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

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

Summary

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

Results information

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

Trial information

Trial identification

Sponsor protocol code	C0524T18

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Janssen Research and Development, Clinical Registry Group-JB BV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Janssen Research and Development, Clinical Registry Group-JB BV, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 February 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 February 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

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

Protection of trial subjects:

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

Background therapy:

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

Evidence for comparator:

No

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

Notes:

Population of trial subjects

Subjects enrolled per country

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

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

Notes:

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

Subject disposition

Recruitment

Recruitment details:

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

Pre-assignment

Screening details:

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

Period 1

Period 1 title	Double blind period (Week 0-54)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Golimumab Induction Responders (GLM-I-Rsp)-Placebo Maintenance

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

Arm type	Experimental

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

Arm description:

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

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

Dosage and administration details:

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

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

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

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

Period 2

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

Blinding implementation details:

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo Extension

Arm description:

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

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

Dosage and administration details:

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

Arm title	Golimumab 50 mg Extension

Arm description:

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

Arm type	Experimental

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

Dosage and administration details:

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

Arm title	Golimumab 100 mg Extension

Arm description:

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

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

Dosage and administration details:

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

Arm title	Golimumab 200 mg Extension

Arm description:

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

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

Dosage and administration details:

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

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

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

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Please note that the subjects enrolled in the study extension period is not the same as of Double bling period. Study extension period is extension of Double blind period with different number of subjects.

Baseline characteristics

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

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

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

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

End points

End points reporting groups

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

Reporting group title	Placebo Extension

Reporting group description:

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

Reporting group title	Golimumab 50 mg Extension

Reporting group description:

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

Reporting group title	Golimumab 100 mg Extension

Reporting group description:

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

Reporting group title	Golimumab 200 mg Extension

Reporting group description:

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

Primary: Number of Subjects in Clinical Response Through Week 54

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

End point description:

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

End point type	Primary

End point timeframe:

Induction Baseline, Week 0 through Week 54

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Primary analysis population included randomly assigned participants in clinical response to golimumab induction at Week 0 of the maintenance study.

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

Statistical analyses

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

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

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

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

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

End point description:

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

End point type	Secondary

End point timeframe:

Week 30 and Week 54

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Primary analysis population included randomly assigned participants in clinical response to golimumab induction at Week 0 of the maintenance study.

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

Statistical analyses

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

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

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

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

End point description:

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

End point type	Secondary

End point timeframe:

Week 30 and Week 54

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Primary analysis population included randomly assigned participants in clinical response to golimumab induction at Week 0 of the maintenance study.

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

Statistical analyses

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

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

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

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

End point description:

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

End point type	Secondary

End point timeframe:

Week 30 and Week 54

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Primary analysis population included randomly assigned participants in clinical response to golimumab induction at Week 0 of the maintenance study.

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

Statistical analyses

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

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

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

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

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

End point description:

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

End point type	Secondary

End point timeframe:

Week 54

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Primary analysis population included randomly assigned participants in clinical response to golimumab induction at Week 0 of the maintenance study.

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

Statistical analyses

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

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

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to week 228

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

Reporting group title	Placebo Extension

Reporting group description:

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

Reporting group title	Golimumab 50 mg Extension

Reporting group description:

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

Reporting group title	Golimumab 100 mg Extension

Reporting group description:

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

Reporting group title	Golimumab 200 mg Extension

Reporting group description:

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

Reporting group title	Placebo - Golimumab 50 mg Extension

Reporting group description:

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

Reporting group title	Placebo-Golimumab 100 mg Extension

Reporting group description:

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

Reporting group title	Golimumab 50 mg to 100 mg Extension

Reporting group description:

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

Reporting group title	Golimumab 100 mg to 200 mg Extension

Reporting group description:

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

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

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

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

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

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

subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 156 (0.64%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression Suicidal			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressive Symptom			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Disorder			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance Abuse			

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

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

subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coronary Artery Disease			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			

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

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

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

Colitis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ulcerative			
subjects affected / exposed	3 / 156 (1.92%)	3 / 154 (1.95%)	6 / 154 (3.90%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Dysplasia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's Disease			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Frequent Bowel Movements			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			

subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Stenosis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			

subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus of Small Bowel			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile Duct Stone			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			

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

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

Back Pain			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	1 / 156 (0.64%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 156 (0.00%)	1 / 154 (0.65%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seronegative Arthritis			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess Intestinal			
subjects affected / exposed	0 / 156 (0.00%)	1 / 154 (0.65%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Abscess			

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

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

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

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

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

subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 156 (0.00%)	0 / 154 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer Metastatic			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder Cancer			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's Disease			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Huerthle Cell Carcinoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Adenocarcinoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cancer			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Epithelial Cancer			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenocarcinoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer Metastatic			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Cancer Metastatic			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
T-Cell Lymphoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Aneurysm Rupture			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyserositis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Dysplasia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Polyp			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Prolapse			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Prolapse			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial Lung Disease			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Infiltration			

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural Effusion			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression Suicidal			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressive Symptom			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Disorder			

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance Abuse			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Liver Function Test Abnormal			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental Poisoning			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional Hernia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular Pseudoaneurysm			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid Artery Stenosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Demyelination			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Paresis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Sclerosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve Root Compression			

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

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

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

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
subjects affected / exposed	1 / 76 (1.32%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Stenosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus of Small Bowel			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile Duct Stone			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			

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

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Bladder Neck Obstruction			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvi-Ureteric Obstruction			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure Acute			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Autoimmune Thyroiditis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seronegative Arthritis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

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

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

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Cyst			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious Colitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar Pneumonia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis Viral			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis Externa			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Sepsis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Cyst			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	1 / 76 (1.32%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Legionella			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Abscess			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Tuberculosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic Shock			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			

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

subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 76 (0.00%)	0 / 25 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo induction responders (PBO-I-Rsp)-Placebo Maintenance	PBO-I-nonRsp-Golimumab 100 mg Maintenance	GLM-I-nonRsp-Golimumab 100 mg Maintenance
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 129 (5.43%)	34 / 230 (14.78%)	63 / 405 (15.56%)
number of deaths (all causes)	0	1	4
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adrenal Adenoma			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal Cell Carcinoma			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			

subjects affected / exposed	1 / 129 (0.78%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Adenoma			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer Metastatic			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder Cancer			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's Disease			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Huerthle Cell Carcinoma			
subjects affected / exposed	0 / 129 (0.00%)	1 / 230 (0.43%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Adenocarcinoma			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cancer			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Epithelial Cancer			

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

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

Pyrexia			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Dysplasia			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Polyp			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Prolapse			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Prolapse			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial Lung Disease			

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

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

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

subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular Pseudoaneurysm			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 129 (0.00%)	1 / 230 (0.43%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	2 / 405 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	1 / 405 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			

subjects affected / exposed	0 / 129 (0.00%)	1 / 230 (0.43%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid Artery Stenosis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Demyelination			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Paresis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Sclerosis			

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

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

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

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

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

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

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

Autoimmune Thyroiditis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
subjects affected / exposed	0 / 129 (0.00%)	1 / 230 (0.43%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	1 / 405 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

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

subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Zoster			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Cyst			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	1 / 405 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious Colitis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar Pneumonia			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis Viral			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis Externa			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Sepsis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Cyst			

subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 129 (0.00%)	1 / 230 (0.43%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Legionella			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Abscess			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	1 / 405 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Tuberculosis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	1 / 405 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 129 (0.00%)	1 / 230 (0.43%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 129 (0.00%)	0 / 230 (0.00%)	1 / 405 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic Shock			

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

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

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

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

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

subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Polyserositis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Dysplasia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Polyp			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Prolapse			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Prolapse			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			

subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial Lung Disease			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Infiltration			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural Effusion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression Suicidal			

subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressive Symptom			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance Abuse			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Liver Function Test Abnormal			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental Poisoning			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 96 (1.04%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 96 (1.04%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular Pseudoaneurysm			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			

subjects affected / exposed	0 / 56 (0.00%)	1 / 96 (1.04%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 56 (0.00%)	2 / 96 (2.08%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid Artery Stenosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Demyelination			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Paresis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			

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

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

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

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

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

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

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

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

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

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

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

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

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

subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 56 (0.00%)	0 / 96 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Golimumab 100 mg Extension	Golimumab 200 mg Extension	Placebo - Golimumab 50 mg Extension
Total subjects affected by serious adverse events			
subjects affected / exposed	91 / 469 (19.40%)	1 / 7 (14.29%)	0 / 1 (0.00%)
number of deaths (all causes)	7	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adrenal Adenoma			

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

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

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

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

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

Depression			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression Suicidal			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressive Symptom			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Disorder			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance Abuse			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Liver Function Test Abnormal			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Accidental Poisoning			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylopathy Traumatic			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular Pseudoaneurysm			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			

subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	2 / 469 (0.43%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid Artery Stenosis			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Demyelination			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Paresis			

subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Sclerosis			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve Root Compression			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

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

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

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

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

subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity Vasculitis			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lichen Sclerosus			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma Gangrenosum			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Bladder Neck Obstruction			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvi-Ureteric Obstruction			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			

subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure Acute			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Autoimmune Thyroiditis			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Osteoarthritis			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seronegative Arthritis			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess Intestinal			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Abscess			
subjects affected / exposed	3 / 469 (0.64%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial Sepsis			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain Abscess			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	0 / 469 (0.00%)	1 / 7 (14.29%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus Infection			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated Tuberculosis			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Pyelonephritis			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extrapulmonary Tuberculosis			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

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

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

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

subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 469 (0.21%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 469 (0.00%)	0 / 7 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo-Golimumab 100 mg Extension	Golimumab 50 mg to 100 mg Extension	Golimumab 100 mg to 200 mg Extension
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 28 (25.00%)	1 / 19 (5.26%)	0 / 10 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

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

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported