitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 2 / 154 (1.30%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 3 / 156 (1.92%) | 6 / 154 (3.90%) | 1 / 154 (0.65%) |
| occurrences (all) | 5 | 6 | 1 |
| Chlamydial Infection | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 2 / 156 (1.28%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences (all) | 2 | 0 | 1 |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 1 / 154 (0.65%) | 1 / 154 (0.65%) |
| occurrences (all) | 1 | 1 | 1 |
| Eyelid Infection | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal Infection | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences (all) | 0 | 0 | 3 |
| Gastroenteritis | | | |
| subjects affected / exposed | 3 / 156 (1.92%) | 2 / 154 (1.30%) | 3 / 154 (1.95%) |
| occurrences (all) | 3 | 3 | 4 |
| Gastroenteritis Viral | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 2 / 154 (1.30%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Giardiasis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences (all) | 0 | 0 | 1 |
| Herpes Zoster | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|-----------------------------|------------------|------------------|-------------------|
| Hordeolum | | | |
| subjects affected / exposed | 1 / 156 (0.64%) | 2 / 154 (1.30%) | 0 / 154 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Influenza | | | |
| subjects affected / exposed | 4 / 156 (2.56%) | 7 / 154 (4.55%) | 2 / 154 (1.30%) |
| occurrences (all) | 4 | 8 | 2 |
| Labyrinthitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 10 / 156 (6.41%) | 14 / 154 (9.09%) | 23 / 154 (14.94%) |
| occurrences (all) | 13 | 20 | 31 |
| Oral Herpes | | | |
| subjects affected / exposed | 3 / 156 (1.92%) | 2 / 154 (1.30%) | 2 / 154 (1.30%) |
| occurrences (all) | 4 | 3 | 4 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 1 / 154 (0.65%) |
| occurrences (all) | 0 | 1 | 1 |
| Pharyngitis | | | |
| subjects affected / exposed | 4 / 156 (2.56%) | 7 / 154 (4.55%) | 5 / 154 (3.25%) |
| occurrences (all) | 4 | 8 | 5 |
| Sinusitis | | | |
| subjects affected / exposed | 3 / 156 (1.92%) | 6 / 154 (3.90%) | 6 / 154 (3.90%) |
| occurrences (all) | 3 | 6 | 6 |
| Skin Infection | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Tinea Cruris | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 1 / 154 (0.65%) | 0 / 154 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tooth Abscess | | | |
| subjects affected / exposed | 0 / 156 (0.00%) | 0 / 154 (0.00%) | 1 / 154 (0.65%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|----------------------|-----------------------|-----------------------|
| Upper Respiratory Tract Infection subjects affected / exposed occurrences (all) | 4 / 156 (2.56%) 6 | 8 / 154 (5.19%) 10 | 8 / 154 (5.19%) 12 |
| Urinary Tract Infection subjects affected / exposed occurrences (all) | 4 / 156 (2.56%) 4 | 3 / 154 (1.95%) 3 | 1 / 154 (0.65%) 1 |
| Viral Infection subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 2 / 154 (1.30%) 3 | 1 / 154 (0.65%) 1 |
| Viral Pharyngitis subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 0 / 154 (0.00%) 0 |
| Viral Upper Respiratory Tract Infection subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 1 / 154 (0.65%) 1 | 1 / 154 (0.65%) 1 |
| Vulvovaginal Candidiasis subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 1 / 154 (0.65%) 1 | 0 / 154 (0.00%) 0 |
| Vulvovaginal Mycotic Infection subjects affected / exposed occurrences (all) | 1 / 156 (0.64%) 1 | 3 / 154 (1.95%) 4 | 1 / 154 (0.65%) 2 |
| Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all) | 0 / 156 (0.00%) 0 | 0 / 154 (0.00%) 0 | 2 / 154 (1.30%) 2 |

| Non-serious adverse events | GLM-I-Rsp-Placebo Maintenance to Golimumab 100 mg | GLM-I-Rsp- Golimumab 50 mg Maintenance to Golimumab 100 mg | GLM-I-Rsp- Golimumab 100 mg Maintenance to Golimumab 200 mg |
|---|---|---|--|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 44 / 76 (57.89%) | 15 / 25 (60.00%) | 10 / 14 (71.43%) |
| Vascular disorders Hot Flush subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Hypertension | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Phlebitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Chest Pain | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 2 / 76 (2.63%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Feeling Cold | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| Influenza Like Illness | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection Site Erythema | | | |
| subjects affected / exposed | 3 / 76 (3.95%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 11 | 0 | 6 |
| Injection Site Induration | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 5 |
| Injection Site Oedema | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection Site Rash | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 4 |
| Oedema Peripheral | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |

| | | | |
|--|---------------------|-----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 2 / 76 (2.63%) 2 | 4 / 25 (16.00%) 14 | 1 / 14 (7.14%) 1 |
| Immune system disorders Drug Hypersensitivity subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Seasonal Allergy subjects affected / exposed occurrences (all) | 1 / 76 (1.32%) 1 | 0 / 25 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| Reproductive system and breast disorders Cervix Haemorrhage Uterine subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 1 / 76 (1.32%) 1 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Dyspnoea subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Nasal Congestion subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| Oropharyngeal Pain subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 1 / 25 (4.00%) 1 | 0 / 14 (0.00%) 0 |
| Upper Respiratory Tract Congestion subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) | 1 / 76 (1.32%) 1 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |

| | | | |
|--|---------------------|---------------------|---------------------|
| Depression subjects affected / exposed occurrences (all) | 1 / 76 (1.32%) 1 | 0 / 25 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| Insomnia subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Investigations | | | |
| Alanine Aminotransferase Increased subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Aspartate Aminotransferase Increased subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Blood Calcium Increased subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Blood Creatinine Increased subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Blood Parathyroid Hormone Increased subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Haemoglobin Decreased subjects affected / exposed occurrences (all) | 2 / 76 (2.63%) 2 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Neutrophil Count Increased subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| Vitamin D Decreased subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| White Blood Cell Count Increased subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| Animal Bite | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod Bite | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bite | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand Fracture | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint Dislocation | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament Sprain | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb Fracture | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| Toxicity to Various Agents | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Demyelination | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 8 / 76 (10.53%) | 2 / 25 (8.00%) | 2 / 14 (14.29%) |
| occurrences (all) | 13 | 2 | 4 |
| Hyperaesthesia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Migraine | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 1 / 76 (1.32%) 1 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 2 / 76 (2.63%) | 1 / 25 (4.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 2 / 25 (8.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Ear and labyrinth disorders | | | |
| Ear Pain | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye disorders | | | |
| Dry Eye | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye Irritation | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myopia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ocular Hyperaemia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision Blurred | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal Discomfort | | | |
| subjects affected / exposed | 2 / 76 (2.63%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Abdominal Pain | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 3 / 76 (3.95%) | 2 / 25 (8.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Abdominal Pain Upper | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 1 | 0 | 1 |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 7 / 76 (9.21%) | 2 / 25 (8.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 10 | 2 | 2 |
| Constipation | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dental Caries | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 4 / 76 (5.26%) | 2 / 25 (8.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 4 | 2 | 1 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 1 / 25 (4.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 1 | 1 | 1 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 2 / 25 (8.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 1 | 2 | 1 |
| Vomiting | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 1 / 76 (1.32%) 1 | 1 / 25 (4.00%) 1 | 0 / 14 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| Alopecia | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blister | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermal Cyst | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 1 / 25 (4.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 1 | 1 |
| Drug Eruption | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 2 | 0 | 1 |
| Rash | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 1 | 0 | 1 |
| Rash Erythematous | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Micturition Urgency | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| Renal Colic | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 7 / 76 (9.21%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 10 | 0 | 1 |
| Back Pain | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 1 | 0 | 1 |
| Muscle Spasms | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in Extremity | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 1 | 0 | 1 |
| Rotator Cuff Syndrome | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Spinal Osteoarthritis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 0 | 1 |
| Infections and infestations | | | |
| Acute Tonsillitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Chlamydial Infection | | | |

| | | | |
|---------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 1 / 25 (4.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 0 | 1 | 1 |
| Eyelid Infection | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal Infection | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 2 / 76 (2.63%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gastroenteritis Viral | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Giardiasis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes Zoster | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Labyrinthitis | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |

| | | | |
|-----------------------------------|----------------|-----------------|-----------------|
| subjects affected / exposed | 7 / 76 (9.21%) | 4 / 25 (16.00%) | 3 / 14 (21.43%) |
| occurrences (all) | 10 | 5 | 4 |
| Oral Herpes | | | |
| subjects affected / exposed | 2 / 76 (2.63%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 2 / 76 (2.63%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 2 | 0 | 1 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 1 / 25 (4.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Skin Infection | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinea Cruris | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 76 (1.32%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Tooth Abscess | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 2 / 25 (8.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 6 / 76 (7.89%) | 3 / 25 (12.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 6 | 5 | 1 |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 2 / 76 (2.63%) | 0 / 25 (0.00%) | 1 / 14 (7.14%) |
| occurrences (all) | 2 | 0 | 1 |
| Viral Infection | | | |
| subjects affected / exposed | 0 / 76 (0.00%) | 0 / 25 (0.00%) | 0 / 14 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral Pharyngitis | | | |

| | | | |
|---|---------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 1 / 76 (1.32%) 2 | 0 / 25 (0.00%) 0 | 1 / 14 (7.14%) 1 |
| Viral Upper Respiratory Tract Infection subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 2 / 14 (14.29%) 3 |
| Vulvovaginal Candidiasis subjects affected / exposed occurrences (all) | 0 / 76 (0.00%) 0 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Vulvovaginal Mycotic Infection subjects affected / exposed occurrences (all) | 1 / 76 (1.32%) 1 | 0 / 25 (0.00%) 0 | 0 / 14 (0.00%) 0 |
| Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all) | 1 / 76 (1.32%) 1 | 1 / 25 (4.00%) 1 | 0 / 14 (0.00%) 0 |

| Non-serious adverse events | Placebo induction responders (PBO-I- Rsp)-Placebo Maintenance | PBO-I-nonRsp- Golimumab 100 mg Maintenance | GLM-I-nonRsp- Golimumab 100 mg Maintenance |
|---|--|--|--|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 67 / 129 (51.94%) | 140 / 230 (60.87%) | 247 / 405 (60.99%) |
| Vascular disorders Hot Flush subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 0 / 230 (0.00%) 0 | 0 / 405 (0.00%) 0 |
| Hypertension subjects affected / exposed occurrences (all) | 1 / 129 (0.78%) 1 | 5 / 230 (2.17%) 5 | 11 / 405 (2.72%) 11 |
| Phlebitis subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 0 / 230 (0.00%) 0 | 1 / 405 (0.25%) 1 |
| General disorders and administration site conditions Chest Pain subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 2 / 230 (0.87%) 2 | 1 / 405 (0.25%) 1 |
| Fatigue | | | |

| | | | |
|-----------------------------|-----------------|-----------------|------------------|
| subjects affected / exposed | 5 / 129 (3.88%) | 6 / 230 (2.61%) | 4 / 405 (0.99%) |
| occurrences (all) | 5 | 7 | 5 |
| Feeling Cold | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza Like Illness | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 5 / 230 (2.17%) | 6 / 405 (1.48%) |
| occurrences (all) | 1 | 7 | 6 |
| Injection Site Erythema | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 3 / 230 (1.30%) | 5 / 405 (1.23%) |
| occurrences (all) | 1 | 5 | 38 |
| Injection Site Induration | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection Site Oedema | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection Site Rash | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Oedema Peripheral | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 2 / 230 (0.87%) | 2 / 405 (0.49%) |
| occurrences (all) | 1 | 2 | 2 |
| Pain | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 4 / 405 (0.99%) |
| occurrences (all) | 0 | 0 | 4 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 9 / 230 (3.91%) | 16 / 405 (3.95%) |
| occurrences (all) | 1 | 11 | 19 |
| Immune system disorders | | | |
| Drug Hypersensitivity | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Seasonal Allergy | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 4 / 405 (0.99%) |
| occurrences (all) | 0 | 0 | 4 |

| | | | |
|--|----------------------|------------------------|------------------------|
| Reproductive system and breast disorders Cervix Haemorrhage Uterine subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 0 / 230 (0.00%) 0 | 0 / 405 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 5 / 129 (3.88%) 5 | 10 / 230 (4.35%) 11 | 18 / 405 (4.44%) 22 |
| Dyspnoea subjects affected / exposed occurrences (all) | 1 / 129 (0.78%) 1 | 2 / 230 (0.87%) 2 | 1 / 405 (0.25%) 1 |
| Nasal Congestion subjects affected / exposed occurrences (all) | 1 / 129 (0.78%) 1 | 2 / 230 (0.87%) 2 | 3 / 405 (0.74%) 3 |
| Oropharyngeal Pain subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 3 / 230 (1.30%) 3 | 10 / 405 (2.47%) 13 |
| Upper Respiratory Tract Congestion subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 1 / 230 (0.43%) 1 | 1 / 405 (0.25%) 1 |
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) | 2 / 129 (1.55%) 2 | 2 / 230 (0.87%) 2 | 3 / 405 (0.74%) 5 |
| Depression subjects affected / exposed occurrences (all) | 4 / 129 (3.10%) 4 | 0 / 230 (0.00%) 0 | 5 / 405 (1.23%) 5 |
| Insomnia subjects affected / exposed occurrences (all) | 2 / 129 (1.55%) 2 | 5 / 230 (2.17%) 9 | 10 / 405 (2.47%) 10 |
| Investigations Alanine Aminotransferase Increased subjects affected / exposed occurrences (all) | 3 / 129 (2.33%) 3 | 6 / 230 (2.61%) 9 | 6 / 405 (1.48%) 7 |
| Aspartate Aminotransferase Increased | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 129 (1.55%) | 2 / 230 (0.87%) | 4 / 405 (0.99%) |
| occurrences (all) | 2 | 4 | 5 |
| Blood Calcium Increased | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood Creatinine Increased | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood Parathyroid Hormone Increased | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoglobin Decreased | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neutrophil Count Increased | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D Decreased | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White Blood Cell Count Increased | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 2 / 405 (0.49%) |
| occurrences (all) | 0 | 1 | 2 |
| Injury, poisoning and procedural complications | | | |
| Animal Bite | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 2 / 405 (0.49%) |
| occurrences (all) | 0 | 0 | 2 |
| Arthropod Bite | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bite | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand Fracture | | | |

| | | | |
|--------------------------------------|-----------------|------------------|------------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Joint Dislocation | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Ligament Sprain | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 3 / 405 (0.74%) |
| occurrences (all) | 0 | 0 | 3 |
| Limb Fracture | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toxicity to Various Agents | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Demyelination | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 6 / 129 (4.65%) | 22 / 230 (9.57%) | 25 / 405 (6.17%) |
| occurrences (all) | 16 | 31 | 66 |
| Hyperaesthesia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 4 / 230 (1.74%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 4 | 1 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 2 / 129 (1.55%) | 10 / 230 (4.35%) | 22 / 405 (5.43%) |
| occurrences (all) | 2 | 11 | 26 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 2 / 230 (0.87%) | 3 / 405 (0.74%) |
| occurrences (all) | 0 | 2 | 4 |
| Leukopenia | | | |

| | | | |
|--|-------------------------|-------------------------|-------------------------|
| subjects affected / exposed occurrences (all) | 1 / 129 (0.78%) 1 | 0 / 230 (0.00%) 0 | 7 / 405 (1.73%) 8 |
| Ear and labyrinth disorders Ear Pain subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 1 / 230 (0.43%) 1 | 2 / 405 (0.49%) 2 |
| Eye disorders Dry Eye subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 1 / 230 (0.43%) 1 | 0 / 405 (0.00%) 0 |
| Eye Irritation subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 0 / 230 (0.00%) 0 | 0 / 405 (0.00%) 0 |
| Myopia subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 0 / 230 (0.00%) 0 | 0 / 405 (0.00%) 0 |
| Ocular Hyperaemia subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 0 / 230 (0.00%) 0 | 0 / 405 (0.00%) 0 |
| Vision Blurred subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 0 / 230 (0.00%) 0 | 0 / 405 (0.00%) 0 |
| Gastrointestinal disorders Abdominal Discomfort subjects affected / exposed occurrences (all) | 1 / 129 (0.78%) 1 | 0 / 230 (0.00%) 0 | 3 / 405 (0.74%) 3 |
| Abdominal Pain subjects affected / exposed occurrences (all) | 5 / 129 (3.88%) 5 | 9 / 230 (3.91%) 12 | 21 / 405 (5.19%) 27 |
| Abdominal Pain Upper subjects affected / exposed occurrences (all) | 2 / 129 (1.55%) 2 | 2 / 230 (0.87%) 6 | 6 / 405 (1.48%) 6 |
| Colitis Ulcerative subjects affected / exposed occurrences (all) | 17 / 129 (13.18%) 17 | 25 / 230 (10.87%) 26 | 49 / 405 (12.10%) 52 |
| Constipation | | | |

| | | | |
|--|-----------------|-----------------|------------------|
| subjects affected / exposed | 2 / 129 (1.55%) | 5 / 230 (2.17%) | 6 / 405 (1.48%) |
| occurrences (all) | 2 | 5 | 7 |
| Dental Caries | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 1 | 1 |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 129 (1.55%) | 3 / 230 (1.30%) | 7 / 405 (1.73%) |
| occurrences (all) | 3 | 4 | 7 |
| Dyspepsia | | | |
| subjects affected / exposed | 3 / 129 (2.33%) | 4 / 230 (1.74%) | 2 / 405 (0.49%) |
| occurrences (all) | 3 | 4 | 2 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 2 / 405 (0.49%) |
| occurrences (all) | 0 | 1 | 2 |
| Haematochezia | | | |
| subjects affected / exposed | 5 / 129 (3.88%) | 1 / 230 (0.43%) | 4 / 405 (0.99%) |
| occurrences (all) | 5 | 1 | 5 |
| Haemorrhoids | | | |
| subjects affected / exposed | 3 / 129 (2.33%) | 4 / 230 (1.74%) | 7 / 405 (1.73%) |
| occurrences (all) | 4 | 6 | 7 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 6 / 129 (4.65%) | 3 / 230 (1.30%) | 16 / 405 (3.95%) |
| occurrences (all) | 6 | 3 | 20 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 1 / 230 (0.43%) | 7 / 405 (1.73%) |
| occurrences (all) | 1 | 2 | 9 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 2 / 405 (0.49%) |
| occurrences (all) | 0 | 1 | 2 |
| Alopecia | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 2 / 230 (0.87%) | 1 / 405 (0.25%) |
| occurrences (all) | 1 | 2 | 1 |

| | | | |
|---|-----------------|-----------------|------------------|
| Blister | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermal Cyst | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Drug Eruption | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Eczema | | | |
| subjects affected / exposed | 2 / 129 (1.55%) | 2 / 230 (0.87%) | 1 / 405 (0.25%) |
| occurrences (all) | 2 | 5 | 1 |
| Rash | | | |
| subjects affected / exposed | 2 / 129 (1.55%) | 7 / 230 (3.04%) | 11 / 405 (2.72%) |
| occurrences (all) | 2 | 12 | 12 |
| Rash Erythematous | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Micturition Urgency | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 2 / 230 (0.87%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 2 | 1 |
| Renal Colic | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---------------------------------|-----------------|------------------|------------------|
| Arthralgia | | | |
| subjects affected / exposed | 7 / 129 (5.43%) | 11 / 230 (4.78%) | 29 / 405 (7.16%) |
| occurrences (all) | 8 | 14 | 34 |
| Back Pain | | | |
| subjects affected / exposed | 5 / 129 (3.88%) | 6 / 230 (2.61%) | 10 / 405 (2.47%) |
| occurrences (all) | 5 | 6 | 10 |
| Muscle Spasms | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 3 / 230 (1.30%) | 4 / 405 (0.99%) |
| occurrences (all) | 0 | 3 | 5 |
| Pain in Extremity | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 5 / 230 (2.17%) | 2 / 405 (0.49%) |
| occurrences (all) | 0 | 6 | 2 |
| Rotator Cuff Syndrome | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Spinal Osteoarthritis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Acute Tonsillitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 1 / 230 (0.43%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 1 | 1 |
| Bronchitis | | | |
| subjects affected / exposed | 2 / 129 (1.55%) | 1 / 230 (0.43%) | 10 / 405 (2.47%) |
| occurrences (all) | 2 | 1 | 10 |
| Chlamydial Infection | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 3 / 405 (0.74%) |
| occurrences (all) | 0 | 0 | 3 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 4 / 230 (1.74%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 5 | 1 |
| Eyelid Infection | | | |

| | | | |
|-----------------------------|-----------------|------------------|------------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal Infection | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 3 / 230 (1.30%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 2 / 129 (1.55%) | 4 / 230 (1.74%) | 4 / 405 (0.99%) |
| occurrences (all) | 2 | 6 | 4 |
| Gastroenteritis Viral | | | |
| subjects affected / exposed | 2 / 129 (1.55%) | 3 / 230 (1.30%) | 4 / 405 (0.99%) |
| occurrences (all) | 2 | 3 | 5 |
| Giardiasis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes Zoster | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 4 / 230 (1.74%) | 2 / 405 (0.49%) |
| occurrences (all) | 0 | 4 | 2 |
| Hordeolum | | | |
| subjects affected / exposed | 2 / 129 (1.55%) | 3 / 230 (1.30%) | 1 / 405 (0.25%) |
| occurrences (all) | 2 | 3 | 1 |
| Influenza | | | |
| subjects affected / exposed | 7 / 129 (5.43%) | 7 / 230 (3.04%) | 10 / 405 (2.47%) |
| occurrences (all) | 8 | 7 | 10 |
| Labyrinthitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 5 / 129 (3.88%) | 17 / 230 (7.39%) | 33 / 405 (8.15%) |
| occurrences (all) | 5 | 30 | 48 |
| Oral Herpes | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 3 / 230 (1.30%) | 6 / 405 (1.48%) |
| occurrences (all) | 0 | 6 | 10 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 1 / 405 (0.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngitis | | | |

| | | | |
|---|-----------------|------------------|------------------|
| subjects affected / exposed | 0 / 129 (0.00%) | 7 / 230 (3.04%) | 6 / 405 (1.48%) |
| occurrences (all) | 0 | 10 | 7 |
| Sinusitis | | | |
| subjects affected / exposed | 3 / 129 (2.33%) | 5 / 230 (2.17%) | 9 / 405 (2.22%) |
| occurrences (all) | 3 | 8 | 11 |
| Skin Infection | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinea Cruris | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 1 / 230 (0.43%) | 1 / 405 (0.25%) |
| occurrences (all) | 1 | 1 | 1 |
| Tooth Abscess | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 1 / 230 (0.43%) | 1 / 405 (0.25%) |
| occurrences (all) | 1 | 1 | 1 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 6 / 129 (4.65%) | 16 / 230 (6.96%) | 20 / 405 (4.94%) |
| occurrences (all) | 7 | 27 | 21 |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 4 / 129 (3.10%) | 2 / 230 (0.87%) | 2 / 405 (0.49%) |
| occurrences (all) | 4 | 2 | 2 |
| Viral Infection | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 3 / 230 (1.30%) | 4 / 405 (0.99%) |
| occurrences (all) | 2 | 3 | 5 |
| Viral Pharyngitis | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 0 / 230 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 0 / 129 (0.00%) | 4 / 230 (1.74%) | 4 / 405 (0.99%) |
| occurrences (all) | 0 | 4 | 4 |
| Vulvovaginal Candidiasis | | | |
| subjects affected / exposed | 1 / 129 (0.78%) | 2 / 230 (0.87%) | 1 / 405 (0.25%) |
| occurrences (all) | 1 | 2 | 1 |

| | | | |
|---|----------------------|----------------------|----------------------|
| Vulvovaginal Mycotic Infection subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 0 / 230 (0.00%) 0 | 1 / 405 (0.25%) 1 |
| Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all) | 0 / 129 (0.00%) 0 | 1 / 230 (0.43%) 1 | 1 / 405 (0.25%) 1 |

| Non-serious adverse events | PBO-I-Rsp-Placebo Maintenance to Golimumab 100 mg | Placebo Extension | Golimumab 50 mg Extension |
|---|---|---------------------|------------------------------|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 30 / 56 (53.57%) | 43 / 96 (44.79%) | 58 / 93 (62.37%) |
| Vascular disorders Hot Flush subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Hypertension subjects affected / exposed occurrences (all) | 2 / 56 (3.57%) 2 | 0 / 96 (0.00%) 0 | 3 / 93 (3.23%) 4 |
| Phlebitis subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| General disorders and administration site conditions Chest Pain subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 2 / 93 (2.15%) 2 |
| Fatigue subjects affected / exposed occurrences (all) | 3 / 56 (5.36%) 4 | 1 / 96 (1.04%) 1 | 2 / 93 (2.15%) 3 |
| Feeling Cold subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Influenza Like Illness subjects affected / exposed occurrences (all) | 1 / 56 (1.79%) 1 | 1 / 96 (1.04%) 1 | 2 / 93 (2.15%) 2 |
| Injection Site Erythema | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 15 |
| Injection Site Induration | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection Site Oedema | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection Site Rash | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema Peripheral | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 3 / 96 (3.13%) | 7 / 93 (7.53%) |
| occurrences (all) | 1 | 3 | 12 |
| Immune system disorders | | | |
| Drug Hypersensitivity | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Seasonal Allergy | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 0 / 96 (0.00%) | 3 / 93 (3.23%) |
| occurrences (all) | 1 | 0 | 3 |
| Reproductive system and breast disorders | | | |
| Cervix Haemorrhage Uterine | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 2 / 56 (3.57%) | 8 / 96 (8.33%) | 4 / 93 (4.30%) |
| occurrences (all) | 2 | 10 | 4 |
| Dyspnoea | | | |

| | | | |
|--------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal Congestion | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 3 |
| Oropharyngeal Pain | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 0 / 96 (0.00%) | 4 / 93 (4.30%) |
| occurrences (all) | 1 | 0 | 5 |
| Upper Respiratory Tract Congestion | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 1 / 96 (1.04%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 2 / 96 (2.08%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Depression | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 1 | 0 | 1 |
| Insomnia | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 2 / 96 (2.08%) | 1 / 93 (1.08%) |
| occurrences (all) | 1 | 2 | 2 |
| Investigations | | | |
| Alanine Aminotransferase Increased | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 2 / 93 (2.15%) |
| occurrences (all) | 0 | 0 | 2 |
| Aspartate Aminotransferase Increased | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood Calcium Increased | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood Creatinine Increased | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood Parathyroid Hormone Increased | | | |

| | | | |
|--|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoglobin Decreased | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Neutrophil Count Increased | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D Decreased | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White Blood Cell Count Increased | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal Bite | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 1 |
| Arthropod Bite | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 2 / 93 (2.15%) |
| occurrences (all) | 0 | 0 | 2 |
| Bite | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand Fracture | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint Dislocation | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament Sprain | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 2 / 96 (2.08%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Limb Fracture | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Toxicity to Various Agents subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Nervous system disorders | | | |
| Demyelination | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 3 / 56 (5.36%) | 1 / 96 (1.04%) | 6 / 93 (6.45%) |
| occurrences (all) | 14 | 2 | 11 |
| Hyperaesthesia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Migraine | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 1 / 96 (1.04%) | 0 / 93 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 2 / 96 (2.08%) | 1 / 93 (1.08%) |
| occurrences (all) | 1 | 4 | 1 |
| Eosinophilia | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 0 / 96 (0.00%) | 2 / 93 (2.15%) |
| occurrences (all) | 1 | 0 | 2 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Ear Pain | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Dry Eye | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye Irritation | | | |

| | | | |
|-----------------------------|-----------------|------------------|------------------|
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 1 |
| Myopia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ocular Hyperaemia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision Blurred | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal Discomfort | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 1 / 96 (1.04%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 1 | 1 |
| Abdominal Pain | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 4 / 96 (4.17%) | 6 / 93 (6.45%) |
| occurrences (all) | 0 | 4 | 7 |
| Abdominal Pain Upper | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 1 / 96 (1.04%) | 3 / 93 (3.23%) |
| occurrences (all) | 0 | 1 | 5 |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 7 / 56 (12.50%) | 20 / 96 (20.83%) | 17 / 93 (18.28%) |
| occurrences (all) | 7 | 22 | 22 |
| Constipation | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 4 / 93 (4.30%) |
| occurrences (all) | 0 | 0 | 4 |
| Dental Caries | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 1 / 96 (1.04%) | 0 / 93 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 4 / 96 (4.17%) | 7 / 93 (7.53%) |
| occurrences (all) | 1 | 5 | 8 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 1 / 96 (1.04%) | 1 / 93 (1.08%) |
| occurrences (all) | 1 | 1 | 1 |

| | | | |
|--|----------------|----------------|----------------|
| Flatulence | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 1 / 96 (1.04%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 2 / 96 (2.08%) | 3 / 93 (3.23%) |
| occurrences (all) | 0 | 3 | 5 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 2 / 96 (2.08%) | 3 / 93 (3.23%) |
| occurrences (all) | 0 | 2 | 3 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 1 |
| Nausea | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 4 / 96 (4.17%) | 2 / 93 (2.15%) |
| occurrences (all) | 1 | 5 | 2 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 3 / 96 (3.13%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 2 / 93 (2.15%) |
| occurrences (all) | 0 | 0 | 2 |
| Blister | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermal Cyst | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 1 |
| Drug Eruption | | | |

| | | | |
|---|---------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 1 / 56 (1.79%) 1 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Eczema subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 2 / 56 (3.57%) 2 | 1 / 96 (1.04%) 1 | 3 / 93 (3.23%) 10 |
| Rash Erythematous subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Micturition Urgency subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Pollakiuria subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Renal Colic subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 2 / 56 (3.57%) 2 | 5 / 96 (5.21%) 6 | 9 / 93 (9.68%) 14 |
| Back Pain subjects affected / exposed occurrences (all) | 1 / 56 (1.79%) 1 | 1 / 96 (1.04%) 1 | 2 / 93 (2.15%) 2 |
| Muscle Spasms subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Pain in Extremity | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 1 / 93 (1.08%) 1 |
| Rotator Cuff Syndrome subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Spinal Osteoarthritis subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Infections and infestations | | | |
| Acute Tonsillitis subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Bronchitis subjects affected / exposed occurrences (all) | 2 / 56 (3.57%) 2 | 1 / 96 (1.04%) 1 | 4 / 93 (4.30%) 4 |
| Chlamydial Infection subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Clostridium Difficile Infection subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Conjunctivitis subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 3 / 93 (3.23%) 3 |
| Eyelid Infection subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 0 / 93 (0.00%) 0 |
| Fungal Infection subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 1 / 96 (1.04%) 1 | 0 / 93 (0.00%) 0 |
| Gastroenteritis subjects affected / exposed occurrences (all) | 1 / 56 (1.79%) 1 | 0 / 96 (0.00%) 0 | 5 / 93 (5.38%) 5 |
| Gastroenteritis Viral subjects affected / exposed occurrences (all) | 0 / 56 (0.00%) 0 | 0 / 96 (0.00%) 0 | 2 / 93 (2.15%) 2 |

| | | | |
|-----------------------------|----------------|----------------|------------------|
| Giardiasis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes Zoster | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 1 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 1 |
| Influenza | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 3 / 96 (3.13%) | 9 / 93 (9.68%) |
| occurrences (all) | 1 | 3 | 9 |
| Labyrinthitis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 3 / 56 (5.36%) | 5 / 96 (5.21%) | 10 / 93 (10.75%) |
| occurrences (all) | 3 | 5 | 17 |
| Oral Herpes | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 1 / 96 (1.04%) | 1 / 93 (1.08%) |
| occurrences (all) | 1 | 1 | 1 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 1 / 96 (1.04%) | 6 / 93 (6.45%) |
| occurrences (all) | 0 | 1 | 7 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 3 / 96 (3.13%) | 5 / 93 (5.38%) |
| occurrences (all) | 1 | 3 | 6 |
| Skin Infection | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 3 |
| Tinea Cruris | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------|----------------|----------------|
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 1 / 96 (1.04%) | 2 / 93 (2.15%) |
| occurrences (all) | 1 | 1 | 2 |
| Tooth Abscess | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 0 | 1 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 4 / 56 (7.14%) | 4 / 96 (4.17%) | 6 / 93 (6.45%) |
| occurrences (all) | 5 | 5 | 8 |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 2 / 96 (2.08%) | 2 / 93 (2.15%) |
| occurrences (all) | 1 | 4 | 3 |
| Viral Infection | | | |
| subjects affected / exposed | 2 / 56 (3.57%) | 2 / 96 (2.08%) | 3 / 93 (3.23%) |
| occurrences (all) | 2 | 2 | 3 |
| Viral Pharyngitis | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 1 / 96 (1.04%) | 1 / 93 (1.08%) |
| occurrences (all) | 0 | 1 | 1 |
| Vulvovaginal Candidiasis | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 0 / 96 (0.00%) | 1 / 93 (1.08%) |
| occurrences (all) | 1 | 0 | 1 |
| Vulvovaginal Mycotic Infection | | | |
| subjects affected / exposed | 0 / 56 (0.00%) | 0 / 96 (0.00%) | 0 / 93 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 1 / 96 (1.04%) | 1 / 93 (1.08%) |
| occurrences (all) | 1 | 1 | 1 |

| Non-serious adverse events | Golimumab 100 mg Extension | Golimumab 200 mg Extension | Placebo - Golimumab 50 mg Extension |
|--|-------------------------------|-------------------------------|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 329 / 469 (70.15%) | 6 / 7 (85.71%) | 1 / 1 (100.00%) |

| | | | |
|--|------------------|----------------|---------------|
| Vascular disorders | | | |
| Hot Flush | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 12 / 469 (2.56%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 13 | 0 | 0 |
| Phlebitis | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| General disorders and administration site conditions | | | |
| Chest Pain | | | |
| subjects affected / exposed | 6 / 469 (1.28%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 12 / 469 (2.56%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 12 | 1 | 0 |
| Feeling Cold | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza Like Illness | | | |
| subjects affected / exposed | 6 / 469 (1.28%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 7 | 0 | 0 |
| Injection Site Erythema | | | |
| subjects affected / exposed | 7 / 469 (1.49%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 48 | 1 | 0 |
| Injection Site Induration | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 25 | 0 | 0 |
| Injection Site Oedema | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Injection Site Rash | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Oedema Peripheral | | | |

| | | | |
|--|------------------------|---------------------|--------------------|
| subjects affected / exposed occurrences (all) | 6 / 469 (1.28%) 6 | 1 / 7 (14.29%) 3 | 0 / 1 (0.00%) 0 |
| Pain subjects affected / exposed occurrences (all) | 1 / 469 (0.21%) 1 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 31 / 469 (6.61%) 36 | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 |
| Immune system disorders Drug Hypersensitivity subjects affected / exposed occurrences (all) | 2 / 469 (0.43%) 2 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Seasonal Allergy subjects affected / exposed occurrences (all) | 11 / 469 (2.35%) 12 | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 |
| Reproductive system and breast disorders Cervix Haemorrhage Uterine subjects affected / exposed occurrences (all) | 0 / 469 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 36 / 469 (7.68%) 42 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Dyspnoea subjects affected / exposed occurrences (all) | 7 / 469 (1.49%) 9 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Nasal Congestion subjects affected / exposed occurrences (all) | 9 / 469 (1.92%) 10 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Oropharyngeal Pain subjects affected / exposed occurrences (all) | 19 / 469 (4.05%) 22 | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 |
| Upper Respiratory Tract Congestion subjects affected / exposed occurrences (all) | 3 / 469 (0.64%) 4 | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 |
| Psychiatric disorders | | | |

| | | | |
|--------------------------------------|------------------|----------------|---------------|
| Anxiety | | | |
| subjects affected / exposed | 12 / 469 (2.56%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 12 | 1 | 0 |
| Depression | | | |
| subjects affected / exposed | 10 / 469 (2.13%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 11 | 1 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 8 / 469 (1.71%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 10 | 1 | 0 |
| Investigations | | | |
| Alanine Aminotransferase Increased | | | |
| subjects affected / exposed | 7 / 469 (1.49%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 10 | 0 | 0 |
| Aspartate Aminotransferase Increased | | | |
| subjects affected / exposed | 6 / 469 (1.28%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Blood Calcium Increased | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood Creatinine Increased | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Blood Parathyroid Hormone Increased | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoglobin Decreased | | | |
| subjects affected / exposed | 4 / 469 (0.85%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Neutrophil Count Increased | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Vitamin D Decreased | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White Blood Cell Count Increased | | | |

| | | | |
|--|------------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 1 / 469 (0.21%) 1 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Animal Bite | | | |
| subjects affected / exposed occurrences (all) | 0 / 469 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Arthropod Bite | | | |
| subjects affected / exposed occurrences (all) | 3 / 469 (0.64%) 3 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Bite | | | |
| subjects affected / exposed occurrences (all) | 0 / 469 (0.00%) 0 | 0 / 7 (0.00%) 0 | 1 / 1 (100.00%) 1 |
| Hand Fracture | | | |
| subjects affected / exposed occurrences (all) | 1 / 469 (0.21%) 1 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Joint Dislocation | | | |
| subjects affected / exposed occurrences (all) | 1 / 469 (0.21%) 1 | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 |
| Ligament Sprain | | | |
| subjects affected / exposed occurrences (all) | 5 / 469 (1.07%) 6 | 1 / 7 (14.29%) 2 | 0 / 1 (0.00%) 0 |
| Limb Fracture | | | |
| subjects affected / exposed occurrences (all) | 0 / 469 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Toxicity to Various Agents | | | |
| subjects affected / exposed occurrences (all) | 0 / 469 (0.00%) 0 | 1 / 7 (14.29%) 1 | 0 / 1 (0.00%) 0 |
| Nervous system disorders | | | |
| Demyelination | | | |
| subjects affected / exposed occurrences (all) | 0 / 469 (0.00%) 0 | 0 / 7 (0.00%) 0 | 0 / 1 (0.00%) 0 |
| Headache | | | |
| subjects affected / exposed occurrences (all) | 36 / 469 (7.68%) 63 | 1 / 7 (14.29%) 3 | 1 / 1 (100.00%) 1 |
| Hyperaesthesia | | | |

| | | | |
|--------------------------------------|------------------|----------------|---------------|
| subjects affected / exposed | 1 / 469 (0.21%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Migraine | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 20 / 469 (4.26%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 24 | 2 | 0 |
| Eosinophilia | | | |
| subjects affected / exposed | 7 / 469 (1.49%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 7 | 1 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Ear Pain | | | |
| subjects affected / exposed | 4 / 469 (0.85%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Eye disorders | | | |
| Dry Eye | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Eye Irritation | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Myopia | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ocular Hyperaemia | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision Blurred | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gastrointestinal disorders | | | |

| | | | |
|-----------------------------|--------------------|----------------|-----------------|
| Abdominal Discomfort | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal Pain | | | |
| subjects affected / exposed | 28 / 469 (5.97%) | 0 / 7 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 34 | 0 | 1 |
| Abdominal Pain Upper | | | |
| subjects affected / exposed | 11 / 469 (2.35%) | 0 / 7 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 17 | 0 | 1 |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 111 / 469 (23.67%) | 2 / 7 (28.57%) | 0 / 1 (0.00%) |
| occurrences (all) | 178 | 6 | 0 |
| Constipation | | | |
| subjects affected / exposed | 11 / 469 (2.35%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 13 | 0 | 0 |
| Dental Caries | | | |
| subjects affected / exposed | 3 / 469 (0.64%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 32 / 469 (6.82%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 48 | 1 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 14 / 469 (2.99%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 17 | 1 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 3 / 469 (0.64%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 10 / 469 (2.13%) | 0 / 7 (0.00%) | 1 / 1 (100.00%) |
| occurrences (all) | 13 | 0 | 3 |
| Haemorrhoids | | | |
| subjects affected / exposed | 13 / 469 (2.77%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 15 | 0 | 0 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 3 / 469 (0.64%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |

| | | | |
|--|------------------|----------------|---------------|
| Nausea | | | |
| subjects affected / exposed | 19 / 469 (4.05%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 21 | 1 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 15 / 469 (3.20%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 17 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 7 / 469 (1.49%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 4 / 469 (0.85%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Blister | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermal Cyst | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 4 / 469 (0.85%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Drug Eruption | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eczema | | | |
| subjects affected / exposed | 7 / 469 (1.49%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 8 | 1 | 0 |
| Rash | | | |
| subjects affected / exposed | 16 / 469 (3.41%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 19 | 1 | 0 |
| Rash Erythematous | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |

| | | | |
|---|------------------|----------------|---------------|
| Dysuria | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Micturition Urgency | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Renal Colic | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 24 / 469 (5.12%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 29 | 0 | 0 |
| Back Pain | | | |
| subjects affected / exposed | 30 / 469 (6.40%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 33 | 0 | 0 |
| Muscle Spasms | | | |
| subjects affected / exposed | 3 / 469 (0.64%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| Pain in Extremity | | | |
| subjects affected / exposed | 7 / 469 (1.49%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Rotator Cuff Syndrome | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Spinal Osteoarthritis | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Acute Tonsillitis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bronchitis | | | |

| | | | |
|---------------------------------|------------------|----------------|---------------|
| subjects affected / exposed | 21 / 469 (4.48%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 23 | 0 | 0 |
| Chlamydial Infection | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 3 / 469 (0.64%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 5 / 469 (1.07%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Eyelid Infection | | | |
| subjects affected / exposed | 0 / 469 (0.00%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal Infection | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 23 / 469 (4.90%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 24 | 0 | 0 |
| Gastroenteritis Viral | | | |
| subjects affected / exposed | 8 / 469 (1.71%) | 2 / 7 (28.57%) | 0 / 1 (0.00%) |
| occurrences (all) | 9 | 2 | 0 |
| Giardiasis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Herpes Zoster | | | |
| subjects affected / exposed | 14 / 469 (2.99%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 14 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 5 / 469 (1.07%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 9 | 1 | 0 |
| Influenza | | | |
| subjects affected / exposed | 37 / 469 (7.89%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 44 | 0 | 0 |
| Labyrinthitis | | | |

| | | | |
|-----------------------------------|-------------------|----------------|-----------------|
| subjects affected / exposed | 0 / 469 (0.00%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 77 / 469 (16.42%) | 2 / 7 (28.57%) | 1 / 1 (100.00%) |
| occurrences (all) | 164 | 4 | 4 |
| Oral Herpes | | | |
| subjects affected / exposed | 21 / 469 (4.48%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 40 | 1 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 23 / 469 (4.90%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 35 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 42 / 469 (8.96%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 57 | 0 | 0 |
| Skin Infection | | | |
| subjects affected / exposed | 2 / 469 (0.43%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Tinea Cruris | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 4 / 469 (0.85%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 4 | 3 | 0 |
| Tooth Abscess | | | |
| subjects affected / exposed | 5 / 469 (1.07%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 39 / 469 (8.32%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 71 | 1 | 0 |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 14 / 469 (2.99%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 18 | 0 | 0 |
| Viral Infection | | | |

| | | | |
|---|------------------|----------------|---------------|
| subjects affected / exposed | 9 / 469 (1.92%) | 1 / 7 (14.29%) | 0 / 1 (0.00%) |
| occurrences (all) | 9 | 2 | 0 |
| Viral Pharyngitis | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 11 / 469 (2.35%) | 2 / 7 (28.57%) | 0 / 1 (0.00%) |
| occurrences (all) | 22 | 4 | 0 |
| Vulvovaginal Candidiasis | | | |
| subjects affected / exposed | 4 / 469 (0.85%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Vulvovaginal Mycotic Infection | | | |
| subjects affected / exposed | 4 / 469 (0.85%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 469 (0.21%) | 0 / 7 (0.00%) | 0 / 1 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| Non-serious adverse events | Placebo-Golimumab 100 mg Extension | Golimumab 50 mg to 100 mg Extension | Golimumab 100 mg to 200 mg Extension |
|---|---------------------------------------|--|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 19 / 28 (67.86%) | 11 / 19 (57.89%) | 7 / 10 (70.00%) |
| Vascular disorders | | | |
| Hot Flush | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Phlebitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Chest Pain | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| Fatigue | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Feeling Cold | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza Like Illness | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Injection Site Erythema | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Injection Site Induration | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection Site Oedema | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection Site Rash | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema Peripheral | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Drug Hypersensitivity | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Seasonal Allergy | | | |

| | | | |
|--|---------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 1 / 28 (3.57%) 1 | 1 / 19 (5.26%) 1 | 0 / 10 (0.00%) 0 |
| Reproductive system and breast disorders Cervix Haemorrhage Uterine subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 2 / 28 (7.14%) 2 | 0 / 19 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| Dyspnoea subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 19 (0.00%) 0 | 1 / 10 (10.00%) 1 |
| Nasal Congestion subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 19 (0.00%) 0 | 1 / 10 (10.00%) 1 |
| Oropharyngeal Pain subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 1 / 19 (5.26%) 2 | 1 / 10 (10.00%) 1 |
| Upper Respiratory Tract Congestion subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| Depression subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 10 (0.00%) 0 |
| Insomnia subjects affected / exposed occurrences (all) | 1 / 28 (3.57%) 2 | 0 / 19 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| Investigations Alanine Aminotransferase Increased subjects affected / exposed occurrences (all) | 1 / 28 (3.57%) 1 | 0 / 19 (0.00%) 0 | 1 / 10 (10.00%) 1 |

| | | | |
|--|----------------|----------------|-----------------|
| Aspartate Aminotransferase Increased | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Blood Calcium Increased | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood Creatinine Increased | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood Parathyroid Hormone Increased | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemoglobin Decreased | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neutrophil Count Increased | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D Decreased | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| White Blood Cell Count Increased | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal Bite | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Arthropod Bite | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Bite | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand Fracture | | | |

| | | | |
|--------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Joint Dislocation | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament Sprain | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb Fracture | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toxicity to Various Agents | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Demyelination | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Headache | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Hyperaesthesia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |

| | | | |
|--|-----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| Ear and labyrinth disorders Ear Pain subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| Eye disorders Dry Eye subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 1 / 19 (5.26%) 2 | 0 / 10 (0.00%) 0 |
| Eye Irritation subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| Myopia subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| Ocular Hyperaemia subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 1 / 19 (5.26%) 2 | 0 / 10 (0.00%) 0 |
| Vision Blurred subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 10 (0.00%) 0 |
| Gastrointestinal disorders Abdominal Discomfort subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 10 (0.00%) 0 |
| Abdominal Pain subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 19 (0.00%) 0 | 1 / 10 (10.00%) 1 |
| Abdominal Pain Upper subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 10 (0.00%) 0 |
| Colitis Ulcerative subjects affected / exposed occurrences (all) | 7 / 28 (25.00%) 10 | 2 / 19 (10.53%) 2 | 3 / 10 (30.00%) 4 |
| Constipation | | | |

| | | | |
|--|----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 28 (3.57%) | 1 / 19 (5.26%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Dental Caries | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 2 / 10 (20.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 2 / 19 (10.53%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

| | | | |
|---|-----------------|----------------|-----------------|
| Blister | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermal Cyst | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 3 / 28 (10.71%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Drug Eruption | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Eczema | | | |
| subjects affected / exposed | 3 / 28 (10.71%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash Erythematous | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Renal and urinary disorders | | | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Micturition Urgency | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal Colic | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---------------------------------|-----------------|----------------|-----------------|
| Arthralgia | | | |
| subjects affected / exposed | 3 / 28 (10.71%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 4 | 0 | 1 |
| Back Pain | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Muscle Spasms | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pain in Extremity | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rotator Cuff Syndrome | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Spinal Osteoarthritis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Acute Tonsillitis | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 3 / 28 (10.71%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Chlamydial Infection | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid Infection | | | |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Fungal Infection | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 0 / 19 (0.00%) | 2 / 10 (20.00%) |
| occurrences (all) | 2 | 0 | 2 |
| Gastroenteritis Viral | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Giardiasis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Herpes Zoster | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Labyrinthitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 4 / 28 (14.29%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 7 | 0 | 1 |
| Oral Herpes | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |

| | | | |
|---|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Skin Infection | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinea Cruris | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth Abscess | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 2 / 28 (7.14%) | 2 / 19 (10.53%) | 2 / 10 (20.00%) |
| occurrences (all) | 4 | 3 | 7 |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Viral Infection | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Viral Pharyngitis | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 1 / 19 (5.26%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 0 / 28 (0.00%) | 0 / 19 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginal Candidiasis | | | |
| subjects affected / exposed | 1 / 28 (3.57%) | 0 / 19 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |

| | | | |
|---|---------------------|---------------------|----------------------|
| Vulvovaginal Mycotic Infection subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 1 / 19 (5.26%) 1 | 0 / 10 (0.00%) 0 |
| Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences (all) | 0 / 28 (0.00%) 0 | 1 / 19 (5.26%) 1 | 1 / 10 (10.00%) 1 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|--|
| 03 April 2012 | Amendment included the change of the Sponsor name from Centocor to Janssen Research and Development, LLC and some minor editorial changes. |
| 04 December 2012 | Amendment includes addition of a physical examination at the final efficacy visit and addition of a full skin examination on a yearly basis as well as at the time of the subject's final efficacy visit |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported