



Clinical trial results:

Post-Marketing Observational Cohort Study of Patients with Inflammatory Bowel Disease (IBD) Treated With CT-P13 in Usual Clinical Practice(CONNECT-IBD)

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2014-005192-89 |
| Trial protocol | FI |
| Global end of trial date | 31 October 2018 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 06 February 2022 |
| First version publication date | 06 February 2022 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | C1231001 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02539368 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Pfizer, Inc. |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017 |
| Public contact | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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 | 20 August 2019 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|-----------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 31 October 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To characterise the population and drug utilisation patterns of patients treated with CT-P13 for CD or UC in the context of SOC Remicade and to explore the long-term safety profile of CT-P13 in the treatment of patients with CD or UC in the context of SOC Remicade.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials subjects were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 22 April 2015 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety, Efficacy |
| Long term follow-up duration | 2 Years |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|---------------------|
| Country: Number of subjects enrolled | Belgium: 23 |
| Country: Number of subjects enrolled | Czechia: 36 |
| Country: Number of subjects enrolled | Finland: 38 |
| Country: Number of subjects enrolled | France: 622 |
| Country: Number of subjects enrolled | Germany: 623 |
| Country: Number of subjects enrolled | Greece: 87 |
| Country: Number of subjects enrolled | Hungary: 56 |
| Country: Number of subjects enrolled | Italy: 257 |
| Country: Number of subjects enrolled | Netherlands: 54 |
| Country: Number of subjects enrolled | Portugal: 54 |
| Country: Number of subjects enrolled | Slovakia: 60 |
| Country: Number of subjects enrolled | Spain: 451 |
| Country: Number of subjects enrolled | United Kingdom: 182 |
| Worldwide total number of subjects | 2543 |
| EEA total number of subjects | 2361 |

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) | 2387 |
| From 65 to 84 years | 152 |
| 85 years and over | 4 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 2565 subjects were enrolled in the study, out of which 22 subjects were not eligible to receive treatment for any of the treatment groups. Hence, only those subjects who received treatment during the study observation period were included in the subjects flow section.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|--------|
| Are arms mutually exclusive? | Yes |
| Arm title | CT-P13 |

Arm description:

Subjects diagnosed with either Crohn's Disease (CD) or Ulcerative Colitis (UC), and who were biologic naive initiating CT-P13 and received CT-P13 continuously, or subjects who were treated with CT-P13 continuously, or who were treated with CT-P13 then switched to other anti-tumor necrosis factors (TNFs) therapy except Remicade or non-biologic treatment during the study, or those who switched to CT-P13 from an alternative biologic therapy (except Remicade) due to non-responsiveness to or intolerance with existing therapy were enrolled in this group. Subjects received CT-P13 continuously in accordance with usual clinical practice of Inflammatory bowel disease (IBD) at the discretion of the physician and observed for a duration of approximately 24 months.

| | |
|--|------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Infliximab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for concentrate |
| Routes of administration | Intravenous use |

Dosage and administration details:

Infliximab was administered following local standard of care. As per summary of product characteristics: Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the first infusion.

Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and

6 weeks after the first infusion, then every 8 weeks thereafter.

| | |
|------------------|----------|
| Arm title | Remicade |
|------------------|----------|

Arm description:

Subjects diagnosed with either CD or UC, and who were biologic naive initiating Remicade and received Remicade continuously, or subjects who were treated with Remicade continuously, or who were treated with Remicade then switched to other anti-TNFs therapy (except CT-P13) or non-biologic treatment during the study, or those who switched to Remicade from an alternative biologic therapy (except CT-P13) due to non-responsiveness or intolerance were enrolled in this group. Subjects received Remicade in accordance with usual clinical practice of IBD at the discretion of the physician and observed for a duration of approximately 24 months.

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

| | |
|--|------------------------|
| Investigational medicinal product name | Remicade |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for concentrate |
| Routes of administration | Intravenous use |

Dosage and administration details:

Remicade was administered following local standard of care. As per summary of product characteristics: Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the first infusion.

Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

| | |
|------------------|----------------------------------|
| Arm title | Switched From Remicade to CT-P13 |
|------------------|----------------------------------|

Arm description:

Subjects diagnosed with either CD or UC and who were previously treated with Remicade continuously as per usual clinical practice of IBD, switched to CT-P13 once, either at enrollment or during the study were observed for a duration of approximately 24 months.

| | |
|--|------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Infliximab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for concentrate |
| Routes of administration | Intravenous use |

Dosage and administration details:

Infliximab was administered following local standard of care. As per summary of product characteristics: Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the first infusion.

Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

| | |
|------------------|----------------------------------|
| Arm title | Switched From CT-P13 to Remicade |
|------------------|----------------------------------|

Arm description:

Subjects diagnosed with either CD or UC and who were previously treated with CT-P13 continuously as per usual clinical practice of IBD, switched to Remicade once, either at enrollment or during the study were observed for a duration of approximately 24 months.

| | |
|--|------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Remicade |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for concentrate |
| Routes of administration | Intravenous use |

Dosage and administration details:

Remicade was administered following local standard of care. As per summary of product characteristics: Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the first infusion.

Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

| | |
|------------------|--------------------|
| Arm title | Multiple Switchers |
|------------------|--------------------|

Arm description:

Subjects with CD or UC with at least 2 switches between Remicade and CT-P13 during the study, were observed for a duration of approximately 24 months. Both Remicade and CT-P13 were administered as per usual clinical practice of IBD.

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

| | |
|--|------------------------|
| Investigational medicinal product name | Remicade |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for concentrate |
| Routes of administration | Intravenous use |

Dosage and administration details:

Remicade was administered following local standard of care. As per summary of product characteristics: Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the first infusion.

Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

| | |
|--|------------------------|
| Investigational medicinal product name | Infliximab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for concentrate |
| Routes of administration | Intravenous use |

Dosage and administration details:

Infliximab was administered following local standard of care. As per summary of product characteristics: Crohn's disease: 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the first infusion.

Ulcerative colitis: 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

| Number of subjects in period 1 | CT-P13 | Remicade | Switched From Remicade to CT-P13 |
|---------------------------------------|--------|----------|----------------------------------|
| Started | 1522 | 494 | 358 |
| Completed | 1117 | 393 | 291 |
| Not completed | 405 | 101 | 67 |
| Adverse event, serious fatal | 4 | 2 | 1 |
| Consent withdrawn by subject | 44 | 35 | 9 |
| Physician decision | 49 | 15 | 7 |
| Subject Non-compliant | 13 | 2 | 1 |
| Adverse event, non-fatal | 44 | 5 | 9 |
| Unspecified | 145 | 18 | 24 |
| Lost to follow-up | 96 | 21 | 16 |
| Missing | 10 | 3 | - |

| Number of subjects in period 1 | Switched From CT-P13 to Remicade | Multiple Switchers |
|---------------------------------------|----------------------------------|--------------------|
| Started | 67 | 102 |
| Completed | 60 | 88 |
| Not completed | 7 | 14 |
| Adverse event, serious fatal | - | - |
| Consent withdrawn by subject | 1 | 3 |
| Physician decision | - | 2 |

| | | |
|--------------------------|---|---|
| Subject Non-compliant | 1 | - |
| Adverse event, non-fatal | - | 3 |
| Unspecified | 1 | 3 |
| Lost to follow-up | 4 | 3 |
| Missing | - | - |

Baseline characteristics

Reporting groups

| | |
|--|----------------------------------|
| Reporting group title | CT-P13 |
| Reporting group description: | |
| Subjects diagnosed with either Crohn's Disease (CD) or Ulcerative Colitis (UC), and who were biologic naive initiating CT-P13 and received CT-P13 continuously, or subjects who were treated with CT-P13 continuously, or who were treated with CT-P13 then switched to other anti-tumor necrosis factors (TNFs) therapy except Remicade or non-biologic treatment during the study, or those who switched to CT-P13 from an alternative biologic therapy (except Remicade) due to non-responsiveness to or intolerance with existing therapy were enrolled in this group. Subjects received CT-P13 continuously in accordance with usual clinical practice of Inflammatory bowel disease (IBD) at the discretion of the physician and observed for a duration of approximately 24 months. | |
| Reporting group title | Remicade |
| Reporting group description: | |
| Subjects diagnosed with either CD or UC, and who were biologic naive initiating Remicade and received Remicade continuously, or subjects who were treated with Remicade continuously, or who were treated with Remicade then switched to other anti-TNFs therapy (except CT-P13) or non-biologic treatment during the study, or those who switched to Remicade from an alternative biologic therapy (except CT-P13) due to non-responsiveness or intolerance were enrolled in this group. Subjects received Remicade in accordance with usual clinical practice of IBD at the discretion of the physician and observed for a duration of approximately 24 months. | |
| Reporting group title | Switched From Remicade to CT-P13 |
| Reporting group description: | |
| Subjects diagnosed with either CD or UC and who were previously treated with Remicade continuously as per usual clinical practice of IBD, switched to CT-P13 once, either at enrollment or during the study were observed for a duration of approximately 24 months. | |
| Reporting group title | Switched From CT-P13 to Remicade |
| Reporting group description: | |
| Subjects diagnosed with either CD or UC and who were previously treated with CT-P13 continuously as per usual clinical practice of IBD, switched to Remicade once, either at enrollment or during the study were observed for a duration of approximately 24 months. | |
| Reporting group title | Multiple Switchers |
| Reporting group description: | |
| Subjects with CD or UC with at least 2 switches between Remicade and CT-P13 during the study, were observed for a duration of approximately 24 months. Both Remicade and CT-P13 were administered as per usual clinical practice of IBD. | |

| Reporting group values | CT-P13 | Remicade | Switched From Remicade to CT-P13 |
|--|--------|----------|----------------------------------|
| Number of subjects | 1522 | 494 | 358 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 1420 | 474 | 331 |
| From 65-84 years | 99 | 20 | 27 |
| 85 years and over | 3 | 0 | 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Age Continuous Units: years arithmetic mean standard deviation | 39.8 ± 14.65 | 38.8 ± 12.74 | 40.9 ± 14.14 |
| Sex: Female, Male Units: Subjects | | | |
| Female | 750 | 233 | 158 |
| Male | 772 | 261 | 200 |
| Subjects With Medical History of Smoking Units: Subjects | | | |
| Subjects With Smoking History | 320 | 94 | 70 |
| Subjects with no Smoking History | 1202 | 400 | 288 |
| Subjects With a History of Cancer Units: Subjects | | | |
| Subjects With Cancer History | 41 | 10 | 6 |
| Subjects with no Cancer History | 1481 | 484 | 352 |
| Subjects With Stoma Status Units: Subjects | | | |
| Subjects With Stoma Status | 33 | 13 | 14 |
| Subjects With no Stoma Status | 1489 | 481 | 344 |
| Subjects With a History Surgery | | | |
| Surgery status was a categorical variable defined as yes if the subject had prior surgical treatment related to the treatment of CD or UC. | | | |
| Units: Subjects | | | |
| Subjects With Surgery History | 395 | 165 | 116 |
| Subjects With no Surgery History | 1127 | 329 | 242 |
| Subjects With a History of Fistula Disease Units: Subjects | | | |
| Subjects With History of Fistula Disease | 304 | 124 | 86 |
| Subjects With no History of Fistula Disease | 1218 | 370 | 272 |
| Race/Ethnicity, Customized Units: Subjects | | | |
| American Indian or Alaska Native | 4 | 1 | 0 |
| Asian | 5 | 3 | 5 |
| Native Hawaiian or Other Pacific Islander | 1 | 0 | 0 |
| Black or African American | 7 | 0 | 1 |
| White | 1080 | 391 | 275 |
| Other | 267 | 60 | 49 |
| Unknown or Not Reported | 158 | 39 | 28 |

| Reporting group values | Switched From CT-P13 to Remicade | Multiple Switchers | Total |
|--|----------------------------------|--------------------|-------|
| Number of subjects | 67 | 102 | 2543 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |

| | | | |
|--|---------|---------|------|
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 65 | 97 | 2387 |
| From 65-84 years | 2 | 4 | 152 |
| 85 years and over | 0 | 1 | 4 |
| Age Continuous | | | |
| Units: years | | | |
| arithmetic mean | 41.1 | 38.4 | |
| standard deviation | ± 13.96 | ± 13.23 | - |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 29 | 48 | 1218 |
| Male | 38 | 54 | 1325 |
| Subjects With Medical History of Smoking | | | |
| Units: Subjects | | | |
| Subjects With Smoking History | 12 | 17 | 513 |
| Subjects with no Smoking History | 55 | 85 | 2030 |
| Subjects With a History of Cancer | | | |
| Units: Subjects | | | |
| Subjects With Cancer History | 1 | 4 | 62 |
| Subjects with no Cancer History | 66 | 98 | 2481 |
| Subjects With Stoma Status | | | |
| Units: Subjects | | | |
| Subjects With Stoma Status | 3 | 2 | 65 |
| Subjects With no Stoma Status | 64 | 100 | 2478 |
| Subjects With a History Surgery | | | |
| Surgery status was a categorical variable defined as yes if the subject had prior surgical treatment related to the treatment of CD or UC. | | | |
| Units: Subjects | | | |
| Subjects With Surgery History | 23 | 32 | 731 |
| Subjects With no Surgery History | 44 | 70 | 1812 |
| Subjects With a History of Fistula Disease | | | |
| Units: Subjects | | | |
| Subjects With History of Fistula Disease | 19 | 28 | 561 |
| Subjects With no History of Fistula Disease | 48 | 74 | 1982 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 5 |
| Asian | 0 | 0 | 13 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 1 |
| Black or African American | 0 | 0 | 8 |
| White | 55 | 83 | 1884 |
| Other | 11 | 14 | 401 |
| Unknown or Not Reported | 1 | 5 | 231 |

End points

End points reporting groups

| | |
|--|----------------------------------|
| Reporting group title | CT-P13 |
| Reporting group description: Subjects diagnosed with either Crohn's Disease (CD) or Ulcerative Colitis (UC), and who were biologic naive initiating CT-P13 and received CT-P13 continuously, or subjects who were treated with CT-P13 continuously, or who were treated with CT-P13 then switched to other anti-tumor necrosis factors (TNFs) therapy except Remicade or non-biologic treatment during the study, or those who switched to CT-P13 from an alternative biologic therapy (except Remicade) due to non-responsiveness to or intolerance with existing therapy were enrolled in this group. Subjects received CT-P13 continuously in accordance with usual clinical practice of Inflammatory bowel disease (IBD) at the discretion of the physician and observed for a duration of approximately 24 months. | |
| Reporting group title | Remicade |
| Reporting group description: Subjects diagnosed with either CD or UC, and who were biologic naive initiating Remicade and received Remicade continuously, or subjects who were treated with Remicade continuously, or who were treated with Remicade then switched to other anti-TNFs therapy (except CT-P13) or non-biologic treatment during the study, or those who switched to Remicade from an alternative biologic therapy (except CT-P13) due to non-responsiveness or intolerance were enrolled in this group. Subjects received Remicade in accordance with usual clinical practice of IBD at the discretion of the physician and observed for a duration of approximately 24 months. | |
| Reporting group title | Switched From Remicade to CT-P13 |
| Reporting group description: Subjects diagnosed with either CD or UC and who were previously treated with Remicade continuously as per usual clinical practice of IBD, switched to CT-P13 once, either at enrollment or during the study were observed for a duration of approximately 24 months. | |
| Reporting group title | Switched From CT-P13 to Remicade |
| Reporting group description: Subjects diagnosed with either CD or UC and who were previously treated with CT-P13 continuously as per usual clinical practice of IBD, switched to Remicade once, either at enrollment or during the study were observed for a duration of approximately 24 months. | |
| Reporting group title | Multiple Switchers |
| Reporting group description: Subjects with CD or UC with at least 2 switches between Remicade and CT-P13 during the study, were observed for a duration of approximately 24 months. Both Remicade and CT-P13 were administered as per usual clinical practice of IBD. | |

Primary: Disease Characteristics of Subjects: Disease Duration

| | |
|---|--|
| End point title | Disease Characteristics of Subjects: Disease Duration ^[1] |
| End point description: Disease duration was defined as the number of months from initial diagnosis of inflammatory bowel disease (CD or UC) to the date of informed consent, which was recorded at the time of enrollment into the study (baseline). Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period. Here, 'Overall number of subjects analysed' signifies number of subjects evaluable for this end point. | |
| End point type | Primary |
| End point timeframe: Baseline (Day 1) | |
| Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: No statistical analyses was planned for this end point | |

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|-------------------------------|-----------------|------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1519 | 494 | 358 | 67 |
| Units: months | | | | |
| median (full range (min-max)) | 63.0 (0 to 579) | 112.5 (0 to 632) | 120.0 (2 to 593) | 86.0 (0 to 519) |

| End point values | Multiple Switchers | | | |
|-------------------------------|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: months | | | | |
| median (full range (min-max)) | 101.0 (9 to 457) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Switched Treatment

| | |
|-----------------|---|
| End point title | Number of Subjects Who Switched Treatment ^{[2][3]} |
|-----------------|---|

End point description:

Here, number of subjects with either UC or CD, who switched from remicade to CT-P13; switched from CT-P13 to remicade and multiple switchers were reported. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period.

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

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses was planned for this end point

[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: The endpoint is reporting data for the arms specified

| End point values | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade | Multiple Switchers | |
|-----------------------------|----------------------------------|----------------------------------|--------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 358 | 67 | 102 | |
| Units: Subjects | | | | |
| Crohn's Disease | 237 | 47 | 72 | |
| Ulcerative Colitis | 121 | 20 | 30 | |

Statistical analyses

No statistical analyses for this end point

Primary: Reasons for Switching Treatment by Subjects

| | |
|-----------------|--|
| End point title | Reasons for Switching Treatment by Subjects ^[4] |
|-----------------|--|

End point description:

Reasons for switch were not captured in electronic data capture. Hence, due to change in planned analysis, data was not collected and analysed.

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

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses was planned for this end point

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|-----------------------------|------------------|------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0 ^[5] | 0 ^[6] | 0 ^[7] | 0 ^[8] |
| Units: Subjects | | | | |

Notes:

[5] - Reasons for switch were not captured in electronic data capture.

[6] - Reasons for switch were not captured in electronic data capture.

[7] - Reasons for switch were not captured in electronic data capture.

[8] - Reasons for switch were not captured in electronic data capture.

| End point values | Multiple Switchers | | | |
|-----------------------------|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 0 ^[9] | | | |
| Units: Subjects | | | | |

Notes:

[9] - Reasons for switch were not captured in electronic data capture.

Statistical analyses

No statistical analyses for this end point

Primary: Total Dose of Infusion Received

| | |
|-----------------|---|
| End point title | Total Dose of Infusion Received ^[10] |
|-----------------|---|

End point description:

Total dose of infusion received by the subjects was calculated. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period. Here, 'Overall number of subjects analysed' signifies number of subjects evaluable for this outcome measure. "99999" here signifies data was not available.

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

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses was planned for this end point

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|-------------------------------|-------------------------|-------------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1520 | 493 | 358 | 67 |
| Units: milligram | | | | |
| median (full range (min-max)) | 99999 (-99999 to 99999) | 99999 (-99999 to 99999) | 99999 (-99999 to 99999) | 99999 (-99999 to 99999) |

| End point values | Multiple Switchers | | | |
|-------------------------------|-------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: milligram | | | | |
| median (full range (min-max)) | 99999 (-99999 to 99999) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects by Frequency of Infusion Received

| | |
|-----------------|--|
| End point title | Number of Subjects by Frequency of Infusion Received ^[11] |
|-----------------|--|

End point description:

Number of subjects by infusion frequency (weeks) were reported at baseline and categorized as follows: once a week; once every 2 weeks; once every 3 weeks; once every 4 weeks; once every 5 weeks; once every 6 weeks; once every 7 weeks; once every 8 weeks and others. Here, 'Others' category included all the frequencies apart from the mentioned categories. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period. Here, 'Overall number of subjects analysed' signifies number of subjects evaluable for this end point.

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

End point timeframe:

Baseline (Day 1)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses was planned for this end point

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|-----------------------------|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1283 | 433 | 317 | 60 |
| Units: Subjects | | | | |
| Once a week | 5 | 0 | 0 | 0 |
| Once every 2 weeks | 140 | 5 | 11 | 3 |

| | | | | |
|--------------------|-----|-----|-----|----|
| Once every 3 weeks | 1 | 0 | 0 | 0 |
| Once every 4 weeks | 109 | 47 | 32 | 9 |
| Once every 5 weeks | 7 | 8 | 5 | 0 |
| Once every 6 weeks | 84 | 67 | 43 | 3 |
| Once every 7 weeks | 9 | 27 | 14 | 2 |
| Once every 8 weeks | 804 | 247 | 198 | 42 |
| Other | 124 | 32 | 14 | 1 |

| End point values | Multiple Switchers | | | |
|-----------------------------|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 85 | | | |
| Units: Subjects | | | | |
| Once a week | 0 | | | |
| Once every 2 weeks | 3 | | | |
| Once every 3 weeks | 1 | | | |
| Once every 4 weeks | 7 | | | |
| Once every 5 weeks | 4 | | | |
| Once every 6 weeks | 15 | | | |
| Once every 7 weeks | 4 | | | |
| Once every 8 weeks | 47 | | | |
| Other | 4 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects who had Change in Infusion Dose

| | |
|-----------------|--|
| End point title | Number of Subjects who had Change in Infusion Dose ^[12] |
|-----------------|--|

End point description:

Subjects who had change in the dose of infusion (either dose reduction or increase in dose) were included and reported. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period.

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

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses was planned for this end point

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|-----------------------------|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1522 | 494 | 358 | 67 |
| Units: Subjects | 479 | 110 | 89 | 28 |

| | | | | |
|-----------------------------|--------------------|--|--|--|
| End point values | Multiple Switchers | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: Subjects | 31 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects who had Change in Infusion Dose Categorized Based on Reasons of Change

| | |
|-----------------|---|
| End point title | Number of Subjects who had Change in Infusion Dose Categorized Based on Reasons of Change ^[13] |
|-----------------|---|

End point description:

Subjects who had change in infusion dose due to various reasons such as principal investigator's decision, subject's decisions, loss of response, lack of compliance, hypersensitivity, occurrence of adverse event (including adverse event special interest [AESI]/ serious adverse event [SAE]), positive for antibodies and other were reported. Here, 'Others' category included all reasons apart from the mentioned categories. A subject could have different reasons of dose change across visits, hence could be counted in more than one category. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period. Here, 'Overall number of subjects analysed' signifies number of subjects evaluable for this end point.

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

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses was planned for this end point

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|--|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 479 | 110 | 89 | 28 |
| Units: Subjects | | | | |
| Principal Investigator's Decision | 213 | 61 | 31 | 26 |
| Participant's Decision | 5 | 2 | 0 | 0 |
| Loss of response | 142 | 27 | 17 | 3 |
| Lack of compliance | 3 | 1 | 0 | 0 |
| Hypersensitivity | 4 | 1 | 1 | 0 |
| Occurrence of Adverse Event (including AESI/SAE) | 23 | 3 | 3 | 0 |
| Positive for antibodies | 5 | 2 | 2 | 0 |
| Other | 142 | 26 | 42 | 2 |

| End point values | Multiple Switchers | | | |
|--|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 31 | | | |
| Units: Subjects | | | | |
| Principal Investigator's Decision | 16 | | | |
| Participant's Decision | 0 | | | |
| Loss of response | 12 | | | |
| Lack of compliance | 0 | | | |
| Hypersensitivity | 0 | | | |
| Occurrence of Adverse Event (including AESI/SAE) | 2 | | | |
| Positive for antibodies | 0 | | | |
| Other | 9 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Took Concomitant Medications Related to the Treatment of Crohn's Disease (CD) or Ulcerative Colitis (UC)

| | |
|-----------------|---|
| End point title | Number of Subjects Who Took Concomitant Medications Related to the Treatment of Crohn's Disease (CD) or Ulcerative Colitis (UC) ^[14] |
|-----------------|---|

End point description:

Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period.

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

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses was planned for this end point

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|-----------------------------|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1522 | 494 | 358 | 67 |
| Units: Subjects | 1025 | 262 | 187 | 39 |

| End point values | Multiple Switchers | | | |
|-----------------------------|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: Subjects | 67 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Treatment-Emergent Adverse Event (AEs), Serious Adverse Events (SAEs) and Adverse Event With Special Interest (AESIs)

| | |
|-----------------|---|
| End point title | Number of Subjects With Treatment-Emergent Adverse Event (AEs), Serious Adverse Events (SAEs) and Adverse Event With Special Interest (AESIs) ^[15] |
|-----------------|---|

End point description:

An AE was any untoward medical occurrence in a subject who received study treatment without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death, initial or prolonged inpatient hospitalization, life-threatening experience (immediate risk of dying), persistent or significant disability or incapacity, congenital anomaly. Treatment-emergent were events between first dose of infusion up to month 24, that were absent before treatment or that worsened relative to pretreatment state. Hypersensitivity was the pre-defined TEAE of special interest for this study. AEs included both serious and non-serious adverse events. Safety analysis population included all subjects who received at least 1 dose of study drug during the observation period.

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

End point timeframe:

From baseline to follow-up period (up to a maximum duration of 2 years)

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses was planned for this end point

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|-----------------------------|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1522 | 494 | 358 | 67 |
| Units: Subjects | | | | |
| TEAEs | 621 | 133 | 130 | 15 |
| SAEs | 256 | 43 | 57 | 10 |
| TEAEs of Special Interest | 189 | 49 | 37 | 8 |

| End point values | Multiple Switchers | | | |
|-----------------------------|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: Subjects | | | | |
| TEAEs | 30 | | | |
| SAEs | 15 | | | |
| TEAEs of Special Interest | 11 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Remaining in Clinical Remission or Relapse

| | |
|-----------------|---|
| End point title | Number of Subjects Remaining in Clinical Remission or Relapse |
|-----------------|---|

End point description:

Clinical remission: total Mayo score of 2 points or lower, with no individual sub score exceeding 1 point. An instrument designed to measure disease activity, consists of 4 sub scores: stool frequency, rectal bleeding, findings of centrally read flexible proctosigmoidoscopy and physician's global assessment, each sub score graded from 0 to 3: higher scores indicate more severe disease. The scores were added to give a total score range of 0 to 12: higher scores indicate more severe disease. The relapse of clinical remission was defined as the time from date of first attaining CR to date of relapse or death from any cause, whichever occurred first. Full analysis set (FAS)=all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes (clinical assessment of disease activity, laboratory and imaging results related to assessment of CD or UC). Number analysed =subjects evaluable at specified time points for each arm.

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

End point timeframe:

Months 6, 12, 18 and 24

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|---|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1516 | 492 | 358 | 67 |
| Units: Subjects | | | | |
| Month 6: Remission (n=1036,335,280,54,74) | 870 | 312 | 261 | 51 |
| Month 12: Remission (n=914,306,240,47,64) | 802 | 288 | 224 | 45 |
| Month 18: Remission (n=703,268,203,32,66) | 633 | 257 | 192 | 31 |
| Month 24: Remission (n=424,191,157,24,43) | 386 | 184 | 148 | 23 |
| Month 6: Relapse (n=1036,335,280,54,74) | 166 | 23 | 19 | 3 |
| Month 12: Relapse (n=914,306,240,47,64) | 112 | 18 | 16 | 2 |
| Month 18: Relapse (n=703,268,203,32,66) | 70 | 11 | 11 | 1 |
| Month 24: Relapse (n=424,191,157,24,43) | 38 | 7 | 9 | 1 |

| | | | | |
|------------------|--------------------|--|--|--|
| End point values | Multiple Switchers | | | |
|------------------|--------------------|--|--|--|

| | | | | |
|---|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: Subjects | | | | |
| Month 6: Remission (n=1036,335,280,54,74) | 70 | | | |
| Month 12: Remission (n= 914,306,240,47,64) | 58 | | | |
| Month 18: Remission (n= 703,268,203,32,66) | 61 | | | |
| Month 24: Remission (n= 424,191,157,24,43) | 39 | | | |
| Month 6: Relapse (n=1036,335,280,54,74) | 4 | | | |
| Month 12: Relapse (n= 914,306,240,47,64) | 6 | | | |
| Month 18: Relapse (n= 703,268,203,32,66) | 5 | | | |
| Month 24: Relapse (n= 424,191,157,24,43) | 4 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects With Shift From Baseline in Harvey Bradshaw Index (HBI) According to Clinical Remission

| | |
|-----------------|---|
| End point title | Crohn's Disease: Number of Subjects With Shift From Baseline in Harvey Bradshaw Index (HBI) According to Clinical Remission |
|-----------------|---|

End point description:

HBI: simple index of CD activity, measures 5 criteria; the general well-being (0=very well to 4=terrible), abdominal pain (0=none to 3=severe), number of liquid stools per day (no maximum score), presence of an abdominal mass on physical exam (0=none to 3= definite and tender), and whether any complications 0=no complications, 1=Arthralgia; 2=Uveitis; 3=Erythema nodosum; 4=Aphthous ulcer; 5=Pyoderma gangrenosum; 6=Anal fissure; 7=New fistula 8=abscess. Total HBI score: sum of all 5 individual criteria. Minimum score: 0, no pre-specified maximum score as it depends on the number of liquid stools. Higher HBI scores=greater disease activity. Level of disease activity: CR (score less than [$<$] 5), MD (score equal to [=] 5-7), Mod D (score=8-16) and SD (score more than [$>$] 16). FAS was analyzed. "Number of Subjects Analyzed" = number of subjects evaluable for this end point; "number analysed" = subjects evaluable at specific time points.

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

End point timeframe:

Baseline, Months 6, 12, 18 and 24

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|--|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 969 | 348 | 237 | 47 |
| Units: Subjects | | | | |
| At Baseline (n=969,348,237,47,72) | 606 | 246 | 150 | 29 |
| Baseline-CR; Month 6-CR (n=606,246,150,29,49) | 485 | 211 | 125 | 24 |

| | | | | |
|--|-----|-----|-----|----|
| Baseline-CR; Month 6-MD (n=606,246,150,29,49) | 42 | 11 | 11 | 2 |
| Baseline-CR; Month 6-Mod D (n=606,246,150,29,49) | 23 | 8 | 2 | 1 |
| Baseline-CR; Month 6-SD (n=606,246,150,29,49) | 1 | 1 | 0 | 0 |
| Baseline-CR; Month 6-Missing (n=606,246,150,29,49) | 55 | 15 | 12 | 2 |
| Baseline-CR; Month 12-CR (n=606,246,150,29,49) | 429 | 182 | 109 | 22 |
| Baseline-CR; Month 12-MD (n=606,246,150,29,49) | 36 | 14 | 8 | 3 |
| Baseline-CR; Month 12-Mod D (n=606,246,150,29,49) | 20 | 4 | 5 | 1 |
| Baseline-CR; Month 12-SD (n=606,246,150,29,49) | 0 | 0 | 0 | 0 |
| Baseline-CR; Month 12-Missing (n=606,246,150,29,49) | 121 | 46 | 28 | 3 |
| Baseline-CR; Month 18-CR (n=606,246,150,29,49) | 326 | 143 | 96 | 17 |
| Baseline-CR; Month 18-MD (n=606,246,150,29,49) | 25 | 11 | 4 | 0 |
| Baseline-CR; Month 18-Mod D (n=606,246,150,29,49) | 8 | 4 | 2 | 0 |
| Baseline-CR; Month 18-SD (n=606,246,150,29,49) | 0 | 0 | 0 | 0 |
| Baseline-CR; Month 18-Missing (n=606,246,150,29,49) | 247 | 88 | 48 | 12 |
| Baseline-CR; Month 24-CR (n=606,246,150,29,49) | 194 | 98 | 68 | 11 |
| Baseline-CR; Month 24-MD (n=606,246,150,29,49) | 16 | 7 | 3 | 1 |
| Baseline-CR; Month 24-Mod D (n=606,246,150,29,49) | 5 | 1 | 3 | 0 |
| Baseline-CR; Month 24-SD (n=606,246,150,29,49) | 0 | 0 | 1 | 0 |
| Baseline-CR; Month 24-Missing (n=606,246,150,29,49) | 391 | 140 | 75 | 17 |

| End point values | Multiple Switchers | | | |
|---|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 72 | | | |
| Units: Subjects | | | | |
| At Baseline (n=969,348,237,47,72) | 49 | | | |
| Baseline-CR; Month 6-CR (n=606,246,150,29,49) | 43 | | | |
| Baseline-CR; Month 6-MD (n=606,246,150,29,49) | 4 | | | |
| Baseline-CR; Month 6-Mod D (n=606,246,150,29,49) | 0 | | | |
| Baseline-CR; Month 6-SD (n=606,246,150,29,49) | 0 | | | |
| Baseline-CR; Month 6-Missing (n=606,246,150,29,49) | 2 | | | |
| Baseline-CR; Month 12-CR (n=606,246,150,29,49) | 42 | | | |

| | | | | |
|--|----|--|--|--|
| Baseline-CR; Month 12-MD (n=606,246,150,29,49) | 1 | | | |
| Baseline-CR; Month 12-Mod D (n=606,246,150,29,49) | 0 | | | |
| Baseline-CR; Month 12-SD (n=606,246,150,29,49) | 0 | | | |
| Baseline-CR; Month 12-Missing (n=606,246,150,29,49) | 6 | | | |
| Baseline-CR; Month 18-CR (n=606,246,150,29,49) | 37 | | | |
| Baseline-CR; Month 18-MD (n=606,246,150,29,49) | 1 | | | |
| Baseline-CR; Month 18-Mod D (n=606,246,150,29,49) | 1 | | | |
| Baseline-CR; Month 18-SD (n=606,246,150,29,49) | 0 | | | |
| Baseline-CR; Month18-Missing (n=606,246,150,29,49) | 10 | | | |
| Baseline-CR; Month 24-CR (n=606,246,150,29,49) | 28 | | | |
| Baseline-CR; Month 24-MD (n=606,246,150,29,49) | 2 | | | |
| Baseline-CR; Month 24-Mod D (n=606,246,150,29,49) | 0 | | | |
| Baseline-CR; Month 24-SD (n=606,246,150,29,49) | 0 | | | |
| Baseline-CR; Month24-Missing (n=606,246,150,29,49) | 19 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects With Shift From Baseline in Harvey Bradshaw Index (HBI) According to Disease Activity

| | |
|-----------------|---|
| End point title | Crohn's Disease: Number of Subjects With Shift From Baseline in Harvey Bradshaw Index (HBI) According to Disease Activity |
|-----------------|---|

End point description:

HBI: simple index of CD activity, measures 5 criteria; the general well-being (0=very well to 4=terrible), abdominal pain (0=none to 3=severe), number of liquid stools per day (no maximum score), presence of an abdominal mass on physical exam (0=none to 3= definite and tender), and whether any complications 0=no complications, 1=Arthralgia; 2=Uveitis; 3=Erythema nodosum; 4=Aphthous ulcer; 5=Pyoderma gangrenosum; 6=Anal fissure; 7=New fistula 8=abscess. Total HBI score: sum of all 5 individual criteria. Minimum score: 0, no pre-specified maximum score as it depends on the number of liquid stools. Higher HBI scores=greater disease activity. The level of disease activity was interpreted as clinical remission (CR) (HBI score < 5), mild disease (MD) (HBI score = 5 to 7), moderate disease (Mod D) (HBI score = 8 to 16) and severe disease (SD) (HBI score >16). Number analysed =subjects evaluable at specified time points for each arm.

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

End point timeframe:

Baseline, Months 6, 12, 18 and 24

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|---|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 969 | 348 | 237 | 47 |
| Units: Subjects | | | | |
| At Baseline: MD (n=969,348,237,47,72) | 137 | 45 | 24 | 10 |
| At Baseline: Mod D (n=969,348,237,47,72) | 91 | 22 | 15 | 4 |
| At Baseline: SD (n=969,348,237,47,72) | 6 | 2 | 0 | 0 |
| Baseline-MD; Month 6-CR (n=137,45,24,10,7) | 82 | 21 | 9 | 5 |
| Baseline-MD; Month 6-MD (n=137,45,24,10,7) | 30 | 13 | 11 | 4 |
| Baseline-MD; Month 6-Mod D (n=137,45,24,10,7) | 12 | 8 | 3 | 0 |
| Baseline-MD; Month 6-SD (n=137,45,24,10,7) | 0 | 0 | 1 | 0 |
| Baseline-MD; Month 6-Missing (n=137,45,24,10,7) | 13 | 3 | 0 | 1 |
| Baseline-Mod D; Month 6-CR (n=91,22,15,4,3) | 39 | 4 | 6 | 3 |
| Baseline-Mod D; Month 6-MD (n=91,22,15,4,3) | 19 | 6 | 2 | 1 |
| Baseline-Mod D; Month 6-Mod D (n=91,22,15,4,3) | 25 | 8 | 6 | 0 |
| Baseline-Mod D; Month 6-SD (n=91,22,15,4,3) | 1 | 0 | 0 | 0 |
| Baseline-Mod D; Month 6-Missing (n=91,22,15,4,3) | 7 | 4 | 1 | 0 |
| Baseline-SD; Month 6-CR (n=6,2,0,0,0) | 1 | 1 | 0 | 0 |
| Baseline-SD; Month 6-MD (n=6,2,0,0,0) | 2 | 0 | 0 | 0 |
| Baseline-SD; Month 6-Mod D (n=6,2,0,0,0) | 2 | 0 | 0 | 0 |
| Baseline-SD; Month 6-SD (n=6,2,0,0,0) | 0 | 1 | 0 | 0 |
| Baseline-SD; Month 6-Missing (n=6,2,0,0,0) | 1 | 0 | 0 | 0 |
| Baseline-MD; Month 12-CR (n=137,45,24,10,7) | 81 | 24 | 14 | 6 |
| Baseline-MD; Month 12-MD (n=137,45,24,10,7) | 16 | 6 | 3 | 2 |
| Baseline-MD; Month 12-Mod D (n=137,45,24,10,7) | 7 | 6 | 3 | 0 |
| Baseline-MD; Month 12-SD (n=137,45,24,10,7) | 1 | 0 | 0 | 0 |
| Baseline-MD; Month 12-Missing (n=137,45,24,10,7) | 32 | 9 | 4 | 2 |
| Baseline-Mod D; Month 12-CR (n=91,22,15,4,3) | 39 | 6 | 4 | 3 |
| Baseline-Mod D; Month 12-MD (n=91,22,15,4,3) | 15 | 9 | 0 | 1 |
| Baseline-Mod D; Month 12-Mod D (n=91,22,15,4,3) | 16 | 2 | 6 | 0 |
| Baseline-Mod D; Month 12-SD (n=91,22,15,4,3) | 0 | 0 | 0 | 0 |
| Baseline-Mod D; Month 12-Missing (n=91,22,15,4,3) | 21 | 5 | 5 | 0 |
| Baseline-SD; Month 12-CR (n=6,2,0,0,0) | 1 | 1 | 0 | 0 |
| Baseline-SD; Month 12-MD (n=6,2,0,0,0) | 2 | 0 | 0 | 0 |

| | | | | |
|--|----|----|----|---|
| Baseline-SD; Month 12-Mod D (n=6,2,0,0,0) | 1 | 0 | 0 | 0 |
| Baseline-SD; Month 12-SD (n=6,2,0,0,0) | 0 | 1 | 0 | 0 |
| Baseline-SD; Month 12-Missing (n=6,2,0,0,0) | 2 | 0 | 0 | 0 |
| Baseline-MD; Month 18-CR (n=137,45,24,10,7) | 60 | 24 | 12 | 2 |
| Baseline-MD; Month 18-MD (n=137,45,24,10,7) | 10 | 6 | 1 | 4 |
| Baseline-MD; Month 18-Mod D (n=137,45,24,10,7) | 4 | 2 | 1 | 0 |
| Baseline-MD; Month 18-SD (n=137,45,24,10,7) | 2 | 0 | 0 | 0 |
| Baseline-MD; Month 18-Missing (n=137,45,24,10,7) | 61 | 13 | 10 | 4 |
| Baseline-Mod D; Month 18-CR (n=91,22,15,4,3) | 30 | 4 | 2 | 3 |
| Baseline-Mod D; Month 18-MD (n=91,22,15,4,3) | 13 | 7 | 2 | 1 |
| Baseline-Mod D; Month 18-Mod D (n=91,22,15,4,3) | 14 | 3 | 3 | 0 |
| Baseline-Mod D; Month 18-SD (n=91,22,15,4,3) | 0 | 0 | 0 | 0 |
| Baseline-Mod D; Month 18-Missing (n=91,22,15,4,3) | 34 | 8 | 8 | 0 |
| Baseline-SD; Month 18-CR (n=6,2,0,0,0) | 1 | 1 | 0 | 0 |
| Baseline-SD; Month 18-MD (n=6,2,0,0,0) | 2 | 1 | 0 | 0 |
| Baseline-SD; Month 18-Mod D (n=6,2,0,0,0) | 1 | 0 | 0 | 0 |
| Baseline-SD; Month 18-SD (n=6,2,0,0,0) | 0 | 0 | 0 | 0 |
| Baseline-SD; Month 18-Missing (n=6,2,0,0,0) | 2 | 0 | 0 | 0 |
| Baseline-MD; Month 24-CR (n=137,45,24,10,7) | 34 | 13 | 8 | 5 |
| Baseline-MD; Month 24-MD (n=137,45,24,10,7) | 15 | 6 | 2 | 1 |
| Baseline-MD; Month 24-Mod D (n=137,45,24,10,7) | 2 | 1 | 1 | 0 |
| Baseline-MD; Month 24-SD (n=137,45,24,10,7) | 1 | 0 | 0 | 0 |
| Baseline-MD; Month 24-Missing (n=137,45,24,10,7) | 85 | 25 | 13 | 4 |
| Baseline-Mod D; Month 24-CR (n=91,22,15,4,3) | 23 | 3 | 4 | 3 |
| Baseline-Mod D; Month 24-MD (n=91,22,15,4,3) | 5 | 2 | 1 | 0 |
| Baseline-Mod D; Month 24-Mod D (n=91,22,15,4,3) | 10 | 9 | 3 | 1 |
| Baseline-Mod D; Month 24-SD (n=91,22,15,4,3) | 1 | 0 | 0 | 0 |
| Baseline-Mod D; Month 24-Missing (n=91,22,15,4,3) | 52 | 8 | 7 | 0 |
| Baseline-SD; Month 24-CR (n=6,2,0,0,0) | 0 | 1 | 0 | 0 |
| Baseline-SD; Month 24-MD (n=6,2,0,0,0) | 2 | 0 | 0 | 0 |
| Baseline-SD; Month 24-Mod D (n=6,2,0,0,0) | 0 | 0 | 0 | 0 |

| | | | | |
|--|---|---|---|---|
| Baseline-SD; Month 24-SD (n=6,2,0,0,0) | 0 | 1 | 0 | 0 |
| Baseline-SD; Month 24-Missing (n=6,2,0,0,0) | 4 | 0 | 0 | 0 |

| End point values | Multiple Switchers | | | |
|---|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 72 | | | |
| Units: Subjects | | | | |
| At Baseline: MD (n=969,348,237,47,72) | 7 | | | |
| At Baseline: Mod D (n=969,348,237,47,72) | 3 | | | |
| At Baseline: SD (n=969,348,237,47,72) | 0 | | | |
| Baseline-MD; Month 6-CR (n=137,45,24,10,7) | 3 | | | |
| Baseline-MD; Month 6-MD (n=137,45,24,10,7) | 1 | | | |
| Baseline-MD; Month 6-Mod D (n=137,45,24,10,7) | 2 | | | |
| Baseline-MD; Month 6-SD (n=137,45,24,10,7) | 1 | | | |
| Baseline-MD; Month 6-Missing (n=137,45,24,10,7) | 0 | | | |
| Baseline-Mod D; Month 6-CR (n=91,22,15,4,3) | 2 | | | |
| Baseline-Mod D; Month 6-MD (n=91,22,15,4,3) | 0 | | | |
| Baseline-Mod D; Month 6-Mod D (n=91,22,15,4,3) | 0 | | | |
| Baseline-Mod D; Month 6-SD (n=91,22,15,4,3) | 0 | | | |
| Baseline-Mod D; Month 6-Missing (n=91,22,15,4,3) | 1 | | | |
| Baseline-SD; Month 6-CR (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 6-MD (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 6-Mod D (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 6-SD (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 6-Missing (n=6,2,0,0,0) | 0 | | | |
| Baseline-MD; Month 12-CR (n=137,45,24,10,7) | 4 | | | |
| Baseline-MD; Month 12-MD (n=137,45,24,10,7) | 1 | | | |
| Baseline-MD; Month 12-Mod D (n=137,45,24,10,7) | 1 | | | |
| Baseline-MD; Month 12-SD (n=137,45,24,10,7) | 1 | | | |
| Baseline-MD; Month 12-Missing (n=137,45,24,10,7) | 0 | | | |
| Baseline-Mod D; Month 12-CR (n=91,22,15,4,3) | 3 | | | |
| Baseline-Mod D; Month 12-MD (n=91,22,15,4,3) | 0 | | | |
| Baseline-Mod D; Month 12-Mod D (n=91,22,15,4,3) | 0 | | | |

| | | | | |
|--|---|--|--|--|
| Baseline-Mod D; Month 12-SD (n=91,22,15,4,3) | 0 | | | |
| Baseline-Mod D; Month 12-Missing (n=91,22,15,4,3) | 0 | | | |
| Baseline-SD; Month 12-CR (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 12-MD (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 12-Mod D (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 12-SD (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 12-Missing (n=6,2,0,0,0) | 0 | | | |
| Baseline-MD; Month 18-CR (n=137,45,24,10,7) | 2 | | | |
| Baseline-MD; Month 18-MD (n=137,45,24,10,7) | 3 | | | |
| Baseline-MD; Month 18-Mod D (n=137,45,24,10,7) | 2 | | | |
| Baseline-MD; Month 18-SD (n=137,45,24,10,7) | 0 | | | |
| Baseline-MD; Month 18-Missing (n=137,45,24,10,7) | 0 | | | |
| Baseline-Mod D; Month 18-CR (n=91,22,15,4,3) | 2 | | | |
| Baseline-Mod D; Month 18-MD (n=91,22,15,4,3) | 1 | | | |
| Baseline-Mod D; Month 18-Mod D (n=91,22,15,4,3) | 0 | | | |
| Baseline-Mod D; Month 18-SD (n=91,22,15,4,3) | 0 | | | |
| Baseline-Mod D; Month 18-Missing (n=91,22,15,4,3) | 0 | | | |
| Baseline-SD; Month 18-CR (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 18-MD (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 18-Mod D (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 18-SD (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 18-Missing (n=6,2,0,0,0) | 0 | | | |
| Baseline-MD; Month 24-CR (n=137,45,24,10,7) | 2 | | | |
| Baseline-MD; Month 24-MD (n=137,45,24,10,7) | 2 | | | |
| Baseline-MD; Month 24-Mod D (n=137,45,24,10,7) | 2 | | | |
| Baseline-MD; Month 24-SD (n=137,45,24,10,7) | 0 | | | |
| Baseline-MD; Month 24-Missing (n=137,45,24,10,7) | 1 | | | |
| Baseline-Mod D; Month 24-CR (n=91,22,15,4,3) | 1 | | | |
| Baseline-Mod D; Month 24-MD (n=91,22,15,4,3) | 1 | | | |
| Baseline-Mod D; Month 24-Mod D (n=91,22,15,4,3) | 0 | | | |
| Baseline-Mod D; Month 24-SD (n=91,22,15,4,3) | 0 | | | |

| | | | | |
|--|---|--|--|--|
| Baseline-Mod D; Month 24-Missing (n=91,22,15,4,3) | 1 | | | |
| Baseline-SD; Month 24-CR (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 24-MD (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 24-Mod D (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 24-SD (n=6,2,0,0,0) | 0 | | | |
| Baseline-SD; Month 24-Missing (n=6,2,0,0,0) | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ulcerative Colitis: Number of Subjects With Shift From Baseline in Partial Mayo Scoring System According to Clinical Remission

| | |
|-----------------|--|
| End point title | Ulcerative Colitis: Number of Subjects With Shift From Baseline in Partial Mayo Scoring System According to Clinical Remission |
|-----------------|--|

End point description:

Mayo Score: instrument to measure disease activity of UC. Score ranges: 0-12 points. There are 4 sub scores: graded from 0-3. Higher scores: more severe disease. Partial Mayo Score (PMS) (Mayo score without endoscopy) is comprised of 3 parameters: stool frequency from 0 (normal number of stools) to 3 (having ≥ 5 stools more than normal), the presence of rectal bleeding (0=no blood seen to 3=blood alone passes), and physician's global assessment (0=normal to 3=severe disease). Total PMS: sum of all parameters, score from 0 (normal or inactive disease) to 9 (severe disease). Score was calculated if data was available for at least 1 of 3 sub scores. Level of disease activity: clinical remission (CR) (PMS < 2), mild disease (MD) (PMS=2-4), moderate disease (Mod D) (PMS=5-6) and severe disease (SD) (PMS > 6). FAS was analysed. "Number of Subjects Analysed" = number of subjects evaluable for this end point; "number analysed" = subjects evaluable at specific time points.

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

End point timeframe:

Baseline, Months 6, 12, 18 and 24

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|--|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 547 | 144 | 121 | 20 |
| Units: Subjects | | | | |
| At Baseline (n=547,144,121,20,30) | 169 | 83 | 55 | 9 |
| Baseline-CR; Month 6-CR (n=169,83,55,9,13) | 117 | 65 | 40 | 7 |
| Baseline-CR; Month 6-MD (n=169,83,55,9,13) | 27 | 9 | 7 | 2 |
| Baseline-CR; Month 6-Mod D (n=169,83,55,9,13) | 7 | 0 | 1 | 0 |
| Baseline-CR; Month 6-SD (n=169,83,55,9,13) | 1 | 0 | 1 | 0 |
| Baseline-CR; Month 6-Missing (n=169,83,55,9,13) | 17 | 9 | 6 | 0 |

| | | | | |
|---|-----|----|----|---|
| Baseline-CR; Month 12-CR (n=169,83,55,9,13) | 107 | 65 | 30 | 8 |
| Baseline-CR; Month 12-MD (n=169,83,55,9,13) | 24 | 4 | 10 | 0 |
| Baseline-CR; Month 12-Mod D (n=169,83,55,9,13) | 5 | 0 | 1 | 0 |
| Baseline-CR; Month 12-SD (n=169,83,55,9,13) | 1 | 0 | 0 | 0 |
| Baseline-CR; Month 12-Missing (n=169,83,55,9,13) | 32 | 14 | 14 | 1 |
| Baseline-CR; Month 18-CR (n=169,83,55,9,13) | 88 | 55 | 25 | 3 |
| Baseline-CR; Month 18-MD (n=169,83,55,9,13) | 13 | 8 | 4 | 0 |
| Baseline-CR; Month 18-Mod D (n=169,83,55,9,13) | 6 | 0 | 2 | 0 |
| Baseline-CR; Month 18-SD (n=169,83,55,9,13) | 2 | 0 | 1 | 0 |
| Baseline-CR; Month 18-Missing (n=169,83,55,9,13) | 60 | 20 | 23 | 6 |
| Baseline-CR; Month 24-CR (n=169,83,55,9,13) | 57 | 38 | 22 | 3 |
| Baseline-CR; Month 24-MD (n=169,83,55,9,13) | 7 | 5 | 3 | 0 |
| Baseline-CR; Month 24-Mod D (n=169,83,55,9,13) | 2 | 1 | 1 | 0 |
| Baseline-CR; Month 24-SD (n=169,83,55,9,13) | 0 | 0 | 0 | 0 |
| Baseline-CR; Month 24-Missing (n=169,83,55,9,13) | 103 | 39 | 29 | 6 |

| End point values | Multiple Switchers | | | |
|---|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 30 | | | |
| Units: Subjects | | | | |
| At Baseline (n=547,144,121,20,30) | 13 | | | |
| Baseline-CR; Month 6-CR (n=169,83,55,9,13) | 9 | | | |
| Baseline-CR; Month 6-MD (n=169,83,55,9,13) | 2 | | | |
| Baseline-CR; Month 6-Mod D (n=169,83,55,9,13) | 1 | | | |
| Baseline-CR; Month 6-SD (n=169,83,55,9,13) | 0 | | | |
| Baseline-CR; Month 6-Missing (n=169,83,55,9,13) | 1 | | | |
| Baseline-CR; Month 12-CR (n=169,83,55,9,13) | 8 | | | |
| Baseline-CR; Month 12-MD (n=169,83,55,9,13) | 4 | | | |
| Baseline-CR; Month 12-Mod D (n=169,83,55,9,13) | 1 | | | |
| Baseline-CR; Month 12-SD (n=169,83,55,9,13) | 0 | | | |
| Baseline-CR; Month 12-Missing (n=169,83,55,9,13) | 0 | | | |

| | | | | |
|---|---|--|--|--|
| Baseline-CR; Month 18-CR (n=169,83,55,9,13) | 9 | | | |
| Baseline-CR; Month 18-MD (n=169,83,55,9,13) | 0 | | | |
| Baseline-CR; Month 18-Mod D (n=169,83,55,9,13) | 3 | | | |
| Baseline-CR; Month 18-SD (n=169,83,55,9,13) | 0 | | | |
| Baseline-CR; Month 18-Missing (n=169,83,55,9,13) | 1 | | | |
| Baseline-CR; Month 24-CR (n=169,83,55,9,13) | 6 | | | |
| Baseline-CR; Month 24-MD (n=169,83,55,9,13) | 0 | | | |
| Baseline-CR; Month 24-Mod D (n=169,83,55,9,13) | 0 | | | |
| Baseline-CR; Month 24-SD (n=169,83,55,9,13) | 0 | | | |
| Baseline-CR; Month 24-Missing (n=169,83,55,9,13) | 7 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ulcerative Colitis: Number of Subjects With Shift From Baseline in Partial Mayo Scoring System According to Disease Activity

| | |
|---|--|
| End point title | Ulcerative Colitis: Number of Subjects With Shift From Baseline in Partial Mayo Scoring System According to Disease Activity |
| End point description: | |
| Mayo Score: instrument to measure disease activity of UC. Score ranges: 0-12 points. There are 4 sub scores: graded from 0-3. Higher scores: more severe disease. Partial Mayo Score (PMS) (Mayo score without endoscopy) is comprised of 3 parameters: stool frequency from 0 (normal number of stools) to 3 (having ≥ 5 stools more than normal), the presence of rectal bleeding (0=no blood seen to 3=blood alone passes), and physician's global assessment (0=normal to 3=severe disease). Total PMS: sum of all parameters, score from 0 (normal or inactive disease) to 9 (severe disease). Score was calculated if data was available for at least 1 of 3 sub scores. Level of disease activity: clinical remission (CR) (PMS < 2), mild disease (MD) (PMS=2-4), moderate disease (Mod D) (PMS=5-6) and severe disease (SD) (PMS > 6). FAS was analysed. "Number of Subjects Analysed" = number of subjects evaluable for this end point; "number analysed" = subjects evaluable at specific time points. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Months 6, 12, 18 and 24 | |

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|--|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 547 | 144 | 121 | 20 |
| Units: Subjects | | | | |
| At Baseline: MD (n=547,144,121,20,30) | 157 | 30 | 28 | 4 |
| At Baseline: Mod D (n=547,144,121,20,30) | 76 | 13 | 9 | 3 |
| At Baseline: SD (n=547,144,121,20,30) | 47 | 5 | 3 | 0 |

| | | | | |
|---|----|----|----|---|
| Baseline-MD; Month 6-CR (n=157,30,28,4,9) | 71 | 12 | 19 | 3 |
| Baseline-MD; Month 6-MD (n=157,30,28,4,9) | 48 | 12 | 4 | 1 |
| Baseline-MD; Month 6-Mod D (n=157,30,28,4,9) | 18 | 2 | 1 | 0 |
| Baseline-MD; Month 6-SD (n=157,30,28,4,9) | 7 | 0 | 1 | 0 |
| Baseline-MD; Month 6-Missing (n=157,30,28,4,9) | 13 | 4 | 3 | 0 |
| Baseline-Mod D; Month 6-CR (n=76,13,9,3,4) | 18 | 3 | 2 | 3 |
| Baseline-Mod D; Month 6-MD (n=76,13,9,3,4) | 22 | 8 | 5 | 0 |
| Baseline-Mod D; Month 6-Mod D (n=76,13,9,3,4) | 21 | 0 | 1 | 0 |
| Baseline-Mod D; Month 6-SD (n=76,13,9,3,4) | 8 | 1 | 0 | 0 |
| Baseline-Mod D; Month 6-Missing (n=76,13,9,3,4) | 7 | 1 | 1 | 0 |
| Baseline-SD; Month 6-CR (n=47,5,3,0,1) | 8 | 2 | 0 | 0 |
| Baseline-SD; Month 6-MD (n=47,5,3,0,1) | 19 | 1 | 1 | 0 |
| Baseline-SD; Month 6-Mod D (n=47,5,3,0,1) | 6 | 0 | 1 | 0 |
| Baseline-SD; Month 6-SD (n=47,5,3,0,1) | 7 | 0 | 1 | 0 |
| Baseline-SD; Month 6-Missing (n=47,5,3,0,1) | 7 | 2 | 0 | 0 |
| Baseline-MD; Month 12-CR (n=157,30,28,4,9) | 73 | 16 | 14 | 2 |
| Baseline-MD; Month 12-MD (n=157,30,28,4,9) | 38 | 6 | 7 | 1 |
| Baseline-MD; Month 12-Mod D (n=157,30,28,4,9) | 10 | 3 | 1 | 0 |
| Baseline-MD; Month 12-SD (n=157,30,28,4,9) | 3 | 0 | 1 | 1 |
| Baseline-MD; Month 12-Missing (n=157,30,28,4,9) | 33 | 5 | 5 | 0 |
| Baseline-Mod D; Month 12-CR (n=76,13,9,3,4) | 24 | 2 | 4 | 2 |
| Baseline-Mod D; Month 12-MD (n=76,13,9,3,4) | 17 | 6 | 2 | 0 |
| Baseline-Mod D; Month 12-Mod D (n=76,13,9,3,4) | 6 | 1 | 0 | 0 |
| Baseline-Mod D; Month 12-SD (n=76,13,9,3,4) | 2 | 0 | 0 | 0 |
| Baseline-Mod D; Month 12-Missing (n=76,13,9,3,4) | 27 | 4 | 3 | 1 |
| Baseline-SD; Month 12-CR (n=47,5,3,0,1) | 15 | 2 | 0 | 0 |
| Baseline-SD; Month 12-MD (n=47,5,3,0,1) | 8 | 1 | 1 | 0 |
| Baseline-SD; Month 12-Mod D (n=47,5,3,0,1) | 5 | 0 | 2 | 0 |
| Baseline-SD; Month 12-SD (n=47,5,3,0,1) | 2 | 0 | 0 | 0 |
| Baseline-SD; Month 12-Missing (n=47,5,3,0,1) | 17 | 2 | 0 | 0 |
| Baseline-MD; Month 18-CR (n=157,30,28,4,9) | 57 | 14 | 15 | 3 |

| | | | | |
|---|----|----|----|---|
| Baseline-MD; Month 18-MD (n=157,30,28,4,9) | 22 | 5 | 6 | 0 |
| Baseline-MD; Month 18-Mod D (n=157,30,28,4,9) | 8 | 1 | 1 | 0 |
| Baseline-MD; Month 18-SD (n=157,30,28,4,9) | 2 | 0 | 0 | 0 |
| Baseline-MD; Month 18-Missing (n=157,30,28,4,9) | 68 | 10 | 6 | 1 |
| Baseline-Mod D; Month 18-CR (n=76,13,9,3,4) | 23 | 4 | 2 | 1 |
| Baseline-Mod D; Month 18-MD (n=76,13,9,3,4) | 16 | 2 | 1 | 0 |
| Baseline-Mod D; Month 18-Mod D (n=76,13,9,3,4) | 2 | 1 | 1 | 0 |
| Baseline-Mod D; Month 18-SD (n=76,13,9,3,4) | 0 | 0 | 0 | 0 |
| Baseline-Mod D; Month 18-Missing (n=76,13,9,3,4) | 35 | 6 | 5 | 2 |
| Baseline-SD; Month 18-CR (n=47,5,3,0,1) | 15 | 2 | 1 | 0 |
| Baseline-SD; Month 18-MD (n=47,5,3,0,1) | 5 | 1 | 2 | 0 |
| Baseline-SD; Month 18-Mod D (n=47,5,3,0,1) | 3 | 0 | 0 | 0 |
| Baseline-SD; Month 18-SD (n=47,5,3,0,1) | 0 | 0 | 0 | 0 |
| Baseline-SD; Month 18-Missing (n=47,5,3,0,1) | 24 | 2 | 0 | 0 |
| Baseline-MD; Month 24-CR (n=157,30,28,4,9) | 43 | 13 | 13 | 2 |
| Baseline-MD; Month 24-MD (n=157,30,28,4,9) | 10 | 4 | 3 | 0 |
| Baseline-MD; Month 24-Mod D (n=157,30,28,4,9) | 5 | 1 | 1 | 0 |
| Baseline-MD; Month 24-SD (n=157,30,28,4,9) | 0 | 0 | 0 | 0 |
| Baseline-MD; Month 24-Missing (n=157,30,28,4,9) | 99 | 12 | 11 | 2 |
| Baseline-Mod D; Month 24-CR (n=76,13,9,3,4) | 15 | 2 | 0 | 0 |
| Baseline-Mod D; Month 24-MD (n=76,13,9,3,4) | 11 | 3 | 0 | 0 |
| Baseline-Mod D; Month 24-Mod D (n=76,13,9,3,4) | 1 | 0 | 1 | 0 |
| Baseline-Mod D; Month 24-SD (n=76,13,9,3,4) | 2 | 1 | 1 | 0 |
| Baseline-Mod D; Month 24-Missing (n=76,13,9,3,4) | 47 | 7 | 7 | 3 |
| Baseline-SD; Month 24-CR (n=47,5,3,0,1) | 8 | 2 | 0 | 0 |
| Baseline-SD; Month 24-MD (n=47,5,3,0,1) | 8 | 1 | 1 | 0 |
| Baseline-SD; Month 24-Mod D (n=47,5,3,0,1) | 1 | 0 | 0 | 0 |
| Baseline-SD; Month 24-SD (n=47,5,3,0,1) | 0 | 0 | 0 | 0 |
| Baseline-SD; Month 24-Missing (n=47,5,3,0,1) | 30 | 2 | 2 | 0 |

| End point values | Multiple Switchers | | | |
|---|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 30 | | | |
| Units: Subjects | | | | |
| At Baseline: MD (n=547,144,121,20,30) | 9 | | | |
| At Baseline: Mod D (n=547,144,121,20,30) | 4 | | | |
| At Baseline: SD (n=547,144,121,20,30) | 1 | | | |
| Baseline-MD; Month 6-CR (n=157,30,28,4,9) | 3 | | | |
| Baseline-MD; Month 6-MD (n=157,30,28,4,9) | 6 | | | |
| Baseline-MD; Month 6-Mod D (n=157,30,28,4,9) | 0 | | | |
| Baseline-MD; Month 6-SD (n=157,30,28,4,9) | 0 | | | |
| Baseline-MD; Month 6-Missing (n=157,30,28,4,9) | 0 | | | |
| Baseline-Mod D; Month 6-CR (n=76,13,9,3,4) | 2 | | | |
| Baseline-Mod D; Month 6-MD (n=76,13,9,3,4) | 2 | | | |
| Baseline-Mod D; Month 6-Mod D (n=76,13,9,3,4) | 0 | | | |
| Baseline-Mod D; Month 6-SD (n=76,13,9,3,4) | 0 | | | |
| Baseline-Mod D; Month 6-Missing (n=76,13,9,3,4) | 0 | | | |
| Baseline-SD; Month 6-CR (n=47,5,3,0,1) | 1 | | | |
| Baseline-SD; Month 6-MD (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 6-Mod D (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 6-SD (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 6-Missing (n=47,5,3,0,1) | 0 | | | |
| Baseline-MD; Month 12-CR (n=157,30,28,4,9) | 2 | | | |
| Baseline-MD; Month 12-MD (n=157,30,28,4,9) | 5 | | | |
| Baseline-MD; Month 12-Mod D (n=157,30,28,4,9) | 1 | | | |
| Baseline-MD; Month 12-SD (n=157,30,28,4,9) | 0 | | | |
| Baseline-MD; Month 12-Missing (n=157,30,28,4,9) | 1 | | | |
| Baseline-Mod D; Month 12-CR (n=76,13,9,3,4) | 1 | | | |
| Baseline-Mod D; Month 12-MD (n=76,13,9,3,4) | 2 | | | |
| Baseline-Mod D; Month 12-Mod D (n=76,13,9,3,4) | 0 | | | |
| Baseline-Mod D; Month 12-SD (n=76,13,9,3,4) | 0 | | | |
| Baseline-Mod D; Month 12-Missing (n=76,13,9,3,4) | 1 | | | |
| Baseline-SD; Month 12-CR (n=47,5,3,0,1) | 1 | | | |

| | | | | |
|---|---|--|--|--|
| Baseline-SD; Month 12-MD (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 12-Mod D (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 12-SD (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 12-Missing (n=47,5,3,0,1) | 0 | | | |
| Baseline-MD; Month 18-CR (n=157,30,28,4,9) | 3 | | | |
| Baseline-MD; Month 18-MD (n=157,30,28,4,9) | 2 | | | |
| Baseline-MD; Month 18-Mod D (n=157,30,28,4,9) | 1 | | | |
| Baseline-MD; Month 18-SD (n=157,30,28,4,9) | 0 | | | |
| Baseline-MD; Month 18-Missing (n=157,30,28,4,9) | 3 | | | |
| Baseline-Mod D; Month 18-CR (n=76,13,9,3,4) | 1 | | | |
| Baseline-Mod D; Month 18-MD (n=76,13,9,3,4) | 2 | | | |
| Baseline-Mod D; Month 18-Mod D (n=76,13,9,3,4) | 0 | | | |
| Baseline-Mod D; Month 18-SD (n=76,13,9,3,4) | 0 | | | |
| Baseline-Mod D; Month 18-Missing (n=76,13,9,3,4) | 1 | | | |
| Baseline-SD; Month 18-CR (n=47,5,3,0,1) | 1 | | | |
| Baseline-SD; Month 18-MD (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 18-Mod D (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 18-SD (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 18-Missing (n=47,5,3,0,1) | 0 | | | |
| Baseline-MD; Month 24-CR (n=157,30,28,4,9) | 5 | | | |
| Baseline-MD; Month 24-MD (n=157,30,28,4,9) | 1 | | | |
| Baseline-MD; Month 24-Mod D (n=157,30,28,4,9) | 0 | | | |
| Baseline-MD; Month 24-SD (n=157,30,28,4,9) | 0 | | | |
| Baseline-MD; Month 24-Missing (n=157,30,28,4,9) | 3 | | | |
| Baseline-Mod D; Month 24-CR (n=76,13,9,3,4) | 2 | | | |
| Baseline-Mod D; Month 24-MD (n=76,13,9,3,4) | 1 | | | |
| Baseline-Mod D; Month 24-Mod D (n=76,13,9,3,4) | 0 | | | |
| Baseline-Mod D; Month 24-SD (n=76,13,9,3,4) | 0 | | | |
| Baseline-Mod D; Month 24-Missing (n=76,13,9,3,4) | 1 | | | |
| Baseline-SD; Month 24-CR (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 24-MD (n=47,5,3,0,1) | 0 | | | |

| | | | | |
|---|---|--|--|--|
| Baseline-SD; Month 24-Mod D (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 24-SD (n=47,5,3,0,1) | 0 | | | |
| Baseline-SD; Month 24-Missing (n=47,5,3,0,1) | 1 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Age at Diagnosis

| | |
|-----------------|---|
| End point title | Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Age at Diagnosis |
|-----------------|---|

End point description:

The Montreal classification index for CD was used to classify the extent of the disease activity. It consisted of three parameters: age at diagnosis, location and behavior of the disease activity. There were four different age groups categorized: 16 years or younger, 17-40 years, over 40 years and missing. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, "Overall number of subjects analysed" =Number of subjects evaluable for this outcome measure and number analysed =subjects evaluable at specified rows for each arm.

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

End point timeframe:

At Baseline

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|-----------------------------|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 777 | 240 | 164 | 37 |
| Units: Subjects | | | | |
| 16 years or younger | 61 | 33 | 21 | 4 |
| 17-40 years | 553 | 174 | 115 | 25 |
| Over 40 years | 162 | 33 | 28 | 8 |
| Missing | 1 | 0 | 0 | 0 |

| End point values | Multiple Switchers | | | |
|-----------------------------|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: Subjects | | | | |
| 16 years or younger | 6 | | | |
| 17-40 years | 39 | | | |
| Over 40 years | 5 | | | |
| Missing | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Location

| | |
|-----------------|---|
| End point title | Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Location |
|-----------------|---|

End point description:

The Montreal classification index for CD was used to classify the extent of the disease activity. It consisted of three parameters: age at diagnosis, location and behavior of the disease activity. There are four different disease locations presented: Location 1 (L1) is terminal ileum (TI), Location 2 (L2) is colon, Location 3 (L3) is ileocolon (IC) and Location 4 (L4) is upper gastrointestinal (UGI). The first three categories (L1-L3) was combined with L4 where disease sites coexisted. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, "Overall number of subjects analysed" =Number of subjects evaluable for this outcome measure and number analysed= subjects evaluable at specified time points for each arm.

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

End point timeframe:

Baseline, Months 6, 12, 18 and 24

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|---|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 969 | 348 | 237 | 47 |
| Units: Subjects | | | | |
| Baseline: Location L1 TI (n=777,240,164,37,50) | 257 | 62 | 34 | 6 |
| Month 6: Location L1 TI (n=589,202,127,33,44) | 202 | 49 | 26 | 7 |
| Month 12: Location L1 TI (n=468,160,104,33,40) | 150 | 38 | 22 | 7 |
| Month 18: Location L1 TI (n=330,124,85,22,36) | 99 | 28 | 16 | 2 |
| Month 24: Location L1 TI (n=190,75,57,18,27) | 60 | 17 | 15 | 0 |
| Baseline: Location L2 Colon (n=777,240,164,37,50) | 135 | 54 | 32 | 14 |
| Month 6: Location L2 Colon (n=589,202,127,33,44) | 105 | 47 | 25 | 12 |
| Month 12: Location L2 Colon (n=468,160,104,33,40) | 84 | 40 | 20 | 14 |
| Month 18: Location L2 Colon (n=330,124,85,22,36) | 53 | 31 | 18 | 10 |
| Month 24: Location L2 Colon (n=190,75,57,18,27) | 41 | 16 | 14 | 9 |
| Baseline: Location L3 IC (n=777,240,164,37,50) | 329 | 107 | 80 | 16 |

| | | | | |
|---|-----|----|----|----|
| Month 6: Location L3 IC (n=589,202,127,33,44) | 236 | 94 | 65 | 13 |
| Month 12: Location L3 IC (n=468,160,104,33,40) | 200 | 71 | 55 | 11 |
| Month 18: Location L3 IC (n=330,124,85,22,36) | 150 | 55 | 40 | 8 |
| Month 24: Location L3 IC (n=190,75,57,18,27) | 74 | 33 | 22 | 9 |
| Baseline: L4 UGI (n=777,240,164,37,50) | 14 | 4 | 4 | 1 |
| Month 6: L4 UGI (n=589,202,127,33,44) | 12 | 2 | 3 | 1 |
| Month 12: L4 UGI (n=468,160,104,33,40) | 10 | 3 | 2 | 1 |
| Month 18: L4 UGI (n=330,124,85,22,36) | 8 | 5 | 4 | 1 |
| Month 24: L4 UGI (n=190,75,57,18,27) | 7 | 6 | 3 | 0 |
| Baseline: L1 TI,L4 UGI (n=777,240,164,37,50) | 21 | 2 | 1 | 0 |
| Month 6: L1 TI, L4 UGI (n=589,202,127,33,44) | 15 | 2 | 1 | 0 |
| Month 12: L1 TI,L4 UGI (n=468,160,104,33,40) | 11 | 2 | 1 | 0 |
| Month 18: L1 TI,L4 UGI (n=330,124,85,22,36) | 13 | 0 | 0 | 0 |
| Month 24: L1 TI,L4 UGI (n=190,75,57,18,27) | 2 | 0 | 0 | 0 |
| Baseline: L2 Colon,L4 UGI (n=777,240,164,37,50) | 6 | 2 | 1 | 0 |
| Month 6: L2 Colon,L4 UGI (n=589,202,127,33,44) | 3 | 3 | 0 | 0 |
| Month 12: L2 Colon,L4 UGI (n=468,160,104,33,40) | 2 | 1 | 0 | 0 |
| Month 18: L2 Colon,L4 UGI (n=330,124,85,22,36) | 2 | 1 | 0 | 0 |
| Month 24: L2 Colon,L4 UGI (n=190,75,57,18,27) | 0 | 1 | 0 | 0 |
| Baseline: L3 IC, L4 UGI (n=777,240,164,37,50) | 14 | 8 | 12 | 0 |
| Month 6: L3 IC,L4 UGI (n=589,202,127,33,44) | 11 | 5 | 7 | 0 |
| Month 12: L3 IC, L4 UGI (n=468,160,104,33,40) | 8 | 5 | 4 | 0 |
| Month 18: L3 IC,L4 UGI (n=330,124,85,22,36) | 5 | 4 | 7 | 1 |
| Month 24: L3 IC,L4 UGI (n=190,75,57,18,27) | 5 | 2 | 3 | 0 |
| Baseline: Location Missing (n=777,240,164,37,50) | 1 | 1 | 0 | 0 |
| Month 6: Location Missing (n=589,202,127,33,44) | 5 | 0 | 0 | 0 |
| Month 12: Location Missing (n=468,160,104,33,40) | 3 | 0 | 0 | 0 |
| Month 18: Location Missing (n=330,124,85,22,36) | 0 | 0 | 0 | 0 |
| Month 24: Location Missing (n=190,75,57,18,27) | 1 | 0 | 0 | 0 |

| End point values | Multiple Switchers | | | |
|--|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 72 | | | |
| Units: Subjects | | | | |
| Baseline: Location L1 TI (n=777,240,164,37,50) | 11 | | | |
| Month 6: Location L1 TI (n=589,202,127,33,44) | 9 | | | |
| Month 12: Location L1 TI (n=468,160,104,33,40) | 7 | | | |
| Month 18: Location L1 TI (n=330,124,85,22,36) | 8 | | | |
| Month 24: Location L1 TI (n=190,75,57,18,27) | 5 | | | |
| Baseline: Location L2 Colon (n=777,240,164,37,50) | 8 | | | |
| Month 6: Location L2 Colon (n=589,202,127,33,44) | 11 | | | |
| Month 12: Location L2 Colon (n=468,160,104,33,40) | 10 | | | |
| Month 18: Location L2 Colon (n=330,124,85,22,36) | 9 | | | |
| Month 24: Location L2 Colon (n=190,75,57,18,27) | 5 | | | |
| Baseline: Location L3 IC (n=777,240,164,37,50) | 28 | | | |
| Month 6: Location L3 IC (n=589,202,127,33,44) | 22 | | | |
| Month 12: Location L3 IC (n=468,160,104,33,40) | 21 | | | |
| Month 18: Location L3 IC (n=330,124,85,22,36) | 17 | | | |
| Month 24: Location L3 IC (n=190,75,57,18,27) | 14 | | | |
| Baseline: L4 UGI (n=777,240,164,37,50) | 0 | | | |
| Month 6: L4 UGI (n=589,202,127,33,44) | 0 | | | |
| Month 12: L4 UGI (n=468,160,104,33,40) | 1 | | | |
| Month 18: L4 UGI (n=330,124,85,22,36) | 1 | | | |
| Month 24: L4 UGI (n=190,75,57,18,27) | 1 | | | |
| Baseline: L1 TI,L4 UGI (n=777,240,164,37,50) | 1 | | | |
| Month 6: L1 TI, L4 UGI (n=589,202,127,33,44) | 0 | | | |
| Month 12: L1 TI,L4 UGI (n=468,160,104,33,40) | 0 | | | |
| Month 18: L1 TI,L4 UGI (n=330,124,85,22,36) | 0 | | | |
| Month 24: L1 TI,L4 UGI (n=190,75,57,18,27) | 0 | | | |
| Baseline: L2 Colon,L4 UGI (n=777,240,164,37,50) | 1 | | | |
| Month 6: L2 Colon,L4 UGI (n=589,202,127,33,44) | 0 | | | |
| Month 12: L2 Colon,L4 UGI (n=468,160,104,33,40) | 0 | | | |

| | | | | |
|---|---|--|--|--|
| Month 18: L2 Colon,L4 UGI (n=330,124,85,22,36) | 0 | | | |
| Month 24: L2 Colon,L4 UGI (n=190,75,57,18,27) | 0 | | | |
| Baseline: L3 IC, L4 UGI (n=777,240,164,37,50) | 1 | | | |
| Month 6: L3 IC,L4 UGI (n=589,202,127,33,44) | 2 | | | |
| Month 12: L3 IC, L4 UGI (n=468,160,104,33,40) | 1 | | | |
| Month 18: L3 IC,L4 UGI (n=330,124,85,22,36) | 1 | | | |
| Month 24: L3 IC,L4 UGI (n=190,75,57,18,27) | 2 | | | |
| Baseline: Location Missing (n=777,240,164,37,50) | 0 | | | |
| Month 6: Location Missing (n=589,202,127,33,44) | 0 | | | |
| Month 12: Location Missing (n=468,160,104,33,40) | 0 | | | |
| Month 18: Location Missing (n=330,124,85,22,36) | 0 | | | |
| Month 24: Location Missing (n=190,75,57,18,27) | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Behavior of the Disease Activity

| | |
|-----------------|---|
| End point title | Crohn's Disease: Number of Subjects Categorised on the Basis of Montreal Classification Index by Behavior of the Disease Activity |
|-----------------|---|

End point description:

The Montreal classification index for CD was used to classify the extent of the disease activity. It consists of two parameters: location and behavior of the disease activity. There were 4 different categories for the behavior of the disease activity: Behaviour 1 (B1) was nonstricturing (NS), nonpenetrating (NP); Behaviour 2 (B2) was structuring (s); Behaviour 3 (B3) was penetrating (P) and p as perianal disease (p). The first 3 categories (B1 to B3) could be added with p to indicate coexisting perianal disease. Perianal disease (p) was defined as the presence of perianal abscesses or fistulae. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, Overall number of subjects analysed =Number of subjects evaluable for this end point. Number analysed= subjects evaluable at specified time points for each arm.

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

End point timeframe:

Baseline, Months 6, 12, 18 and 24

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|--|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 969 | 348 | 237 | 47 |
| Units: Subjects | | | | |
| At Baseline: B1 NS, NP (n=777,240,164,37,50) | 324 | 92 | 66 | 9 |
| Month 6: B1 NS, NP (n=589,202,127,33,44) | 242 | 68 | 46 | 10 |
| Month 12: B1 NS, NP (n=468,160,104,33,40) | 191 | 56 | 40 | 10 |
| Month 18: B1 NS, NP (n=330,124,85,22,36) | 135 | 44 | 26 | 4 |
| Month 24: B1 NS, NP (n=190,75,57,18,27) | 77 | 35 | 20 | 3 |
| At Baseline: B2 Stricturing (n=777,240,164,37,50) | 165 | 40 | 43 | 9 |
| Month 6: B2 Stricturing (n=589,202,127,33,44) | 122 | 29 | 36 | 8 |
| Month 12: B2 Stricturing (n=468,160,104,33,40) | 94 | 26 | 28 | 6 |
| Month 18: B2 Stricturing (n=330,124,85,22,36) | 77 | 24 | 26 | 4 |
| Month 24: B2 Stricturing (n=190,75,57,18,27) | 47 | 8 | 15 | 3 |
| At Baseline: B3 Penetrating (n=777,240,164,37,50) | 84 | 32 | 16 | 6 |
| Month 6: B3 Penetrating (n=589,202,127,33,44) | 64 | 32 | 14 | 5 |
| Month 12: B3 Penetrating (n=468,160,104,33,40) | 48 | 26 | 12 | 5 |
| Month 18: B3 Penetrating (n=330,124,85,22,36) | 26 | 16 | 9 | 4 |
| Month 24: B3 Penetrating (n=190,75,57,18,27) | 18 | 8 | 4 | 4 |
| Baseline: Behavior p (n=777,240,164,37,50) | 34 | 5 | 7 | 2 |
| Month 6: Behavior p (n=589,202,127,33,44) | 27 | 5 | 4 | 1 |
| Month 12: Behavior p (n=468,160,104,33,40) | 17 | 7 | 1 | 1 |
| Month 18: Behavior p (n=330,124,85,22,36) | 10 | 4 | 1 | 1 |
| Month 24: Behavior p (n=190,75,57,18,27) | 4 | 3 | 1 | 1 |
| Baseline: B2 s, B3 Penetrating(n=777,240,164,37,50) | 1 | 0 | 0 | 0 |
| Month 6: B2 s, B3 Penetrating(n=589,202,127,33,44) | 0 | 0 | 0 | 0 |
| Month 12: B2 s, B3 Penetrating(n=468,160,104,33,40) | 0 | 0 | 0 | 0 |
| Month 18: B2 s, B3 Penetrating(n=330,124,85,22,36) | 1 | 0 | 0 | 0 |
| Month 24: B2 s, B3 Penetrating(n=190,75,57,18,27) | 0 | 0 | 0 | 0 |
| Baseline: B1 NS,NP, p (n=777,240,164,37,50) | 77 | 33 | 16 | 5 |
| Month 6: B1 NS,NP, p (n=589,202,127,33,44) | 64 | 34 | 11 | 5 |
| Month 12: B1 NS,NP, p (n=468,160,104,33,40) | 60 | 20 | 9 | 6 |

| | | | | |
|---|----|----|----|---|
| Month 18: B1 NS,NP, p (n=330,124,85,22,36) | 40 | 15 | 11 | 5 |
| Month 24: B1 NS,NP, p (n=190,75,57,18,27) | 23 | 8 | 6 | 5 |
| At Baseline: B2 s, p (n=777,240,164,37,50) | 32 | 8 | 4 | 1 |
| Month 6: B2 s, p (n=589,202,127,33,44) | 22 | 5 | 3 | 1 |
| Month 12: B2 s, p (n=468,160,104,33,40) | 22 | 5 | 3 | 2 |
| Month 18: B2 s, p (n=330,124,85,22,36) | 14 | 1 | 1 | 0 |
| Month 24: B2 s, p (n=190,75,57,18,27) | 5 | 1 | 1 | 0 |
| Baseline: B2 s, B3 P, p (n=777,240,164,37,50) | 0 | 0 | 0 | 0 |
| Month 6: B2 s, B3 P, p (n=589,202,127,33,44) | 1 | 0 | 0 | 0 |
| Month 12: B2 s, B3 P, p (n=468,160,104,33,40) | 0 | 0 | 0 | 0 |
| Month 18: B2 s, B3 P, p (n=330,124,85,22,36) | 0 | 0 | 0 | 0 |
| Month 24: B2 s, B3 P, p (n=190,75,57,18,27) | 0 | 0 | 0 | 0 |
| At Baseline: B3 P, p (n=777,240,164,37,50) | 57 | 30 | 12 | 5 |
| Month 6: B3 P, p (n=589,202,127,33,44) | 42 | 29 | 13 | 3 |
| Month 12: Behavior B3 P, p (n=468,160,104,33,40) | 33 | 20 | 11 | 3 |
| Month 18: B3 P, p (n=330,124,85,22,36) | 27 | 20 | 11 | 4 |
| Month 24: B3 P, p (n=190,75,57,18,27) | 15 | 12 | 10 | 2 |
| Baseline: Behavior Missing (n=777,240,164,37,50) | 3 | 0 | 0 | 0 |
| Month 6: Behavior Missing (n=589,202,127,33,44) | 5 | 0 | 0 | 0 |
| Month 12: Behavior Missing (n=468,160,104,33,40) | 3 | 0 | 0 | 0 |
| Month 18: Behavior Missing (n=330,124,85,22,36) | 0 | 0 | 0 | 0 |
| Month 24: Behavior Missing (n=190,75,57,18,27) | 1 | 0 | 0 | 0 |

| End point values | Multiple Switchers | | | |
|---|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 72 | | | |
| Units: Subjects | | | | |
| At Baseline: B1 NS, NP (n=777,240,164,37,50) | 17 | | | |
| Month 6: B1 NS, NP (n=589,202,127,33,44) | 14 | | | |
| Month 12: B1 NS, NP (n=468,160,104,33,40) | 17 | | | |
| Month 18: B1 NS, NP (n=330,124,85,22,36) | 13 | | | |
| Month 24: B1 NS, NP (n=190,75,57,18,27) | 7 | | | |

| | | | | |
|--|----|--|--|--|
| At Baseline: B2 Structuring (n=777,240,164,37,50) | 13 | | | |
| Month 6: B2 Structuring (n=589,202,127,33,44) | 12 | | | |
| Month 12: B2 Structuring (n=468,160,104,33,40) | 9 | | | |
| Month 18: B2 Structuring (n=330,124,85,22,36) | 10 | | | |
| Month 24: B2 Structuring (n=190,75,57,18,27) | 9 | | | |
| At Baseline: B3 Penetrating (n=777,240,164,37,50) | 6 | | | |
| Month 6: B3 Penetrating (n=589,202,127,33,44) | 5 | | | |
| Month 12: B3 Penetrating (n=468,160,104,33,40) | 2 | | | |
| Month 18: B3 Penetrating (n=330,124,85,22,36) | 2 | | | |
| Month 24: B3 Penetrating (n=190,75,57,18,27) | 2 | | | |
| Baseline: Behavior p (n=777,240,164,37,50) | 3 | | | |
| Month 6: Behavior p (n=589,202,127,33,44) | 1 | | | |
| Month 12: Behavior p (n=468,160,104,33,40) | 1 | | | |
| Month 18: Behavior p (n=330,124,85,22,36) | 0 | | | |
| Month 24: Behavior p (n=190,75,57,18,27) | 0 | | | |
| Baseline: B2 s, B3 Penetrating(n=777,240,164,37,50) | 0 | | | |
| Month 6: B2 s, B3 Penetrating(n=589,202,127,33,44) | 0 | | | |
| Month 12: B2 s, B3 Penetrating(n=468,160,104,33,40) | 0 | | | |
| Month 18: B2 s, B3 Penetrating(n=330,124,85,22,36) | 0 | | | |
| Month 24: B2 s, B3 Penetrating(n=190,75,57,18,27) | 0 | | | |
| Baseline: B1 NS,NP, p (n=777,240,164,37,50) | 5 | | | |
| Month 6: B1 NS,NP, p (n=589,202,127,33,44) | 6 | | | |
| Month 12: B1 NS,NP, p (n=468,160,104,33,40) | 6 | | | |
| Month 18: B1 NS,NP, p (n=330,124,85,22,36) | 6 | | | |
| Month 24: B1 NS,NP, p (n=190,75,57,18,27) | 5 | | | |
| At Baseline: B2 s, p (n=777,240,164,37,50) | 1 | | | |
| Month 6: B2 s, p (n=589,202,127,33,44) | 0 | | | |
| Month 12: B2 s, p (n=468,160,104,33,40) | 0 | | | |
| Month 18: B2 s, p (n=330,124,85,22,36) | 0 | | | |
| Month 24: B2 s, p (n=190,75,57,18,27) | 0 | | | |
| Baseline: B2 s, B3 P, p (n=777,240,164,37,50) | 0 | | | |

| | | | | |
|---|---|--|--|--|
| Month 6: B2 s, B3 P, p (n=589,202,127,33,44) | 0 | | | |
| Month 12: B2 s, B3 P, p (n=468,160,104,33,40) | 0 | | | |
| Month 18: B2 s, B3 P, p (n=330,124,85,22,36) | 0 | | | |
| Month 24: B2 s, B3 P, p (n=190,75,57,18,27) | 0 | | | |
| At Baseline: B3 P, p (n=777,240,164,37,50) | 5 | | | |
| Month 6: B3 P, p (n=589,202,127,33,44) | 6 | | | |
| Month 12: Behavior B3 P, p (n=468,160,104,33,40) | 5 | | | |
| Month 18: B3 P, p (n=330,124,85,22,36) | 5 | | | |
| Month 24: B3 P, p (n=190,75,57,18,27) | 4 | | | |
| Baseline: Behavior Missing (n=777,240,164,37,50) | 0 | | | |
| Month 6: Behavior Missing (n=589,202,127,33,44) | 0 | | | |
| Month 12: Behavior Missing (n=468,160,104,33,40) | 0 | | | |
| Month 18: Behavior Missing (n=330,124,85,22,36) | 0 | | | |
| Month 24: Behavior Missing (n=190,75,57,18,27) | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ulcerative Colitis: Number of Subjects Categorised on the Basis of Montreal Classification Index by Extent

| | |
|-----------------|--|
| End point title | Ulcerative Colitis: Number of Subjects Categorised on the Basis of Montreal Classification Index by Extent |
|-----------------|--|

End point description:

The Montreal classification index for Ulcerative Colitis (UC) was used to classify the extent and severity of the disease activity. There were three subgroups of UC defined by extent: Extent 1 (E1) =Ulcerative Proctitis (UP), Extent 2 (E2) =Left-sided UC and Extent 3 (E3) =Extensive UC. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, Overall number of subjects analysed =Number of subjects evaluable for this outcome measure. Number analysed= subjects evaluable at specified time points for each arm.

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

End point timeframe:

Baseline, Months 6, 12, 18 and 24

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|---|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 547 | 144 | 121 | 20 |
| Units: Subjects | | | | |
| Baseline E1 UP (n=380,86,66,16,22) | 41 | 10 | 5 | 0 |
| Month 6 E1 UP (n=302,72,50,15,20) | 31 | 9 | 1 | 0 |
| Month 12 E1 UP (n=224,66,38,14,18) | 17 | 7 | 4 | 0 |
| Month 18 E1 UP (n=168,53,32,8,17) | 15 | 7 | 2 | 0 |
| Month 24 E1 UP (n=101,30,25,5,11) | 14 | 5 | 2 | 0 |
| Baseline E2 Left-sided UC (n=380,86,66,16,22) | 151 | 26 | 30 | 3 |
| Month 6 E2 Left-sided UC (n=302,72,50,15,20) | 109 | 23 | 24 | 3 |
| Month 12 E2 Left-sided UC (n=224,66,38,14,18) | 76 | 21 | 13 | 3 |
| Month 18 E2 Left-sided UC (n=168,53,32,8,17) | 55 | 16 | 12 | 1 |
| Month 24 E2 Left-sided UC (n=101,30,25,5,11) | 26 | 10 | 8 | 1 |
| Baseline E3 Extensive UC (n=380,86,66,16,22) | 188 | 50 | 31 | 13 |
| Month 6 E3 Extensive UC (n=302,72,50,15,20) | 159 | 40 | 25 | 12 |
| Month 12 E3 Extensive UC (n=224,66,38,14,18) | 128 | 37 | 21 | 11 |
| Month 18 E3 Extensive UC (n=168,53,32,8,17) | 96 | 29 | 18 | 7 |
| Month 24 E3 Extensive UC (n=101,30,25,5,11) | 59 | 15 | 15 | 4 |
| Baseline Missing (n=380,86,66,16,22) | 0 | 0 | 0 | 0 |
| Month 6 Missing (n=302,72,50,15,20) | 3 | 0 | 0 | 0 |
| Month 12 Missing (n=224,66,38,14,18) | 3 | 1 | 0 | 0 |
| Month 18 Missing (n=168,53,32,8,17) | 2 | 1 | 0 | 0 |
| Month 24 Missing (n=101,30,25,5,11) | 2 | 0 | 0 | 0 |

| End point values | Multiple Switchers | | | |
|---|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 30 | | | |
| Units: Subjects | | | | |
| Baseline E1 UP (n=380,86,66,16,22) | 2 | | | |
| Month 6 E1 UP (n=302,72,50,15,20) | 1 | | | |
| Month 12 E1 UP (n=224,66,38,14,18) | 1 | | | |
| Month 18 E1 UP (n=168,53,32,8,17) | 2 | | | |
| Month 24 E1 UP (n=101,30,25,5,11) | 0 | | | |
| Baseline E2 Left-sided UC (n=380,86,66,16,22) | 8 | | | |
| Month 6 E2 Left-sided UC (n=302,72,50,15,20) | 6 | | | |
| Month 12 E2 Left-sided UC (n=224,66,38,14,18) | 7 | | | |
| Month 18 E2 Left-sided UC (n=168,53,32,8,17) | 5 | | | |

| | | | | |
|---|----|--|--|--|
| Month 24 E2 Left-sided UC (n=101,30,25,5,11) | 2 | | | |
| Baseline E3 Extensive UC (n=380,86,66,16,22) | 12 | | | |
| Month 6 E3 Extensive UC (n=302,72,50,15,20) | 13 | | | |
| Month 12 E3 Extensive UC (n=224,66,38,14,18) | 10 | | | |
| Month 18 E3 Extensive UC (n=168,53,32,8,17) | 10 | | | |
| Month 24 E3 Extensive UC (n=101,30,25,5,11) | 9 | | | |
| Baseline Missing (n=380,86,66,16,22) | 0 | | | |
| Month 6 Missing (n=302,72,50,15,20) | 0 | | | |
| Month 12 Missing (n=224,66,38,14,18) | 0 | | | |
| Month 18 Missing (n=168,53,32,8,17) | 0 | | | |
| Month 24 Missing (n=101,30,25,5,11) | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Ulcerative Colitis: Number of Subjects Categorised on the Basis of Montreal Classification Index by Severity

| | |
|-----------------|--|
| End point title | Ulcerative Colitis: Number of Subjects Categorised on the Basis of Montreal Classification Index by Severity |
|-----------------|--|

End point description:

The Montreal classification index for UC was used to classify the extent and severity of the disease activity. UC can be classified broadly into four disease activity/severity categories: Severity 0 (S0) = asymptomatic clinical remission; Severity 1 (S1) = Mild UC (passage of four or fewer stools/day [with or without blood], absence of any systemic illness, and normal inflammatory markers); Severity 2 (S2) = Moderate UC (passage of more than four stools per day but with minimal signs of systemic toxicity) and Severity 3 (S3) = Severe UC (passage of at least six bloody stools daily). FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, Overall number of subjects analysed =Number of subjects evaluable for this outcome measure. Number analysed =subjects evaluable at specified time points for each arm.

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

End point timeframe:

Baseline, Months 6, 12, 18 and 24

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|---------------------------------|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 547 | 144 | 121 | 20 |
| Units: Subjects | | | | |
| Baseline S0 (n=380,86,66,16,22) | 80 | 46 | 24 | 6 |
| Month 6 S0 (n=302,72,50,15,20) | 122 | 40 | 26 | 9 |
| Month 12 S0 (n=224,66,38,14,18) | 110 | 39 | 25 | 10 |
| Month 18 S0 (168,53,32,8,17) | 81 | 35 | 23 | 6 |
| Month 24 S0 (n=101,30,25,5,11) | 71 | 20 | 17 | 3 |
| Baseline S1 (n=380,86,66,16,22) | 75 | 17 | 18 | 6 |

| | | | | |
|--------------------------------------|-----|----|----|---|
| Month 6 S1 (n=302,72,50,15,20) | 70 | 19 | 15 | 3 |
| Month 12 S1 (n=224,66,38,14,18) | 58 | 16 | 5 | 1 |
| Month 18 S1 (168,53,32,8,17) | 41 | 11 | 5 | 0 |
| Month 24 S1 (n=101,30,25,5,11) | 12 | 6 | 5 | 1 |
| Baseline S2 (n=380,86,66,16,22) | 147 | 14 | 19 | 3 |
| Month 6 S2 (n=302,72,50,15,20) | 74 | 7 | 6 | 3 |
| Month 12 S2 (n=224,66,38,14,18) | 40 | 6 | 5 | 2 |
| Month 18 S2 (168,53,32,8,17) | 29 | 5 | 2 | 2 |
| Month 24 S2 (n=101,30,25,5,11) | 12 | 3 | 1 | 1 |
| Baseline S3 (n=380,86,66,16,22) | 75 | 9 | 5 | 1 |
| Month 6 S3 (n=302,72,50,15,20) | 32 | 5 | 3 | 0 |
| Month 12 S3 (n=224,66,38,14,18) | 11 | 3 | 3 | 1 |
| Month 18 S3 (168,53,32,8,17) | 15 | 1 | 2 | 0 |
| Month 24 S3 (n=101,30,25,5,11) | 6 | 1 | 2 | 0 |
| Baseline Missing (n=380,86,66,16,22) | 3 | 0 | 0 | 0 |
| Month 6 Missing (n=302,72,50,15,20) | 4 | 1 | 0 | 0 |
| Month 12 Missing (n=224,66,38,14,18) | 5 | 2 | 0 | 0 |
| Month 18 Missing (168,53,32,8,17) | 2 | 1 | 0 | 0 |
| Month 24 Missing (n=101,30,25,5,11) | 0 | 0 | 0 | 0 |

| End point values | Multiple Switchers | | | |
|--------------------------------------|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 30 | | | |
| Units: Subjects | | | | |
| Baseline S0 (n=380,86,66,16,22) | 6 | | | |
| Month 6 S0 (n=302,72,50,15,20) | 7 | | | |
| Month 12 S0 (n=224,66,38,14,18) | 6 | | | |
| Month 18 S0 (168,53,32,8,17) | 8 | | | |
| Month 24 S0 (n=101,30,25,5,11) | 7 | | | |
| Baseline S1 (n=380,86,66,16,22) | 4 | | | |
| Month 6 S1 (n=302,72,50,15,20) | 9 | | | |
| Month 12 S1 (n=224,66,38,14,18) | 8 | | | |
| Month 18 S1 (168,53,32,8,17) | 4 | | | |
| Month 24 S1 (n=101,30,25,5,11) | 2 | | | |
| Baseline S2 (n=380,86,66,16,22) | 9 | | | |
| Month 6 S2 (n=302,72,50,15,20) | 3 | | | |
| Month 12 S2 (n=224,66,38,14,18) | 4 | | | |
| Month 18 S2 (168,53,32,8,17) | 4 | | | |
| Month 24 S2 (n=101,30,25,5,11) | 2 | | | |
| Baseline S3 (n=380,86,66,16,22) | 3 | | | |
| Month 6 S3 (n=302,72,50,15,20) | 1 | | | |
| Month 12 S3 (n=224,66,38,14,18) | 0 | | | |
| Month 18 S3 (168,53,32,8,17) | 1 | | | |
| Month 24 S3 (n=101,30,25,5,11) | 0 | | | |
| Baseline Missing (n=380,86,66,16,22) | 0 | | | |
| Month 6 Missing (n=302,72,50,15,20) | 0 | | | |
| Month 12 Missing (n=224,66,38,14,18) | 0 | | | |
| Month 18 Missing (168,53,32,8,17) | 0 | | | |

| | | | | |
|-------------------------------------|---|--|--|--|
| Month 24 Missing (n=101,30,25,5,11) | 0 | | | |
|-------------------------------------|---|--|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Crohn's Disease: Number of Subjects Categorised on the Basis of Fistula Drainage Assessment Index

| | |
|-----------------|---|
| End point title | Crohn's Disease: Number of Subjects Categorised on the Basis of Fistula Drainage Assessment Index |
|-----------------|---|

End point description:

The fistula drainage assessment index was used to assess the improvement or remission of the disease activity of Crohn's Disease, based on 6 categories: remission (remission was defined as closure of all fistulae that were draining at baseline for at least two consecutive visits); improvement (improvement defined as a decrease from baseline in the number of open draining fistulae of 50% for at least two consecutive visits); worsened; unchanged; not accessible and missing disease activity. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes. Here, Overall number of subjects analysed =Number of subjects evaluable for this end point. Number analysed= subjects evaluable at specified time points for each arm.

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

End point timeframe:

Baseline, Months 6, 12, 18 and 24

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|---|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 969 | 348 | 237 | 47 |
| Units: Subjects | | | | |
| Baseline: Remission (n=191,58,22,16,12) | 64 | 30 | 14 | 3 |
| Month 6: Remission (n=169,58,26,16,14) | 65 | 29 | 17 | 6 |
| Month 12: Remission (n=121,39,17,14,11) | 50 | 23 | 11 | 9 |
| Month 18: Remission (n=79,26,14,12,10) | 36 | 16 | 9 | 6 |
| Month 24: Remission (n=38,21,12,11,10) | 16 | 12 | 4 | 7 |
| Baseline: Improvement (n=191,58,22,16,12) | 90 | 26 | 5 | 11 |
| Month 6: Improvement (n=169,58,26,16,14) | 62 | 23 | 3 | 9 |
| Month 12: Improvement (n=121,39,17,14,11) | 39 | 8 | 3 | 1 |
| Month 18: Improvement (n=79,26,14,12,10) | 23 | 4 | 1 | 2 |
| Month 24: Improvement (n=38,21,12,11,10) | 8 | 6 | 3 | 3 |
| Baseline: Worsened (n=191,58,22,16,12) | 9 | 0 | 0 | 0 |

| | | | | |
|---|----|---|---|---|
| Month 6: Worsened (n=169,58,26,16,14) | 12 | 1 | 3 | 1 |
| Month 12: Worsened (n=121,39,17,14,11) | 9 | 0 | 0 | 1 |
| Month 18: Worsened (n=79,26,14,12,10) | 5 | 1 | 0 | 2 |
| Month 24: Worsened (n=38,21,12,11,10) | 3 | 0 | 2 | 0 |
| Baseline: Unchanged (n=191,58,22,16,12) | 19 | 2 | 3 | 2 |
| Month 6: Unchanged (n=169,58,26,16,14) | 21 | 5 | 3 | 0 |
| Month 12: Unchanged (n=121,39,17,14,11) | 20 | 8 | 3 | 3 |
| Month 18: Unchanged (n=79,26,14,12,10) | 15 | 5 | 3 | 2 |
| Month 24: Unchanged (n=38,21,12,11,10) | 8 | 3 | 3 | 1 |
| Baseline: Not accessible (n=191,58,22,16,12) | 4 | 0 | 0 | 0 |
| Month 6: Not accessible (n=169,58,26,16,14) | 4 | 0 | 0 | 0 |
| Month 12: Not accessible (n=121,39,17,14,11) | 1 | 0 | 0 | 0 |
| Month 18: Not accessible (n=79,26,14,12,10) | 0 | 0 | 1 | 0 |
| Month 24: Not accessible (n=38,21,12,11,10) | 1 | 0 | 0 | 0 |
| Baseline: Missing (n=191,58,22,16,12) | 5 | 0 | 0 | 0 |
| Month 6: Missing (n=169,58,26,16,14) | 5 | 0 | 0 | 0 |
| Month 12: Missing (n=121,39,17,14,11) | 2 | 0 | 0 | 0 |
| Month 18: Missing (n=79,26,14,12,10) | 0 | 0 | 0 | 0 |
| Month 24: Missing (n=38,21,12,11,10) | 2 | 0 | 0 | 0 |

| End point values | Multiple Switchers | | | |
|--|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 72 | | | |
| Units: Subjects | | | | |
| Baseline: Remission (n=191,58,22,16,12) | 6 | | | |
| Month 6: Remission (n=169,58,26,16,14) | 8 | | | |
| Month 12: Remission (n=121,39,17,14,11) | 9 | | | |
| Month 18: Remission (n=79,26,14,12,10) | 8 | | | |
| Month 24: Remission (n=38,21,12,11,10) | 7 | | | |
| Baseline: Improvement (n=191,58,22,16,12) | 4 | | | |
| Month 6: Improvement (n=169,58,26,16,14) | 4 | | | |
| Month 12: Improvement (n=121,39,17,14,11) | 0 | | | |
| Month 18: Improvement (n=79,26,14,12,10) | 0 | | | |

| | | | | |
|---|---|--|--|--|
| Month 24: Improvement (n=38,21,12,11,10) | 1 | | | |
| Baseline: Worsened (n=191,58,22,16,12) | 0 | | | |
| Month 6: Worsened (n=169,58,26,16,14) | 0 | | | |
| Month 12: Worsened (n=121,39,17,14,11) | 0 | | | |
| Month 18: Worsened (n=79,26,14,12,10) | 0 | | | |
| Month 24: Worsened (n=38,21,12,11,10) | 0 | | | |
| Baseline: Unchanged (n=191,58,22,16,12) | 1 | | | |
| Month 6: Unchanged (n=169,58,26,16,14) | 2 | | | |
| Month 12: Unchanged (n=121,39,17,14,11) | 2 | | | |
| Month 18: Unchanged (n=79,26,14,12,10) | 2 | | | |
| Month 24: Unchanged (n=38,21,12,11,10) | 2 | | | |
| Baseline: Not accessible (n=191,58,22,16,12) | 1 | | | |
| Month 6: Not accessible (n=169,58,26,16,14) | 0 | | | |
| Month 12: Not accessible (n=121,39,17,14,11) | 0 | | | |
| Month 18: Not accessible (n=79,26,14,12,10) | 0 | | | |
| Month 24: Not accessible (n=38,21,12,11,10) | 0 | | | |
| Baseline: Missing (n=191,58,22,16,12) | 0 | | | |
| Month 6: Missing (n=169,58,26,16,14) | 0 | | | |
| Month 12: Missing (n=121,39,17,14,11) | 0 | | | |
| Month 18: Missing (n=79,26,14,12,10) | 0 | | | |
| Month 24: Missing (n=38,21,12,11,10) | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Laboratory Test Results: C-Reactive Protein at Months 6, 12, 18, and 24

| | |
|-----------------|--|
| End point title | Mean Change From Baseline in Laboratory Test Results: C-Reactive Protein at Months 6, 12, 18, and 24 |
|-----------------|--|

End point description:

C-reactive protein (CRP) was a laboratory measurement for evaluation of an acute phase reactant of inflammation through the use of an ultra-sensitive assay. A decrease in the level of CRP indicated reduction in inflammation and therefore improvement. FAS=all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes (clinical assessment of disease activity, laboratory and imaging results related to treatment or assessment of CD or UC). Here, Number analysed= subjects evaluable at specified time points for each arm.

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

End point timeframe:

Baseline, Months 6, 12, 18 and 24

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|--|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1516 | 492 | 358 | 67 |
| Units: milligram per liter (mg/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n=1044,330,229,49,67) | 13.70 (± 43.8) | 10.23 (± 22.6) | 8.79 (± 17.0) | 7.70 (± 11.8) |
| Change at Month 6 (n=933,285,216,45,66) | -1.09 (± 47.4) | 1.46 (± 40.0) | -1.45 (± 14.6) | -1.88 (± 12.3) |
| Change at Month 12 (n=678,243,166,38,55) | -4.87 (± 38.6) | -2.23 (± 17.3) | -1.62 (± 12.2) | 3.88 (± 25.4) |
| Change at Month 18 (n=428,174,122,27,48) | -6.57 (± 45.2) | 0.63 (± 37.7) | -2.45 (± 11.7) | 1.83 (± 12.6) |
| Change at Month 24 (234,131,94,21,32) | 0.33 (± 177.3) | -3.51 (± 18.2) | 3.19 (± 41.7) | 4.17 (± 24.6) |

| End point values | Multiple Switchers | | | |
|--|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: milligram per liter (mg/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n=1044,330,229,49,67) | 12.18 (± 30.7) | | | |
| Change at Month 6 (n=933,285,216,45,66) | 0.94 (± 32.8) | | | |
| Change at Month 12 (n=678,243,166,38,55) | -4.84 (± 30.7) | | | |
| Change at Month 18 (n=428,174,122,27,48) | -0.59 (± 51.8) | | | |
| Change at Month 24 (234,131,94,21,32) | -3.11 (± 19.6) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Laboratory Test Results: Fecal Calprotectin at Months 6, 12, 18, and 24

| | |
|--|--|
| End point title | Mean Change From Baseline in Laboratory Test Results: Fecal Calprotectin at Months 6, 12, 18, and 24 |
| End point description: | |
| Here, the laboratory tests related to the treatment or assessment of Crohn's Disease or Ulcerative Colitis was fecal calprotectin. FAS=all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes (clinical assessment of disease activity, laboratory and imaging results related to treatment or assessment of CD or UC). Here, Number analysed= subjects evaluable at specified time points for each arm. | |
| End point type | Secondary |

End point timeframe:

Baseline, Months 6, 12, 18, and 24

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|---------------------------------------|--------------------|-------------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1516 | 492 | 358 | 67 |
| Units: milligram per kilogram (mg/kg) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n=202,47,35,8,16) | 1066.31 (± 5419.8) | 556.88 (± 916.2) | 362.48 (± 642.8) | 616.03 (± 1023.3) |
| Change at Month 6 (n=107,28,12,5,8) | -283.21 (± 989.0) | -296.95 (± 958.1) | -164.60 (± 440.8) | -648.16 (± 1333.1) |
| Change at Month 12 (n=55,22,10,2,7) | -165.32 (± 691.9) | 361.51 (± 1741.1) | -289.57 (± 1004.9) | -382.73 (± 503.1) |
| Change at Month 18 (n=48,12,9,4,5) | -473.07 (± 1394.3) | 275.48 (± 1518.0) | 88.44 (± 746.8) | -73.94 (± 125.3) |
| Change at Month 24 (n=22,5,6,2,2) | -625.69 (± 1684.7) | -862.40 (± 958.4) | -494.66 (± 1226.4) | -13.35 (± 273.4) |

| End point values | Multiple Switchers | | | |
|---------------------------------------|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: milligram per kilogram (mg/kg) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n=202,47,35,8,16) | 537.58 (± 1471.9) | | | |
| Change at Month 6 (n=107,28,12,5,8) | 224.56 (± 700.1) | | | |
| Change at Month 12 (n=55,22,10,2,7) | -643.67 (± 2339.3) | | | |
| Change at Month 18 (n=48,12,9,4,5) | 109.16 (± 164.4) | | | |
| Change at Month 24 (n=22,5,6,2,2) | -450.98 (± 200.2) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Imaging Test Results

| | |
|-----------------|--|
| End point title | Number of Subjects With Imaging Test Results |
|-----------------|--|

End point description:

Number of subjects who had Imaging test results related to the treatment or assessment of Crohn's Disease or Ulcerative Colitis were reported. FAS =all subjects who received at least 1 dose of study drug and had at least one post-dose assessment of any of the effectiveness outcomes (clinical assessment of disease activity, laboratory and imaging results related to treatment or assessment of CD or UC).

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From baseline up to follow-up period (a maximum of 2 years) | |

| End point values | CT-P13 | Remicade | Switched From Remicade to CT-P13 | Switched From CT-P13 to Remicade |
|-----------------------------|-----------------|-----------------|----------------------------------|----------------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1516 | 492 | 358 | 67 |
| Units: Subjects | 516 | 134 | 106 | 28 |

| End point values | Multiple Switchers | | | |
|-----------------------------|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 102 | | | |
| Units: Subjects | 50 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline to follow-up period (up to a maximum duration of 2 years)

Adverse event reporting additional description:

Same event may appear as both an adverse event (AE) and serious adverse event (SAE). However, what is presented are distinct events. An event may be categorized as serious in 1 subject and as non-serious in another, or a subject may have experienced both a serious and non-serious event. Safety population was evaluated.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 21.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | Remicade |
|-----------------------|----------|

Reporting group description:

Subjects diagnosed with either CD or UC, and who were biologic naive initiating Remicade and received Remicade continuously, or subjects who were treated with Remicade continuously, or who were treated with Remicade then switched to other anti-TNFs therapy (except CT-P13) or non-biologic treatment during the study, or those who switched to Remicade from an alternative biologic therapy (except CT-P13) due to non-responsiveness or intolerance were enrolled in this group. Subjects received Remicade in accordance with usual clinical practice of IBD at the discretion of the physician and observed for a duration of approximately 24 months.

| | |
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| Reporting group title | CT-P13 |
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Reporting group description:

Subjects diagnosed with either Crohn's Disease (CD) or Ulcerative Colitis (UC), and who were biologic naive initiating CT-P13 and received CT-P13 continuously, or subjects who were treated with CT-P13 continuously, or who were treated with CT-P13 then switched to other anti-tumor necrosis factors (TNFs) therapy except Remicade or non-biologic treatment during the study, or those who switched to CT-P13 from an alternative biologic therapy (except Remicade) due to non-responsiveness to or intolerance with existing therapy were enrolled in this group. Subjects received CT-P13 continuously in accordance with usual clinical practice of Inflammatory bowel disease (IBD) at the discretion of the physician and observed for a duration of approximately 24 months.

| | |
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| Reporting group title | Switched From CT-P13 to Remicade |
|-----------------------|----------------------------------|

Reporting group description:

Subjects diagnosed with either CD or UC and who were previously treated with CT-P13 continuously as per usual clinical practice of IBD, switched to Remicade once, either at enrollment or during the study were observed for a duration of approximately 24 months.

| | |
|-----------------------|--------------------|
| Reporting group title | Multiple Switchers |
|-----------------------|--------------------|

Reporting group description:

Subjects with CD or UC with at least 2 switches between Remicade and CT-P13 during the study, were observed for a duration of approximately 24 months. Both Remicade and CT-P13 were administered as per usual clinical practice of IBD.

| | |
|-----------------------|----------------------------------|
| Reporting group title | Switched From Remicade to CT-P13 |
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Reporting group description:

Subjects diagnosed with either CD or UC and who were previously treated with Remicade continuously as per usual clinical practice of IBD, switched to CT-P13 once, either at enrollment or during the study were observed for a duration of approximately 24 months.

| Serious adverse events | Remicade | CT-P13 | Switched From CT-P13 to Remicade |
|---|------------------|---------------------|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 43 / 494 (8.70%) | 256 / 1522 (16.82%) | 10 / 67 (14.93%) |
| number of deaths (all causes) | 2 | 4 | 0 |
| number of deaths resulting from adverse events | 0 | 2 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Breast cancer | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Breast cancer in situ | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Chronic lymphocytic leukaemia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Gastrointestinal stromal tumour | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Intraductal proliferative breast lesion | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| Malignant melanoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Seminoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tongue neoplasm malignant stage unspecified | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 disorders | | | |
| Aneurysm | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Aortic aneurysm rupture | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Behcet's syndrome | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Circulatory collapse | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Femoral artery embolism | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Poor venous access | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vasculitis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| Caesarean section | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Colectomy | | | |

| | | | |
|--|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Ventriculo-peritoneal shunt | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 3 / 494 (0.61%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foetal death | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 | | | |
| Adhesion | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Administration site extravasation | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Alcohol withdrawal syndrome | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-------------------|----------------|
| Condition aggravated | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Drug ineffective | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 11 / 1522 (0.72%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 5 / 11 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Face oedema | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Hernia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Hyperthermia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Impaired healing | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Malaise | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 organ dysfunction syndrome | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Paradoxical drug reaction | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Stenosis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sudden death | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 5 / 1522 (0.33%) | 2 / 67 (2.99%) |
| occurrences causally related to treatment / all | 0 / 0 | 6 / 6 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sarcoidosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Type I hypersensitivity | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Reproductive system and breast disorders | | | |
| Cervix carcinoma | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Female genital tract fistula | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Fibrocystic breast disease | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Gynaecomastia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Ovarian cyst torsion | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostatitis | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 polyp | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 | | | |
| Alveolitis allergic | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Asthma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Lung disorder | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 4 / 1522 (0.26%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary mass | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 symptom | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Psychiatric decompensation | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Psychotic disorder | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Schizophrenia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicide attempt | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| C-reactive protein increased | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| CSF pressure | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Drug specific antibody present | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Liver function test abnormal | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Anastomotic fistula | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anastomotic ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal stoma complication | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Infusion related reaction | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ligament rupture | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Maternal exposure during pregnancy | | | |
| subjects affected / exposed | 3 / 494 (0.61%) | 5 / 1522 (0.33%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Road traffic accident | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Wound | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Cardiac disorders | | | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Angina unstable | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Atrial fibrillation | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Cardiac arrest | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Cardiac failure | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiovascular disorder | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Nervous system disorders | | | |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Headache | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Memory impairment | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Meningioma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Migraine | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Migraine with aura | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Seizure | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Bicytopenia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Microcytic anaemia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Neutropenia | | | |

| | | | |
|---|-----------------|-------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Abdominal incarcerated hernia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 11 / 1522 (0.72%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 12 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 fistula | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 7 / 1522 (0.46%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 7 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |

| | | | |
|---|-----------------|-------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 13 / 1522 (0.85%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 4 / 15 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 3 / 494 (0.61%) | 13 / 1522 (0.85%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 5 / 14 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Crohn's disease | | | |
| subjects affected / exposed | 5 / 494 (1.01%) | 23 / 1522 (1.51%) | 2 / 67 (2.99%) |
| occurrences causally related to treatment / all | 1 / 5 | 3 / 27 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 4 / 1522 (0.26%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea haemorrhagic | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diverticulum | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Duodenal stenosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Duodenitis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Enterocutaneous fistula | | | |

| | | | |
|---|-----------------|-------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Fistula of small intestine | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal anastomotic stenosis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Ileal perforation | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Ileal stenosis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 11 / 1522 (0.72%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 2 / 11 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Inflammatory bowel disease | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Inguinal hernia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 2 / 494 (0.40%) | 5 / 1522 (0.33%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 7 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal perforation | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Intestinal stenosis | | | |
| subjects affected / exposed | 2 / 494 (0.40%) | 8 / 1522 (0.53%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 8 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestinal stenosis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malabsorption | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Nausea | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Obstruction gastric | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Pancreatitis chronic | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Peptic ulcer perforation | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal stenosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Subileus | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 8 / 1522 (0.53%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 10 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Hepatobiliary disorders | | | |
| Bile duct stone | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Cholangitis sclerosing | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Cholelithiasis | | | |
| subjects affected / exposed | 2 / 494 (0.40%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis cholestatic | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Lupus hepatitis | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Skin and subcutaneous tissue disorders | | | |
| Cutaneous vasculitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Dermatitis psoriasiform | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hidradenitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Palmoplantar pustulosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Pustular psoriasis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Rash | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 reaction | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Bladder disorder | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| IgA nephropathy | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Kidney congestion | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal colic | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Renal failure | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Tubulointerstitial nephritis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Endocrine disorders | | | |
| Adrenocorticotrophic hormone deficiency | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Steroid withdrawal syndrome | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Thyroid mass | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 | | | |
| Angiomyolipoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Ankylosing spondylitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |

| | | | |
|---|-----------------|------------------|----------------|
| Arthralgia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis enteropathic | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Back pain | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Fistula | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 disorder | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Muscle rupture | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Rotator cuff syndrome | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sarcopenia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spondylitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Systemic lupus erythematosus | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 4 / 1522 (0.26%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 4 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Abscess | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Abscess intestinal | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 4 / 1522 (0.26%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 5 / 1522 (0.33%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 5 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal fistula infection | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Beta haemolytic streptococcal infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary sepsis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Breast abscess | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chronic tonsillitis | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 4 / 1522 (0.26%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cryptosporidiosis infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 colitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Disseminated tuberculosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Diverticulitis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epididymitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Epstein-Barr virus infection | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Escherichia urinary tract infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Febrile infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 | 2 / 494 (0.40%) | 1 / 1522 (0.07%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis C | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Infected fistula | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Liver abscess | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Measles | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Peritonitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Pneumocystis jirovecii pneumonia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 9 / 1522 (0.59%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 4 / 9 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia influenzal | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Post procedural infection | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 sepsis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 tract infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (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 |
| Rotavirus infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| 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 / 494 (0.00%) | 0 / 1522 (0.00%) | 1 / 67 (1.49%) |
| 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 | 1 / 494 (0.20%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 1 / 1 | 0 / 0 |
| Skin infection | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Staphylococcal sepsis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Subdiaphragmatic abscess | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Tuberculosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Urosepsis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (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 |
| Varicella | | | |

| | | | |
|---|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |
| Metabolism and nutrition disorders | | | |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (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 |

| Serious adverse events | Multiple Switchers | Switched From Remicade to CT-P13 | |
|---|--------------------|----------------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 15 / 102 (14.71%) | 57 / 358 (15.92%) | |
| number of deaths (all causes) | 0 | 1 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer in situ | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic lymphocytic leukaemia | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal stromal tumour | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal proliferative breast lesion | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seminoma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue neoplasm malignant stage unspecified | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Aneurysm | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm rupture | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Behcet's syndrome | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Circulatory collapse | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral artery embolism | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Poor venous access | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vasculitis | | | |

| | | | |
|--|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Caesarean section | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colectomy | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventriculo-peritoneal shunt | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 2 / 358 (0.56%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foetal death | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Adhesion | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Administration site extravasation | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol withdrawal syndrome | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Condition aggravated | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug ineffective | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 5 / 358 (1.40%) | |
| occurrences causally related to treatment / all | 0 / 0 | 5 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Face oedema | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperthermia | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired healing | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malaise | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paradoxical drug reaction | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stenosis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden death | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sarcoidosis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type I hypersensitivity | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Cervix carcinoma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Female genital tract fistula | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibrocystic breast disease | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gynaecomastia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cyst torsion | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine polyp | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Alveolitis allergic | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung disorder | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary mass | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory symptom | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric decompensation | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychotic disorder | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schizophrenia | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicide attempt | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| C-reactive protein increased | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CSF pressure | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug specific antibody present | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test abnormal | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Anastomotic fistula | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|--|-----------------|-----------------|--|
| Anastomotic ulcer haemorrhage subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal stoma complication subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incisional hernia subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infusion related reaction subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament rupture subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Maternal exposure during pregnancy subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural complication subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina unstable | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiovascular disorder | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |

| | | | |
|---|-----------------|-----------------|--|
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 2 / 358 (0.56%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Memory impairment | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningioma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine with aura | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathy peripheral | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Presyncope | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syncope | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bicytopenia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microcytic anaemia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal hernia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal incarcerated hernia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 3 / 358 (0.84%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain lower | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fistula | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Crohn's disease | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 6 / 358 (1.68%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea haemorrhagic | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal stenosis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocutaneous fistula | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fistula of small intestine | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal anastomotic stenosis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileal perforation | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileal stenosis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammatory bowel disease | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal perforation | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal stenosis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal stenosis | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malabsorption | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstruction gastric | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis chronic | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer perforation | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal obstruction | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal stenosis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subileus | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Bile duct stone | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis sclerosing | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis cholestatic | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lupus hepatitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Cutaneous vasculitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis psoriasiform | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hidradenitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Palmoplantar pustulosis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pruritus | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pustular psoriasis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyoderma gangrenosum | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin reaction | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder disorder | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IgA nephropathy | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kidney congestion | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal colic | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal failure | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tubulointerstitial nephritis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Adrenocorticotrophic hormone deficiency | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Steroid withdrawal syndrome | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid mass | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Angiomyolipoma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ankylosing spondylitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis enteropathic | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fistula | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Groin pain | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc disorder | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle rupture | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteonecrosis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sarcopenia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylitis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systemic lupus erythematosus | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess intestinal | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 3 / 358 (0.84%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fistula infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Beta haemolytic streptococcal infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary sepsis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain abscess | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast abscess | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic tonsillitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cryptosporidiosis infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cytomegalovirus colitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disseminated tuberculosis | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epididymitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epstein-Barr virus infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia urinary tract infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 2 / 358 (0.56%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis C | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected fistula | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver abscess | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Measles | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumocystis jirovecii pneumonia | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia influenzal | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia legionella | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural sepsis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotavirus infection | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic shock | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal sepsis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdiaphragmatic abscess | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tuberculosis | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varicella | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Remicade | CT-P13 | Switched From CT-P13 to Remicade |
|---|--------------------|---------------------|----------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 100 / 494 (20.24%) | 442 / 1522 (29.04%) | 7 / 67 (10.45%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Breast cancer | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Malignant melanoma | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Malignant melanoma in situ | | | |

| | | | |
|---|------------------------|-------------------------------|---------------------|
| subjects affected / exposed occurrences (all) | 1 / 494 (0.20%) 1 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Malignant melanoma stage III subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Skin cancer subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 2 / 1522 (0.13%) 2 | 0 / 67 (0.00%) 0 |
| Vascular disorders Haematoma subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Hot flush subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Poor venous access subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Surgical and medical procedures Abortion induced subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Intestinal resection subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Pregnancy, puerperium and perinatal conditions Abortion spontaneous subjects affected / exposed occurrences (all) | 1 / 494 (0.20%) 1 | 2 / 1522 (0.13%) 3 | 0 / 67 (0.00%) 0 |
| Gestational trophoblastic detachment subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| General disorders and administration site conditions Drug ineffective subjects affected / exposed occurrences (all) | 24 / 494 (4.86%) 24 | 187 / 1522 (12.29%) 187 | 0 / 67 (0.00%) 0 |

| | | | |
|---------------------------------------|-----------------|------------------|----------------|
| Dysplasia | | | |
| subjects affected / exposed | 2 / 494 (0.40%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 5 / 1522 (0.33%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 5 | 0 |
| Feeling abnormal | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fibrosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 1 / 67 (1.49%) |
| occurrences (all) | 1 | 1 | 1 |
| Unevaluable event | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immune system disorders | | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hypersensitivity | | | |

| | | | |
|--|------------------------|-------------------------|---------------------|
| subjects affected / exposed occurrences (all) | 10 / 494 (2.02%) 10 | 29 / 1522 (1.91%) 32 | 0 / 67 (0.00%) 0 |
| Serum sickness subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Type I hypersensitivity subjects affected / exposed occurrences (all) | 2 / 494 (0.40%) 2 | 9 / 1522 (0.59%) 9 | 0 / 67 (0.00%) 0 |
| Reproductive system and breast disorders Ovarian cyst subjects affected / exposed occurrences (all) | 1 / 494 (0.20%) 1 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Vaginal haemorrhage subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Dyspnoea subjects affected / exposed occurrences (all) | 1 / 494 (0.20%) 1 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Haemoptysis subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 2 | 0 / 67 (0.00%) 0 |
| Lung disorder subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Nasal discomfort subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Oropharyngeal pain | | | |

| | | | |
|--------------------------------------|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 1 | 1 |
| Respiratory distress | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psychiatric disorders | | | |
| Abnormal dreams | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Anxiety | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depressed mood | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 2 / 494 (0.40%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood count abnormal | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 1 | 1 |
| C-reactive protein increased | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Colonoscopy | | | |

| | | | |
|--|------------------|-------------------|----------------|
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Drug specific antibody present | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 6 / 1522 (0.39%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 6 | 0 |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mean cell volume decreased | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Injury, poisoning and procedural complications | | | |
| Exposure to communicable disease | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 3 / 494 (0.61%) | 24 / 1522 (1.58%) | 0 / 67 (0.00%) |
| occurrences (all) | 4 | 24 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Maternal exposure during pregnancy | | | |
| subjects affected / exposed | 13 / 494 (2.63%) | 34 / 1522 (2.23%) | 0 / 67 (0.00%) |
| occurrences (all) | 14 | 37 | 0 |
| Medication error | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Suture related complication | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Wound | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Wound dehiscence | | | |

| | | | |
|--|----------------------|-----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Cardiac disorders | | | |
| Acute coronary syndrome subjects affected / exposed occurrences (all) | 1 / 494 (0.20%) 1 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Angina pectoris subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Cardiovascular insufficiency subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Nervous system disorders | | | |
| Demyelination subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Dizziness subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Facial paralysis subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 2 / 1522 (0.13%) 2 | 0 / 67 (0.00%) 0 |
| Meningioma subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Demyelinating polyneuropathy subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 4 / 494 (0.81%) 5 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Iron deficiency anaemia | | | |

| | | | |
|--|----------------------|-----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Leukopenia subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 2 / 1522 (0.13%) 2 | 0 / 67 (0.00%) 0 |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Ear and labyrinth disorders Neurosensory hypoacusis subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Eye disorders Dry eye subjects affected / exposed occurrences (all) | 1 / 494 (0.20%) 1 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Retinal vein occlusion subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 1 / 67 (1.49%) 1 |
| Scleritis subjects affected / exposed occurrences (all) | 1 / 494 (0.20%) 1 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Vision blurred subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) | 1 / 494 (0.20%) 1 | 3 / 1522 (0.20%) 3 | 0 / 67 (0.00%) 0 |
| Abdominal tenderness subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Anal fistula subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Colitis | | | |

| | | | |
|---------------------------------------|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Crohn's disease | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 7 / 1522 (0.46%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 8 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Enteritis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastrointestinal anastomotic stenosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Ileal stenosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Intestinal stenosis | | | |
| subjects affected / exposed | 3 / 494 (0.61%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| Large intestinal stenosis | | | |

| | | | |
|-----------------------------|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nausea | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Obstruction gastric | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pancreatic failure | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Pouchitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Subileus | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 0 | 1 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Hepatobiliary disorders | | | |
| Autoimmune hepatitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Cholelithiasis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|--|-----------------|------------------|----------------|
| Cholestasis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hepatic steatosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Non-alcoholic steatohepatitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Actinic keratosis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Blister | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermatitis atopic | | | |

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|-----------------------------|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermatitis psoriasiform | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Drug eruption | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyshidrotic eczema | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Eczema | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Erythema nodosum | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hidradenitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ingrowing nail | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Prurigo | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pruritus generalised | | | |

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|--|----------------------|-------------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Psoriasis subjects affected / exposed occurrences (all) | 3 / 494 (0.61%) 3 | 11 / 1522 (0.72%) 11 | 0 / 67 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 1 / 494 (0.20%) 1 | 3 / 1522 (0.20%) 4 | 0 / 67 (0.00%) 0 |
| Rash erythematous subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 1 / 67 (1.49%) 1 |
| Rebound psoriasis subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Skin lesion subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Skin reaction subjects affected / exposed occurrences (all) | 1 / 494 (0.20%) 2 | 18 / 1522 (1.18%) 19 | 0 / 67 (0.00%) 0 |
| Skin ulcer subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 0 / 1522 (0.00%) 0 | 0 / 67 (0.00%) 0 |
| Urticaria subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Renal and urinary disorders Renal failure subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Endocrine disorders Thyroiditis subjects affected / exposed occurrences (all) | 0 / 494 (0.00%) 0 | 1 / 1522 (0.07%) 1 | 0 / 67 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|------------------------------|------------------|-------------------|----------------|
| Arthralgia | | | |
| subjects affected / exposed | 11 / 494 (2.23%) | 12 / 1522 (0.79%) | 0 / 67 (0.00%) |
| occurrences (all) | 11 | 12 | 0 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropathy | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Back pain | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Lupus-like syndrome | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Osteonecrosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Systemic lupus erythematosus | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Anal abscess | | | |
| subjects affected / exposed | 2 / 494 (0.40%) | 5 / 1522 (0.33%) | 0 / 67 (0.00%) |
| occurrences (all) | 2 | 5 | 0 |
| Anal fistula infection | | | |

| | | | |
|---------------------------------|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 2 / 494 (0.40%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Campylobacter gastroenteritis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Candida infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fungal infection | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastroenteritis | | | |

| | | | |
|-----------------------------|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal infection | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Genital herpes | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Genital herpes zoster | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Groin abscess | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Herpes virus infection | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 4 / 1522 (0.26%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infection | | | |

| | | | |
|-----------------------------------|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Latent tuberculosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 1 / 67 (1.49%) |
| occurrences (all) | 0 | 2 | 1 |
| Nail infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 3 / 494 (0.61%) | 5 / 1522 (0.33%) | 0 / 67 (0.00%) |
| occurrences (all) | 4 | 5 | 0 |
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ophthalmic herpes simplex | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 3 / 1522 (0.20%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Opportunistic infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral herpes | | | |

| | | | |
|-----------------------------|-----------------|------------------|----------------|
| subjects affected / exposed | 1 / 494 (0.20%) | 4 / 1522 (0.26%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Papilloma viral infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Parvovirus B19 infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periodontitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pertussis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 2 / 1522 (0.13%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 4 / 1522 (0.26%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subcutaneous abscess | | | |

| | | | |
|------------------------------------|-----------------|------------------|----------------|
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinea cruris | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinea pedis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tinea versicolour | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ureteritis | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 494 (0.20%) | 3 / 1522 (0.20%) | 1 / 67 (1.49%) |
| occurrences (all) | 1 | 3 | 1 |
| Varicella zoster virus infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vulval abscess | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 0 / 1522 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginal mycotic infection | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Metabolism and nutrition disorders | | | |

| | | | |
|-----------------------------|-----------------|------------------|----------------|
| Cell death | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Iron deficiency | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vitamin B12 deficiency | | | |
| subjects affected / exposed | 0 / 494 (0.00%) | 1 / 1522 (0.07%) | 0 / 67 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| Non-serious adverse events | Multiple Switchers | Switched From Remicade to CT-P13 | |
|---|--------------------|----------------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 21 / 102 (20.59%) | 90 / 358 (25.14%) | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Breast cancer | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Malignant melanoma in situ | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Malignant melanoma stage III | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Skin cancer | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hot flush | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|----------------------|------------------------|--|
| Poor venous access subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Surgical and medical procedures | | | |
| Abortion induced subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Intestinal resection subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 1 / 358 (0.28%) 1 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Gestational trophoblastic detachment subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| General disorders and administration site conditions | | | |
| Drug ineffective subjects affected / exposed occurrences (all) | 9 / 102 (8.82%) 9 | 23 / 358 (6.42%) 23 | |
| Dysplasia subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Fatigue subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 4 / 358 (1.12%) 5 | |
| Feeling abnormal subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 1 / 358 (0.28%) 1 | |
| Fibrosis subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| General physical health deterioration subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |

| | | | |
|--|----------------------|----------------------|--|
| Influenza like illness subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Non-cardiac chest pain subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 1 / 358 (0.28%) 1 | |
| Oedema peripheral subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Pyrexia subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Unevaluable event subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Immune system disorders Drug hypersensitivity subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 1 / 358 (0.28%) 1 | |
| Hypersensitivity subjects affected / exposed occurrences (all) | 1 / 102 (0.98%) 1 | 4 / 358 (1.12%) 5 | |
| Serum sickness subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Type I hypersensitivity subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 1 / 358 (0.28%) 1 | |
| Reproductive system and breast disorders Ovarian cyst subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Vaginal haemorrhage subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|---------------------------------------|-----------------|-----------------|--|
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cough | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Lung disorder | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Nasal discomfort | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Psychiatric disorders | | | |
| Abnormal dreams | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Depressed mood | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Insomnia | | | |

| | | | |
|--|----------------------|----------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Investigations | | | |
| Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Aspartate aminotransferase increased subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Blood alkaline phosphatase increased subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 1 / 358 (0.28%) 1 | |
| Blood count abnormal subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| C-reactive protein increased subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Colonoscopy subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Drug specific antibody present subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Hepatic enzyme increased subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Mean cell volume decreased subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Injury, poisoning and procedural complications | | | |
| Exposure to communicable disease subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Infusion related reaction | | | |

| | | | |
|------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 3 / 358 (0.84%) | |
| occurrences (all) | 0 | 5 | |
| Limb injury | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Maternal exposure during pregnancy | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 9 / 358 (2.51%) | |
| occurrences (all) | 1 | 9 | |
| Medication error | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Suture related complication | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Wound | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Wound dehiscence | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Angina pectoris | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Cardiovascular insufficiency | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Nervous system disorders | | | |
| Demyelination | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Dizziness | | | |

| | | | |
|--|----------------------|----------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 1 / 358 (0.28%) 1 | |
| Facial paralysis subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Headache subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Meningioma subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Demyelinating polyneuropathy subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) | 1 / 102 (0.98%) 1 | 0 / 358 (0.00%) 0 | |
| Iron deficiency anaemia subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Leukopenia subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Ear and labyrinth disorders Neurosensory hypoacusis subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Eye disorders Dry eye subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Retinal vein occlusion | | | |

| | | | |
|---------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Scleritis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 2 / 358 (0.56%) | |
| occurrences (all) | 0 | 2 | |
| Abdominal tenderness | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Anal fistula | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Colitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 2 / 358 (0.56%) | |
| occurrences (all) | 0 | 4 | |
| Crohn's disease | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 3 / 358 (0.84%) | |
| occurrences (all) | 0 | 3 | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Enteritis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Gastrointestinal anastomotic stenosis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |

| | | |
|-----------------------------|-----------------|-----------------|
| Gastrointestinal pain | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Haemorrhoids | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Ileal stenosis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Hiatus hernia | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Intestinal obstruction | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Intestinal stenosis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Large intestinal stenosis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Nausea | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Obstruction gastric | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Oesophagitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pancreatic failure | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pancreatitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |

| | | | |
|--|-----------------|-----------------|--|
| Pouchitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Subileus | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Toothache | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hepatobiliary disorders | | | |
| Autoimmune hepatitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 2 / 358 (0.56%) | |
| occurrences (all) | 0 | 2 | |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hepatic steatosis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Non-alcoholic steatohepatitis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Skin and subcutaneous tissue disorders | | | |

| | | |
|-----------------------------|-----------------|-----------------|
| Acne | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Actinic keratosis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Alopecia | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Blister | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Dermatitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Dermatitis allergic | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dermatitis atopic | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Dermatitis psoriasiform | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Drug eruption | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) |
| occurrences (all) | 1 | 0 |
| Dry skin | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) |
| occurrences (all) | 1 | 0 |
| Dyshidrotic eczema | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Eczema | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |

| | | |
|-----------------------------|-----------------|-----------------|
| Erythema | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Erythema nodosum | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Hidradenitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Ingrowing nail | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Prurigo | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pruritus | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pruritus generalised | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Psoriasis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 3 / 358 (0.84%) |
| occurrences (all) | 0 | 4 |
| Rash | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Rash erythematous | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Rebound psoriasis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Skin lesion | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |

| | | | |
|---|----------------------|----------------------|--|
| Skin reaction subjects affected / exposed occurrences (all) | 3 / 102 (2.94%) 3 | 4 / 358 (1.12%) 4 | |
| Skin ulcer subjects affected / exposed occurrences (all) | 1 / 102 (0.98%) 1 | 0 / 358 (0.00%) 0 | |
| Urticaria subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 1 / 358 (0.28%) 1 | |
| Renal and urinary disorders Renal failure subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Endocrine disorders Thyroiditis subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |
| Arthritis subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 1 / 358 (0.28%) 1 | |
| Arthropathy subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 1 / 358 (0.28%) 1 | |
| Back pain subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 1 / 358 (0.28%) 1 | |
| Lupus-like syndrome subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 2 / 358 (0.56%) 2 | |
| Musculoskeletal discomfort subjects affected / exposed occurrences (all) | 0 / 102 (0.00%) 0 | 0 / 358 (0.00%) 0 | |

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|---------------------------------|-----------------|-----------------|--|
| Osteonecrosis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Systemic lupus erythematosus | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Anal fistula infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 2 / 358 (0.56%) | |
| occurrences (all) | 1 | 3 | |
| Campylobacter gastroenteritis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Candida infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Conjunctivitis | | | |

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| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Cystitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Ear infection | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Erysipelas | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Folliculitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Fungal infection | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gastroenteritis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Gastroenteritis viral | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Gastrointestinal infection | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Genital herpes | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Genital herpes zoster | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) |
| occurrences (all) | 1 | 0 |
| Gingivitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Groin abscess | | |

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|-----------------------------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Herpes simplex | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Herpes virus infection | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Herpes zoster | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 3 / 358 (0.84%) |
| occurrences (all) | 0 | 3 |
| Hordeolum | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Impetigo | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Infection | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Influenza | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Laryngitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Latent tuberculosis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Lower respiratory tract infection | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Nail infection | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Nasopharyngitis | | |

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|-----------------------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 102 (0.00%) | 2 / 358 (0.56%) |
| occurrences (all) | 0 | 2 |
| Onychomycosis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Ophthalmic herpes simplex | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Opportunistic infection | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 2 |
| Oral candidiasis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Oral fungal infection | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Oral herpes | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Otitis media acute | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Papilloma viral infection | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) |
| occurrences (all) | 1 | 0 |
| Parvovirus B19 infection | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Periodontitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pertussis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pneumonia | | |

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|-----------------------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Pyelonephritis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Respiratory tract infection | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Rhinitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Sinusitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Skin infection | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) |
| occurrences (all) | 1 | 0 |
| Subcutaneous abscess | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 358 (0.00%) |
| occurrences (all) | 1 | 0 |
| Tinea cruris | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Tinea pedis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Tinea versicolour | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) |
| occurrences (all) | 0 | 0 |
| Tonsillitis | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) |
| occurrences (all) | 0 | 1 |
| Tooth abscess | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 2 / 358 (0.56%) |
| occurrences (all) | 0 | 2 |
| Ureteritis | | |

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|------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Varicella zoster virus infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Viral infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vulval abscess | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 358 (0.28%) | |
| occurrences (all) | 0 | 1 | |
| Vulvovaginal mycotic infection | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Metabolism and nutrition disorders | | | |
| Cell death | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Iron deficiency | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Vitamin B12 deficiency | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 0 / 358 (0.00%) | |
| occurrences (all) | 0 | 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported