Clinical trial results:
A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Maintenance Therapy in Subjects with Moderately to Severely Active Crohn's Disease

Summary

EudraCT number	2010-022760-12
Trial protocol	DE AT GB BE CZ IS IE FR HU NL DK ES BG IT
Global end of trial date	01 October 2019

Results information

Result version number	v1 (current)
This version publication date	16 October 2020
First version publication date	16 October 2020

Trial information

Trial identification

Sponsor protocol code	CNTO1275CRD3003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01369355
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 US Route 202, Raritan, United States, NJ 08869-0602
Public contact	Janssen Research & Development, LLC, Clinical Registry Group, ClinicalTrialsEU@its.jnj.com
Scientific contact	Janssen Research & Development, LLC, Clinical Registry Group, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 October 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 October 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the study was to assess the efficacy, safety, pharmacokinetics, and immunogenicity of ustekinumab in subjects with moderately to severely active Crohn's disease who had completed the 44-week maintenance study and who, in the opinion of the investigator, would benefit from continued treatment for up to 4 additional years of treatment with ustekinumab.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. Known instances of non-conformance were documented and are not considered to have had an impact on the overall conclusions of this study. Safety evaluations were based upon the adverse events (AEs), serious adverse events (SAEs), clinical laboratory test results (i.e., hematology and serum chemistry), and physical examinations reported throughout the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 September 2011
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	4 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 6
Country: Number of subjects enrolled	Belgium: 31
Country: Number of subjects enrolled	Bulgaria: 21
Country: Number of subjects enrolled	Australia: 38
Country: Number of subjects enrolled	Brazil: 12
Country: Number of subjects enrolled	Canada: 92
Country: Number of subjects enrolled	Czech Republic: 5
Country: Number of subjects enrolled	Germany: 84
Country: Number of subjects enrolled	Denmark: 4
Country: Number of subjects enrolled	Spain: 3
Country: Number of subjects enrolled	France: 64
Country: Number of subjects enrolled	United Kingdom: 67
Country: Number of subjects enrolled	Croatia: 4
Country: Number of subjects enrolled	Hungary: 64
Country: Number of subjects enrolled	Ireland: 1

Country: Number of subjects enrolled	Iceland: 2
Country: Number of subjects enrolled	Israel: 15
Country: Number of subjects enrolled	Italy: 23
Country: Number of subjects enrolled	Japan: 74
Country: Number of subjects enrolled	Korea, Republic of: 22
Country: Number of subjects enrolled	Netherlands: 36
Country: Number of subjects enrolled	New Zealand: 15
Country: Number of subjects enrolled	Poland: 36
Country: Number of subjects enrolled	Russian Federation: 17
Country: Number of subjects enrolled	Serbia: 19
Country: Number of subjects enrolled	United States: 495
Country: Number of subjects enrolled	South Africa: 31
Worldwide total number of subjects	1281
EEA total number of subjects	451

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)	1243
From 65 to 84 years	38
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Out of 1282 subjects enrolled, 1 was excluded from study before assignment to arm/group due to deviation from Good Clinical Practice at 1 study site. Hence 1281 subjects were analyzed. Total 397 subjects who were in clinical response to ustekinumab induction were randomized in maintenance study and considered as primary population.

Pre-assignment

Screening details:

A total of 1281 subjects started however 1084 subjects completed the study in the maintenance whereas out of 718 subjects, 395 completed LTE study.

Period 1

Period 1 title	Week 0 - Week 44 (Maintenance)
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	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance

Arm description:

Subjects (who were in clinical response to ustekinumab IV at Week 8 of an induction study) randomized to receive placebo subcutaneously (SC) every 4 weeks (q4w) in the maintenance study.

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

Dosage and administration details:

Subjects received matching placebo subcutaneously (SC) every 4 weeks (q4w) from Week 0 to 44 in the maintenance study.

Arm title	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance

Arm description:

Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) randomized to receive Ustekinumab SC 90 milligrams (mg) q12w in the maintenance study.

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

Dosage and administration details:

Subjects received matching placebo SC from Week 0 to 44 in the maintenance study.

Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received matching placebo and Ustekinumab SC 90 milligrams (mg) q8w from Week 0 to 44 in the maintenance study.

Arm title	UST-I-Rsp-UST-90 mg Q8W Maintenance

Arm description:

Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) randomized to receive Ustekinumab SC 90 mg q8w in the maintenance study.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Ustekinumab SC 90 mg q12w from Week 0 to 44 in the maintenance study.

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

Arm description:

Subjects (who were in clinical response to placebo IV at Week 8 of an induction study) received placebo SC q4w in the maintenance study; not randomized.

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

Dosage and administration details:

Subjects received matching placebo SC q4w from Week 0 to 44 in the maintenance study.

Arm title	PBO-I-nonRsp - UST-130mg Intravenous/90mg SC Q12W Maintenance

Arm description:

Subjects (who were not in clinical response to placebo IV at Week 8 of an induction study) received Ustekinumab 130 mg IV on entry into maintenance followed by Ustekinumab 90 mg SC q12 weeks beginning at Week 8 of maintenance (if in response); not randomized.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received Ustekinumab SC 90 mg q8w from Week 0 to 44 in the maintenance study.

Arm title	UST-I-nonRsp - UST-90mg Subcutaneously (SC) Q8W Maintenance

Arm description:

Subjects (who were not in clinical response to Ustekinumab IV at Week 8 of an induction study) received Ustekinumab 90 mg SC on entry into maintenance followed by Ustekinumab 90 mg SC q8w beginning at Week 8 of maintenance (if in response); not randomized.

Arm type	Experimental

Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use, Intravenous use

Dosage and administration details:

Subjects received Ustekinumab SC 90 mg q8w from Week 0 to 44 in the maintenance study.

Number of subjects in period 1	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance	UST-I-Rsp-UST-90 mg Q8W Maintenance
Started	133	132	132
Completed	102	103	101
Not completed	31	29	31
Consent withdrawn by subject	6	2	7
Adverse event, non-fatal	9	12	6
Treatment assigned but never received	-	-	1
Unspecified	-	-	-
Lost to follow-up	1	-	1
Lack of efficacy	15	14	15
Protocol deviation	-	1	1

Number of subjects in period 1	Placebo (PBO)-I-Rsp - PBO Maintenance	PBO-I-nonRsp - UST-130mg Intravenous/90mg SC Q12W Maintenance	UST-I-nonRsp - UST-90mg Subcutaneously (SC) Q8W Maintenance
Started	123	285	476
Completed	93	131	204
Not completed	30	154	272
Consent withdrawn by subject	6	8	22
Adverse event, non-fatal	7	14	25
Treatment assigned but never received	-	-	-
Unspecified	-	1	-
Lost to follow-up	2	5	6
Lack of efficacy	15	126	217
Protocol deviation	-	-	2

Period 2

Period 2 title	Long-term Extension (Week 44-272)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	UST-I-Rsp Placebo Long Term Extension (LTE)

Arm description:

Subjects who received placebo SC in the maintenance study, entered the long-term extension (LTE) and continued to receive placebo SC in the LTE study (Week 44 to 272).

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

Dosage and administration details:

Subjects continued to receive placebo SC from Week 44 to 272 in the LTE study.

Arm title	UST-I-Rsp-UST 90 mg SC Q12W LTE

Arm description:

Subjects entered the LTE and continued to receive ustekinumab 90 mg SC q12w in the LTE study (Week 44 to 272).

Arm type	Experimental
Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects continued to receive Ustekinumab 90 mg SC q12w from Week 44 to 272 in the LTE study.

Arm title	UST-I-Rsp/Non-Rsp-UST 90 mg SC Q8W LTE

Arm description:

Subjects entered the LTE and continued to receive ustekinumab 90 mg SC q8w in the LTE study (Week 44 to 272).

Arm type	Experimental
Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects continued to receive Ustekinumab 90 mg SC q8w from Week 44 to 272 in the LTE study.

Number of subjects in period 2[1]	UST-I-Rsp Placebo Long Term Extension (LTE)	UST-I-Rsp-UST 90 mg SC Q12W LTE	UST-I-Rsp/Non-Rsp-UST 90 mg SC Q8W LTE
Started	151	213	354
Completed	0	107	183
Not completed	151	106	171
Adverse event, serious fatal	-	1	3
Physician decision	1	5	11
Consent withdrawn by subject	12	30	47
Adverse event, non-fatal	15	29	53
Subject unblinded to placebo	110	-	-
Study terminated by sponsor	-	1	-
Lost to follow-up	1	5	9
Subject started commercial stelara	-	8	17
Lack of efficacy	12	26	29
Protocol deviation	-	1	2

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: The number of subjects starting the LTE period (ends at 272 Weeks) is different from the maintenance study period (ends at Week 44) as the baseline study arms ends at Week 44 and participants were re-randomized in LTE period as per study design.

Baseline characteristics

Reporting groups	
Reporting group title	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance
Reporting group description:	
Subjects (who were in clinical response to ustekinumab IV at Week 8 of an induction study) randomized to receive placebo subcutaneously (SC) every 4 weeks (q4w) in the maintenance study.	
Reporting group title	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance
Reporting group description:	
Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) randomized to receive Ustekinumab SC 90 milligrams (mg) q12w in the maintenance study.	
Reporting group title	UST-I-Rsp-UST-90 mg Q8W Maintenance
Reporting group description:	
Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) randomized to receive Ustekinumab SC 90 mg q8w in the maintenance study.	
Reporting group title	Placebo (PBO)-I-Rsp - PBO Maintenance
Reporting group description:	
Subjects (who were in clinical response to placebo IV at Week 8 of an induction study) received placebo SC q4w in the maintenance study; not randomized.	
Reporting group title	PBO-I-nonRsp - UST-130mg Intravenous/90mg SC Q12W Maintenance
Reporting group description:	
Subjects (who were not in clinical response to placebo IV at Week 8 of an induction study) received Ustekinumab 130 mg IV on entry into maintenance followed by Ustekinumab 90 mg SC q12 weeks beginning at Week 8 of maintenance (if in response); not randomized.	
Reporting group title	UST-I-nonRsp - UST-90mg Subcutaneously (SC) Q8W Maintenance
Reporting group description:	
Subjects (who were not in clinical response to Ustekinumab IV at Week 8 of an induction study) received Ustekinumab 90 mg SC on entry into maintenance followed by Ustekinumab 90 mg SC q8w beginning at Week 8 of maintenance (if in response); not randomized.	

Reporting group values	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance	UST-I-Rsp-UST-90 mg Q8W Maintenance
Number of subjects	133	132	132
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	129	125	126
From 65 to 84 years	4	7	6
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	39.5	38.6	37.9
standard deviation	± 12.69	± 13.65	± 13.2
Title for Gender Units: subjects			
Female	74	74	76
Male	59	58	56

Reporting group values	Placebo (PBO)-I-Rsp - PBO Maintenance	PBO-I-nonRsp - UST-130mg Intravenous/90mg SC Q12W Maintenance	UST-I-nonRsp - UST-90mg Subcutaneously (SC) Q8W Maintenance
Number of subjects	123	285	476
Title for AgeCategorical			
Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	118	279	466
From 65 to 84 years	5	6	10
85 years and over	0	0	0
Title for AgeContinuous			
Units: years			
arithmetic mean	39.1	39	37.4
standard deviation	± 12.46	± 12.33	± 12.5
Title for Gender			
Units: subjects			
Female	64	149	275
Male	59	136	201

Reporting group values	Total		
Number of subjects	1281		
Title for AgeCategorical			
Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	1243		
From 65 to 84 years	38		
85 years and over	0		
Title for AgeContinuous			
Units: years			
arithmetic mean			
standard deviation	-		
Title for Gender			
Units: subjects			
Female	712		
Male	569		

End points

End points reporting groups

Reporting group title	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance
Reporting group description:	
Subjects (who were in clinical response to ustekinumab IV at Week 8 of an induction study) randomized to receive placebo subcutaneously (SC) every 4 weeks (q4w) in the maintenance study.	
Reporting group title	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance
Reporting group description:	
Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) randomized to receive Ustekinumab SC 90 milligrams (mg) q12w in the maintenance study.	
Reporting group title	UST-I-Rsp-UST-90 mg Q8W Maintenance
Reporting group description:	
Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) randomized to receive Ustekinumab SC 90 mg q8w in the maintenance study.	
Reporting group title	Placebo (PBO)-I-Rsp - PBO Maintenance
Reporting group description:	
Subjects (who were in clinical response to placebo IV at Week 8 of an induction study) received placebo SC q4w in the maintenance study; not randomized.	
Reporting group title	PBO-I-nonRsp - UST-130mg Intravenous/90mg SC Q12W Maintenance
Reporting group description:	
Subjects (who were not in clinical response to placebo IV at Week 8 of an induction study) received Ustekinumab 130 mg IV on entry into maintenance followed by Ustekinumab 90 mg SC q12 weeks beginning at Week 8 of maintenance (if in response); not randomized.	
Reporting group title	UST-I-nonRsp - UST-90mg Subcutaneously (SC) Q8W Maintenance
Reporting group description:	
Subjects (who were not in clinical response to Ustekinumab IV at Week 8 of an induction study) received Ustekinumab 90 mg SC on entry into maintenance followed by Ustekinumab 90 mg SC q8w beginning at Week 8 of maintenance (if in response); not randomized.	
Reporting group title	UST-I-Rsp Placebo Long Term Extension (LTE)
Reporting group description:	
Subjects who received placebo SC in the maintenance study, entered the long-term extension (LTE) and continued to receive placebo SC in the LTE study (Week 44 to 272).	
Reporting group title	UST-I-Rsp-UST 90 mg SC Q12W LTE
Reporting group description:	
Subjects entered the LTE and continued to receive ustekinumab 90 mg SC q12w in the LTE study (Week 44 to 272).	
Reporting group title	UST-I-Rsp/Non-Rsp-UST 90 mg SC Q8W LTE
Reporting group description:	
Subjects entered the LTE and continued to receive ustekinumab 90 mg SC q8w in the LTE study (Week 44 to 272).	

Primary: Number of Subjects with Clinical Remission at Week 44

End point title	Number of Subjects with Clinical Remission at Week 44[1]
End point description:	
Clinical remission at Week 44 was defined as a Crohn's Disease Activity Index (CDAI) score of <150 points (in general, CDAI score ranges from 0 to approximately 600; higher score indicates higher disease activities). CDAI was assessed by collecting information on 8 different Crohn's disease-related variables (extra-intestinal manifestations, abdominal mass, weight, hematocrit, total number of liquid stools, abdominal pain/cramping, use of antidiarrheal drug(s) and/or opiates, and general well-being). A decrease in CDAI over time indicates improvement in disease activity. The primary efficacy analysis	

population in this study was randomized subjects (i.e., subjects who were in clinical response to ustekinumab induction dosing at Week 8 from one of the induction studies CRD3001 and CRD3002) after study restart.

End point type	Primary

End point timeframe:

Week 44

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: As planned, the end point is not reporting statistics for all the arms of baseline period.

End point values	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance	UST-I-Rsp-UST-90 mg Q8W Maintenance	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	131	129	128	
Units: Subjects				
number (not applicable)	47	63	68	

Statistical analyses

Statistical analysis title	Placebo SC, Ustekinumab 90 milligram (mg) SC q12w
Comparison groups	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance v UST-I-Rsp-UST-90 mg Q8W Maintenance
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	= 0.04 [3]
Method	Cochran-Mantel-Haenszel chi-square test

Notes:

[2] - 2-sided Cochran-Mantel-Haenszel chi-square test, stratified by clinical remission at Week 0, Ustekinumab induction dose and the induction study.
[3] - A fixed sequence testing procedure was used to control alpha at 0.05 over the outcome measures.

Statistical analysis title	Placebo SC, Ustekinumab 90 mg SC q8w
Comparison groups	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance v UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance
Number of subjects included in analysis	260
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	= 0.005 [5]
Method	Cochran-Mantel-Haenszel chi-square test

Notes:

[4] - 2-sided Cochran-Mantel-Haenszel chi-square test, stratified by clinical remission at Week 0, Ustekinumab induction dose and the induction study.
[5] - A fixed sequence testing procedure was used to control alpha at 0.05 over the outcome measures.

Secondary: Number of Subjects with Clinical Response at Week 44

End point title	Number of Subjects with Clinical Response at Week 44[6]

End point description:

Clinical response at Week 44 was defined as a reduction from baseline in the Crohn's Disease Activity Index (CDAI) score of greater than or equal (>=) 100 points. Subjects with a baseline CDAI score of >= 220 to less than or equal (<=) 248 were considered to be in clinical response if a CDAI score of less than (<) 150 was attained. A CDAI score of less than 150 indicates clinical remission. A decrease in CDAI score over time indicates improvement in disease activity. The primary efficacy analysis population in this study was randomized subjects (i.e., subjects who were in clinical response to ustekinumab induction dosing at Week 8 from one of the induction studies CRD3001 and CRD3002) after study restart.

End point type	Secondary

End point timeframe:

Week 44

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As planned, the end point is not reporting statistics for all the arms of baseline period.

End point values	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance	UST-I-Rsp-UST-90 mg Q8W Maintenance	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	131	129	128	
Units: subjects				
number (not applicable)	58	75	76	

Statistical analyses

Statistical analysis title	Placebo SC, Ustekinumab 90 milligram (mg) SC q12w
Comparison groups	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance v UST-I-Rsp-UST-90 mg Q8W Maintenance
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	= 0.033 [8]
Method	Cochran-Mantel-Haenszel chi-square test

Notes:

[7] - 2-sided Cochran-Mantel-Haenszel chi-square test, stratified by clinical remission at Week 0, Ustekinumab induction dose and the induction study.
[8] - A fixed sequence testing procedure was used to control alpha at 0.05 over the outcome measures.

Statistical analysis title	Placebo SC, Ustekinumab 90 mg SC q8w
Comparison groups	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance v UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance
Number of subjects included in analysis	260
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	= 0.018 [10]
Method	Cochran-Mantel-Haenszel chi-square test

Notes:

[9] - 2-sided Cochran-Mantel-Haenszel chi-square test, stratified by clinical remission at Week 0, Ustekinumab induction dose and the induction study.
[10] - A fixed sequence testing procedure was used to control alpha at 0.05 over the outcome measures.

Secondary: Number of Subjects in Clinical Remission at Week 44 Among Subjects in Clinical Remission to Ustekinumab at Week 0 of Maintenance Study

End point title	Number of Subjects in Clinical Remission at Week 44 Among Subjects in Clinical Remission to Ustekinumab at Week 0 of Maintenance Study[11]

End point description:

Clinical remission at week 44 was defined as a CDAI score of < 150 points among subjects in clinical remission to Ustekinumab at week 0 of maintenance study. Analysis population included all randomized participants after the study was restarted (who were in clinical remission at Week 0 of maintenance study). Here 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Week 44

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As planned, the end point is not reporting statistics for all the arms of baseline period.

End point values	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance	UST-I-Rsp-UST-90 mg Q8W Maintenance	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	79	78	78	
Units: subjects				
number (not applicable)	36	44	52	

Statistical analyses

Statistical analysis title	Placebo SC, Ustekinumab 90 mg SC q8w
Comparison groups	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance v UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority[12]
P-value	= 0.007 [13]
Method	Cochran-Mantel-Haenszel chi-square test

Notes:

[12] - 2-sided Cochran-Mantel-Haenszel chi-square test, stratified by Ustekinumab induction dose and the induction study.
[13] - A fixed sequence testing procedure was used to control alpha at 0.05 over the outcome measures.

Statistical analysis title	Placebo SC, Ustekinumab 90 milligram (mg) SC q12w
Comparison groups	Ustekinumab Induction Responders(UST-I-Rsp)Placebo

	Maintenance v UST-I-Rsp-UST-90 mg Q8W Maintenance
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority[14]
P-value	= 0.189 [15]
Method	Cochran-Mantel-Haenszel chi-square test

Notes:

[14] - 2-sided Cochran-Mantel-Haenszel chi-square test, stratified by clinical remission at Week 0, Ustekinumab induction dose and the induction study.
[15] - A fixed sequence testing procedure was used to control alpha at 0.05 over the outcome measures.

Secondary: Number of Subjects with Corticosteroid-free Remission at Week 44

End point title	Number of Subjects with Corticosteroid-free Remission at Week 44[16]

End point description:

Corticosteroid-free remission at Week 44 was defined as a CDAI score of <150 points without receiving corticosteroids at Week 44. The primary efficacy analysis population in this study was randomized subjects (i.e., subjects who were in clinical response to ustekinumab induction dosing at Week 8 from one of the induction studies CRD3001 and CRD3002) after study restart. Here 'N' (number of subjects analyzed) signifies number of subjects evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Week 44

Notes:

[16] - 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: As planned, the end point is not reporting statistics for all the arms of baseline period.

End point values	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance	UST-I-Rsp-UST-90 mg Q8W Maintenance	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	131	129	128	
Units: subjects				
number (not applicable)	39	55	60	

Statistical analyses

Statistical analysis title	Placebo SC, Ustekinumab 90 milligram (mg) SC q12w
Comparison groups	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance v UST-I-Rsp-UST-90 mg Q8W Maintenance
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	superiority[17]
P-value	= 0.035 [18]
Method	Cochran-Mantel-Haenszel chi-square test

Notes:

[17] - 2-sided Cochran-Mantel-Haenszel chi-square test, stratified by clinical remission at Week 0, Ustekinumab induction dose and the induction study.

[18] - A fixed sequence testing procedure was used to control alpha at 0.05 over the outcome measures.

Statistical analysis title	Placebo SC, Ustekinumab 90 mg SC q8w
Comparison groups	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance v UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance
Number of subjects included in analysis	260
Analysis specification	Pre-specified
Analysis type	superiority[19]
P-value	= 0.004 [20]
Method	Cochran-Mantel-Haenszel chi-square test

Notes:

[19] - 2-sided Cochran-Mantel-Haenszel chi-square test, stratified by clinical remission at Week 0, Ustekinumab induction dose and the induction study.
[20] - A fixed sequence testing procedure was used to control alpha at 0.05 over the outcome measures.

Secondary: Number of Subjects in Clinical Remission at Week 44 in the Subset of Subjects who were Refractory or Intolerant to Tumor Necrosis Factor (TNF) Antagonist Therapy

End point title	Number of Subjects in Clinical Remission at Week 44 in the Subset of Subjects who were Refractory or Intolerant to Tumor Necrosis Factor (TNF) Antagonist Therapy[21]

End point description:

Clinical remission at Week 44 was defined as a CDAI score of <150 points in the subset of subjects who were refractory or Intolerant to tumor necrosis factor antagonist therapy. The primary efficacy analysis population in this study was randomized subjects (i.e., subjects who were in clinical response to ustekinumab induction dosing at Week 8 from one of the induction studies CRD3001 and CRD3002) after study restart. Here 'N' (number of subjects analyzed) signifies subset of participants at baseline who were refractory or intolerant to tumor necrosis Factor (TNF) antagonist therapy.

End point type	Secondary

End point timeframe:

Week 44

Notes:

[21] - 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: As planned, the end point is not reporting statistics for all the arms of baseline period.

End point values	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance	UST-I-Rsp-UST-90 mg Q8W Maintenance	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	57	56	
Units: subjects				
number (not applicable)	16	22	23	

Statistical analyses

Statistical analysis title	Placebo SC, Ustekinumab 90 milligram (mg) SC q12w
Comparison groups	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance v UST-I-Rsp-UST-90 mg Q8W Maintenance
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority[22]
P-value	= 0.14 [23]
Method	Cochran-Mantel-Haenszel chi-square test

Notes:

[22] - 2 sided Cochran-Mantel-Haenszel chi-square test, stratified by clinical remission status at Week 0 and Ustekinumab induction dose.
[23] - A fixed sequence testing procedure was used to control alpha at 0.05 over the outcome measures.

Statistical analysis title	Placebo SC, Ustekinumab 90 mg SC q8w
Comparison groups	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance v UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[24]
P-value	= 0.102 [25]
Method	Cochran-Mantel-Haenszel chi-square test

Notes:

[24] - 2 sided Cochran-Mantel-Haenszel chi-square test, stratified by clinical remission status at Week 0 and Ustekinumab induction dose.
[25] - A fixed sequence testing procedure was used to control alpha at 0.05 over the outcome measures.

Adverse events information

Timeframe for reporting adverse events:

Up to Week 272

Adverse event reporting additional description:

Safety was analyzed for all treated subjects who received at least 1 administration of study agent in the maintenance (Week 0-44) and LTE study (Week 44-272).

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance

Reporting group description:

Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) received placebo subcutaneously (SC) every 4 weeks (q4w) in the maintenance study (includes events up to the time of loss of response).

Reporting group title	UST-I-Rsp -PBO Maintenance-UST-90mg SC Q8W Maintenance

Reporting group description:

Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) received placebo SC and had dose adjustment to Ustekinumab SC 90 mg q8w (includes events from the time of loss of response onward).

Reporting group title	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance

Reporting group description:

Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) randomized to receive Ustekinumab SC 90 milligrams (mg) q12w in the maintenance study (includes events from the time of loss of response onward).

Reporting group title	UST-I-Rsp-UST 90 mg SC Q12W/Q8W Maintenance

Reporting group description:

Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) received Ustekinumab SC 90 mg q12w and had dose adjustment to Ustekinumab SC 90 mg q8w in the maintenance study (includes events from the time of loss of response onward).

Reporting group title	UST-I-Rsp-UST-90 mg Q8W Maintenance

Reporting group description:

Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) randomized to receive Ustekinumab SC 90 mg q8w in the maintenance study (includes events from the time of loss of response onward).

Reporting group title	UST IV-I-Rsp-UST-90mg Maintenance-UST-90mg SC Q8W Maintenance

Reporting group description:

Subjects (who were in clinical response to Ustekinumab IV at Week 8 of an induction study) received Ustekinumab SC 90 mg q8 weeks and remained on Ustekinumab 90 mg q8w upon loss of response (includes events from the time of loss of response onward).

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

Reporting group description:

Subjects (who were in clinical response to placebo IV at Week 8 of an induction study) received placebo SC; not randomized.

Reporting group title	PBO-I-nonRsp- UST-130mg Intravenous/90mg SC Q12W Maintenance

Reporting group description:

Subjects (who were not in clinical response to placebo IV at Week 8 of an induction study) received Ustekinumab 130 mg IV on entry into maintenance followed by Ustekinumab 90 mg SC q12 weeks beginning at Week 8 of maintenance (if in response); not randomized.

Reporting group title	UST IV-I-nonRsp - UST-90 mg SC Q8W Maintenance

Reporting group description:

Subjects (who were not in clinical response to Ustekinumab IV at Week 8 of an induction study) received Ustekinumab 90 mg SC on entry into maintenance followed by Ustekinumab 90 mg SC q8w beginning at Week 8 of maintenance (if in response); not randomized.

Reporting group title	Placebo Long Term Extension (LTE)

Reporting group description:

Subjects who received placebo SC in the maintenance study, entered the LTE and continued to receive placebo SC in the LTE study (Week 44 to 272).

Reporting group title	UST 90 mg SC Q12W LTE

Reporting group description:

Subjects entered the LTE and continued to receive ustekinumab 90 mg SC q12w in the LTE study (Week 44 to 272).

Reporting group title	UST 90 mg SC Q8W LTE

Reporting group description:

Subjects entered the LTE and continued to receive ustekinumab 90 mg SC q8w in the LTE study (Week 44 to 272).

Serious adverse events	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance	UST-I-Rsp -PBO Maintenance-UST-90mg SC Q8W Maintenance	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 133 (16.54%)	7 / 51 (13.73%)	16 / 132 (12.12%)
number of deaths (all causes)	1	1	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Thyroid Gland			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Myeloid Leukaemia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Adenocarcinoma			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of Breast			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo Maligna			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	1 / 133 (0.75%)	0 / 51 (0.00%)	0 / 132 (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 Adenoma			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic Carcinoma			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary Thyroid Cancer			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Cell Carcinoma			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seminoma			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Intestine Adenocarcinoma			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Dissection			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Stenosis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential Hypertension			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Urgency			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abdominal Hernia Repair			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileostomy Closure			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee Arthroplasty			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Pouch Procedure			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Repair			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature Delivery			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Premature Labour			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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			
Asthenia			
subjects affected / exposed	0 / 133 (0.00%)	1 / 51 (1.96%)	0 / 132 (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
Chest Pain			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysplasia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated Hernia			
subjects affected / exposed	1 / 133 (0.75%)	0 / 51 (0.00%)	0 / 132 (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
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sudden Death			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Breast Prosthesis User			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Miscarriage of Partner			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Abuser			
subjects affected / exposed	1 / 133 (0.75%)	0 / 51 (0.00%)	0 / 132 (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			
Adenomyosis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholin's Cyst			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female Genital Tract Fistula			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menorrhagia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Congestion			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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			
Asphyxia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal Polyps			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Granuloma			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Haematoma			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	1 / 51 (1.96%)	0 / 132 (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
Hallucination			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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			

Blood Electrolytes Abnormal			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram Abnormal			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecal Volume Increased			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Enzyme Increased			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin Increased			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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			
Alcohol Poisoning			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic Transfusion Reaction			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic Haemorrhage			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anastomotic Leak			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Anastomotic Stenosis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heat Stroke			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Anastomosis Complication			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Rupture			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Sprain			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Injury			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Intestinal Perforation			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal Injury			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Fibrous Dysplasia of Bone			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Valve Incompetence			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-Respiratory Arrest			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral Infarction			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia with Lewy Bodies			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 133 (0.75%)	0 / 51 (0.00%)	0 / 132 (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
Idiopathic Intracranial Hypertension			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial Aneurysm			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid Haemorrhage			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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			
Chorioretinopathy			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Adhesions			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Discomfort			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Hernia			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Lower			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Fistula			
subjects affected / exposed	2 / 133 (1.50%)	0 / 51 (0.00%)	0 / 132 (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
Colitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Dysplasia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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	7 / 133 (5.26%)	4 / 51 (7.84%)	5 / 132 (3.79%)
occurrences causally related to treatment / all	1 / 7	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyclic Vomiting Syndrome			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous Fistula			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	1 / 133 (0.75%)	0 / 51 (0.00%)	0 / 132 (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
Epiploic Appendagitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula of Small Intestine			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Stenosis			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory Bowel Disease			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Perforation			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Stenosis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Obstruction			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Perforation			
subjects affected / exposed	1 / 133 (0.75%)	0 / 51 (0.00%)	0 / 132 (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	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss Syndrome			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Stenosis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Prolapse			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Stenosis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	1 / 51 (1.96%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Perforation			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Stenosis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth Impacted			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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			
Pustular Psoriasis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson Syndrome			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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			
Acute Kidney Injury			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End Stage Renal Disease			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	1 / 51 (1.96%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Tubular Necrosis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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			
Adrenal Insufficiency			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.75%)	0 / 51 (0.00%)	0 / 132 (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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Costochondritis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dactylitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	1 / 133 (0.75%)	0 / 51 (0.00%)	0 / 132 (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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Space Narrowing			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	1 / 133 (0.75%)	0 / 51 (0.00%)	0 / 132 (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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Osteoarthritis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Stenosis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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			
Abdominal Abscess			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Infection			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess Intestinal			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acarodermatitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Sinusitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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	1 / 133 (0.75%)	0 / 51 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Fistula Infection			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	2 / 132 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	1 / 132 (0.76%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter Gastroenteritis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Colitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus Colitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Viraemia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	1 / 132 (0.76%)
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 Infectious Mononucleosis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 133 (0.00%)	1 / 51 (1.96%)	0 / 132 (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
Liver Abscess			
subjects affected / exposed	1 / 133 (0.75%)	0 / 51 (0.00%)	0 / 132 (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
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myringitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic Herpes Zoster			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal Abscess			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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	2 / 133 (1.50%)	0 / 51 (0.00%)	0 / 132 (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
Pneumonia Pneumococcal			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Staphylococcal			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Wound Infection			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	1 / 132 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous Colitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Abscess			

subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialoadenitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubo-Ovarian Abscess			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Abscess			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 Device Infection			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Abscess			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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 / 133 (0.00%)	0 / 51 (0.00%)	0 / 132 (0.00%)
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	UST-I-Rsp-UST 90 mg SC Q12W/Q8W Maintenance	UST-I-Rsp-UST-90 mg Q8W Maintenance	UST IV-I-Rsp-UST-90mg Maintenance-UST-90mg SC Q8W Maintenance
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 29 (17.24%)	13 / 131 (9.92%)	6 / 29 (20.69%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Thyroid Gland			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Myeloid Leukaemia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Adenocarcinoma			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of Breast			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo Maligna			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Adenoma			
subjects affected / exposed	0 / 29 (0.00%)	1 / 131 (0.76%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic Carcinoma			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary Thyroid Cancer			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Cell Carcinoma			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seminoma			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Intestine Adenocarcinoma			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Dissection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Stenosis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential Hypertension			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Urgency			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abdominal Hernia Repair			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileostomy Closure			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee Arthroplasty			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Pouch Procedure			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Repair			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature Delivery			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature Labour			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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			
Asthenia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysplasia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Incarcerated Hernia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Death			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Breast Prosthesis User			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Miscarriage of Partner			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Abuser			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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			
Adenomyosis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholin's Cyst			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female Genital Tract Fistula			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menorrhagia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Congestion			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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			
Asphyxia			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal Polyps			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Granuloma			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Haematoma			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood Electrolytes Abnormal			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram Abnormal			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecal Volume Increased			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Enzyme Increased			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin Increased			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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			
Alcohol Poisoning			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic Transfusion Reaction			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic Haemorrhage			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic Leak			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Anastomotic Stenosis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heat Stroke			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Anastomosis Complication			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Rupture			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Sprain			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Injury			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Intestinal Perforation			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal Injury			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Fibrous Dysplasia of Bone			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aortic Valve Incompetence			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-Respiratory Arrest			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral Infarction			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia with Lewy Bodies			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic Intracranial Hypertension			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial Aneurysm			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 29 (0.00%)	1 / 131 (0.76%)	0 / 29 (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
Paraesthesia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid Haemorrhage			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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			
Chorioretinopathy			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Adhesions			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Discomfort			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Hernia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 131 (0.76%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Lower			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Fistula			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Dysplasia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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	3 / 29 (10.34%)	4 / 131 (3.05%)	3 / 29 (10.34%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyclic Vomiting Syndrome			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous Fistula			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiploic Appendagitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula of Small Intestine			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Stenosis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory Bowel Disease			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Perforation			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Stenosis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Obstruction			
subjects affected / exposed	0 / 29 (0.00%)	1 / 131 (0.76%)	0 / 29 (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
Large Intestinal Stenosis			
subjects affected / exposed	0 / 29 (0.00%)	2 / 131 (1.53%)	0 / 29 (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
Large Intestine Perforation			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss Syndrome			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Stenosis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Prolapse			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Stenosis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	1 / 131 (0.76%)	0 / 29 (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
Small Intestinal Perforation			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Stenosis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth Impacted			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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			
Pustular Psoriasis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson Syndrome			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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			
Acute Kidney Injury			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End Stage Renal Disease			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Tubular Necrosis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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			
Adrenal Insufficiency			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dactylitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Space Narrowing			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	1 / 29 (3.45%)	0 / 131 (0.00%)	0 / 29 (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
Spinal Osteoarthritis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Stenosis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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			
Abdominal Abscess			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Infection			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess Intestinal			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acarodermatitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Sinusitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Fistula Infection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter Gastroenteritis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Colitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus Colitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Viraemia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Viral			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Infectious Mononucleosis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver Abscess			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myringitis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic Herpes Zoster			
subjects affected / exposed	0 / 29 (0.00%)	1 / 131 (0.76%)	0 / 29 (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
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal Abscess			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 131 (0.00%)	0 / 29 (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	0 / 29 (0.00%)	1 / 131 (0.76%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Pneumococcal			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Staphylococcal			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Wound Infection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous Colitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Abscess			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialoadenitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubo-Ovarian Abscess			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Abscess			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 Device Infection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	1 / 131 (0.76%)	0 / 29 (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
Wound Abscess			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 / 29 (0.00%)	0 / 131 (0.00%)	0 / 29 (0.00%)
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 (PBO)-I-Rsp PBO Maintenance	PBO-I-nonRsp- UST-130mg Intravenous/90mg SC Q12W Maintenance	UST IV-I-nonRsp - UST-90 mg SC Q8W Maintenance
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 123 (15.45%)	47 / 285 (16.49%)	77 / 476 (16.18%)
number of deaths (all causes)	0	0	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Thyroid Gland			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Myeloid Leukaemia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Adenocarcinoma			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of Breast			

subjects affected / exposed	1 / 123 (0.81%)	0 / 285 (0.00%)	0 / 476 (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
Lentigo Maligna			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Adenoma			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic Carcinoma			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary Thyroid Cancer			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Cell Carcinoma			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seminoma			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Intestine Adenocarcinoma			

subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Uterine Leiomyoma			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Dissection			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Stenosis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	1 / 285 (0.35%)	2 / 476 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential Hypertension			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Urgency			

subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abdominal Hernia Repair			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileostomy Closure			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee Arthroplasty			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Pouch Procedure			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Repair			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature Delivery			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Premature Labour			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
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			
Asthenia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysplasia			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Incarcerated Hernia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	2 / 476 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sudden Death			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Breast Prosthesis User			
subjects affected / exposed	1 / 123 (0.81%)	0 / 285 (0.00%)	0 / 476 (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
Miscarriage of Partner			
subjects affected / exposed	1 / 123 (0.81%)	0 / 285 (0.00%)	0 / 476 (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 Abuser			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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			
Adenomyosis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholin's Cyst			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female Genital Tract Fistula			

subjects affected / exposed	1 / 123 (0.81%)	0 / 285 (0.00%)	0 / 476 (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
Menorrhagia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Congestion			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal Polyps			
subjects affected / exposed	1 / 123 (0.81%)	0 / 285 (0.00%)	0 / 476 (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
Pulmonary Embolism			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Granuloma			

subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Haematoma			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	1 / 285 (0.35%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 123 (0.81%)	1 / 285 (0.35%)	0 / 476 (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
Investigations			

Blood Electrolytes Abnormal			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram Abnormal			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecal Volume Increased			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Enzyme Increased			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Troponin Increased			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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			
Alcohol Poisoning			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic Transfusion Reaction			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic Haemorrhage			
subjects affected / exposed	1 / 123 (0.81%)	0 / 285 (0.00%)	0 / 476 (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

Anastomotic Leak			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Forearm Fracture			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Anastomotic Stenosis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heat Stroke			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Anastomosis Complication			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Rupture			

subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Sprain			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Meniscus Injury			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Injury			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Intestinal Perforation			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal Injury			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic Vertebral Fracture			

subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Fibrous Dysplasia of Bone			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Valve Incompetence			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Cardio-Respiratory Arrest			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Coronary Artery Disease			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral Infarction			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia with Lewy Bodies			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic Intracranial Hypertension			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial Aneurysm			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			

subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Subarachnoid Haemorrhage			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Lymphadenitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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			
Chorioretinopathy			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Adhesions			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Discomfort			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
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 Hernia			

subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Lower			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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	1 / 123 (0.81%)	0 / 285 (0.00%)	0 / 476 (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
Anal Fistula			
subjects affected / exposed	0 / 123 (0.00%)	2 / 285 (0.70%)	0 / 476 (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
Colitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Dysplasia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 123 (0.81%)	0 / 285 (0.00%)	0 / 476 (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	6 / 123 (4.88%)	15 / 285 (5.26%)	30 / 476 (6.30%)
occurrences causally related to treatment / all	0 / 6	0 / 15	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyclic Vomiting Syndrome			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous Fistula			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Enterovesical Fistula			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiploic Appendagitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			

subjects affected / exposed	0 / 123 (0.00%)	2 / 285 (0.70%)	0 / 476 (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
Fistula of Small Intestine			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Stenosis			

subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory Bowel Disease			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Perforation			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Stenosis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	2 / 476 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Perforation			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss Syndrome			
subjects affected / exposed	1 / 123 (0.81%)	0 / 285 (0.00%)	0 / 476 (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
Melaena			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Stenosis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Prolapse			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Stenosis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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	1 / 123 (0.81%)	2 / 285 (0.70%)	10 / 476 (2.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Perforation			

subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Stenosis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth Impacted			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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			
Pustular Psoriasis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson Syndrome			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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			
Acute Kidney Injury			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End Stage Renal Disease			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Tubular Necrosis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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			
Adrenal Insufficiency			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Costochondritis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dactylitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Space Narrowing			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			

subjects affected / exposed	1 / 123 (0.81%)	0 / 285 (0.00%)	0 / 476 (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
Spinal Osteoarthritis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Stenosis			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Infections and infestations			
Abdominal Abscess			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Infection			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess Intestinal			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acarodermatitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Sinusitis			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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 Abscess			

subjects affected / exposed	1 / 123 (0.81%)	3 / 285 (1.05%)	3 / 476 (0.63%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Fistula Infection			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Campylobacter Gastroenteritis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Colitis			
subjects affected / exposed	1 / 123 (0.81%)	1 / 285 (0.35%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			

subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus Colitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Viraemia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	1 / 285 (0.35%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
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 Infectious Mononucleosis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver Abscess			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myringitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic Herpes Zoster			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal Abscess			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Pneumococcal			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Staphylococcal			
subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Postoperative Abscess			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Wound Infection			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous Colitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Abscess			

subjects affected / exposed	0 / 123 (0.00%)	1 / 285 (0.35%)	0 / 476 (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
Sepsis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialoadenitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubo-Ovarian Abscess			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Abscess			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 Device Infection			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	1 / 476 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Abscess			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	0 / 285 (0.00%)	0 / 476 (0.00%)
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 / 123 (0.00%)	2 / 285 (0.70%)	0 / 476 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo Long Term Extension (LTE)	UST 90 mg SC Q12W LTE	UST 90 mg SC Q8W LTE
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 151 (17.22%)	68 / 213 (31.92%)	99 / 354 (27.97%)
number of deaths (all causes)	0	2	4
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Thyroid Gland			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Myeloid Leukaemia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Adenocarcinoma			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of Breast			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo Maligna			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 Adenoma			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic Carcinoma			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Papillary Thyroid Cancer			
subjects affected / exposed	1 / 151 (0.66%)	0 / 213 (0.00%)	0 / 354 (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 Cell Carcinoma			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seminoma			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
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 Intestine Adenocarcinoma			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	1 / 213 (0.47%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Dissection			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Stenosis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			

subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	2 / 354 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential Hypertension			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	1 / 213 (0.47%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Urgency			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abdominal Hernia Repair			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Ileostomy Closure			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Knee Arthroplasty			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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 Pouch Procedure			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Repair			

subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 151 (0.00%)	3 / 213 (1.41%)	3 / 354 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature Delivery			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Premature Labour			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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			
Asthenia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysplasia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated Hernia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	0 / 213 (0.00%)	2 / 354 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	0 / 213 (0.00%)	2 / 354 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Death			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Breast Prosthesis User			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Miscarriage of Partner			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Substance Abuser			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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			
Adenomyosis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholin's Cyst			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female Genital Tract Fistula			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Menorrhagia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Congestion			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Prolapse			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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			
Asphyxia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Chronic Obstructive Pulmonary Disease			

subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal Polyps			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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	1 / 151 (0.66%)	1 / 213 (0.47%)	0 / 354 (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
Pulmonary Granuloma			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Haematoma			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 151 (0.66%)	0 / 213 (0.00%)	0 / 354 (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
Hallucination			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			

subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Hepatobiliary disorders			
Bile Duct Stone			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
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 / 151 (0.00%)	0 / 213 (0.00%)	3 / 354 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood Electrolytes Abnormal			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram Abnormal			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecal Volume Increased			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Enzyme Increased			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin Increased			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
Alcohol Poisoning			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic Transfusion Reaction			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic Haemorrhage			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic Leak			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Contusion			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Anastomotic Stenosis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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

Heat Stroke			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Anastomosis Complication			
subjects affected / exposed	1 / 151 (0.66%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Rupture			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Sprain			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Muscle Injury			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Intestinal Perforation			
subjects affected / exposed	1 / 151 (0.66%)	0 / 213 (0.00%)	0 / 354 (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
Procedural Pain			

subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal Injury			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Fibrous Dysplasia of Bone			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	1 / 151 (0.66%)	2 / 213 (0.94%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Aortic Valve Incompetence			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial Fibrillation			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-Respiratory Arrest			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Cardiomyopathy			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	2 / 213 (0.94%)	0 / 354 (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
Myocardial Infarction			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Nervous system disorders			
Cerebral Infarction			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia with Lewy Bodies			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Headache			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic Intracranial Hypertension			

subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial Aneurysm			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Radiculopathy			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid Haemorrhage			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	0 / 213 (0.00%)	2 / 354 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Chorioretinopathy			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			

subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Adhesions			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
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 Discomfort			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 Hernia			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain			
subjects affected / exposed	2 / 151 (1.32%)	1 / 213 (0.47%)	5 / 354 (1.41%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Lower			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Fissure			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 Fistula			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 Dysplasia			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Constipation			
subjects affected / exposed	1 / 151 (0.66%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's Disease			
subjects affected / exposed	12 / 151 (7.95%)	17 / 213 (7.98%)	32 / 354 (9.04%)
occurrences causally related to treatment / all	0 / 14	2 / 22	0 / 46
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyclic Vomiting Syndrome			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Dysphagia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous Fistula			

subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiploic Appendagitis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Faecaloma			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula of Small Intestine			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 151 (0.00%)	3 / 213 (1.41%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			

subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Haematochezia			
subjects affected / exposed	1 / 151 (0.66%)	1 / 213 (0.47%)	0 / 354 (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
Haemorrhoidal Haemorrhage			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Stenosis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory Bowel Disease			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	1 / 151 (0.66%)	1 / 213 (0.47%)	0 / 354 (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
Intestinal Perforation			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Stenosis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	2 / 354 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			

subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
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 Intestine Perforation			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss Syndrome			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Oesophageal Stenosis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
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 Prolapse			

subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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 Stenosis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
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	4 / 151 (2.65%)	6 / 213 (2.82%)	10 / 354 (2.82%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Perforation			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Stenosis			
subjects affected / exposed	1 / 151 (0.66%)	1 / 213 (0.47%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth Impacted			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pustular Psoriasis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson Syndrome			

subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
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			
Acute Kidney Injury			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End Stage Renal Disease			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nephrolithiasis			
subjects affected / exposed	1 / 151 (0.66%)	2 / 213 (0.94%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 Tubular Necrosis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			

Adrenal Insufficiency			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dactylitis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Fibromyalgia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Space Narrowing			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	1 / 213 (0.47%)	3 / 354 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Osteoarthritis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Stenosis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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			
Abdominal Abscess			
subjects affected / exposed	0 / 151 (0.00%)	2 / 213 (0.94%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Infection			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess Intestinal			

subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Acarodermatitis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Acute Sinusitis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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	1 / 151 (0.66%)	6 / 213 (2.82%)	3 / 354 (0.85%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Fistula Infection			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter Gastroenteritis			

subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 151 (0.00%)	2 / 213 (0.94%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			
subjects affected / exposed	1 / 151 (0.66%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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 Colitis			
subjects affected / exposed	1 / 151 (0.66%)	0 / 213 (0.00%)	0 / 354 (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
Cytomegalovirus Viraemia			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	2 / 354 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	1 / 151 (0.66%)	1 / 213 (0.47%)	2 / 354 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
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 Infectious Mononucleosis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver Abscess			
subjects affected / exposed	1 / 151 (0.66%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Mastitis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Myringitis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Ophthalmic Herpes Zoster			

subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Perirectal Abscess			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	2 / 354 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 / 151 (0.00%)	2 / 213 (0.94%)	2 / 354 (0.56%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Pneumococcal			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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 Staphylococcal			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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	1 / 151 (0.66%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Wound Infection			

subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous Colitis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Pyelonephritis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	2 / 354 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Abscess			
subjects affected / exposed	1 / 151 (0.66%)	0 / 213 (0.00%)	0 / 354 (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
Sepsis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic Shock			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Sialoadenitis			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Tonsillitis			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubo-Ovarian Abscess			

subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Vaginal Abscess			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
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 Device Infection			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Viral Infection			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Abscess			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 151 (0.00%)	2 / 213 (0.94%)	3 / 354 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	1 / 151 (0.66%)	0 / 213 (0.00%)	1 / 354 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	0 / 354 (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
Malnutrition			
subjects affected / exposed	0 / 151 (0.00%)	0 / 213 (0.00%)	0 / 354 (0.00%)
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	Ustekinumab Induction Responders(UST-I-Rsp)Placebo Maintenance	UST-I-Rsp -PBO Maintenance-UST-90mg SC Q8W Maintenance	UST-I-Rsp-UST-90 mg Every 12 Weeks (Q12W) Maintenance
Total subjects affected by non-serious adverse events			
subjects affected / exposed	94 / 133 (70.68%)	34 / 51 (66.67%)	88 / 132 (66.67%)
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 133 (0.75%)	1 / 51 (1.96%)	1 / 132 (0.76%)
occurrences (all)	1	1	1
Nervous system disorders			
Headache			
subjects affected / exposed	15 / 133 (11.28%)	6 / 51 (11.76%)	15 / 132 (11.36%)
occurrences (all)	40	7	19
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 51 (0.00%)	5 / 132 (3.79%)
occurrences (all)	0	0	5
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	6 / 133 (4.51%)	2 / 51 (3.92%)	8 / 132 (6.06%)
occurrences (all)	6	2	8
Injection Site Erythema			
subjects affected / exposed	0 / 133 (0.00%)	1 / 51 (1.96%)	1 / 132 (0.76%)
occurrences (all)	0	1	1
Pyrexia			

subjects affected / exposed	11 / 133 (8.27%)	2 / 51 (3.92%)	11 / 132 (8.33%)
occurrences (all)	18	2	23
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	17 / 133 (12.78%)	3 / 51 (5.88%)	12 / 132 (9.09%)
occurrences (all)	26	3	17
Abdominal Pain Upper			
subjects affected / exposed	3 / 133 (2.26%)	1 / 51 (1.96%)	4 / 132 (3.03%)
occurrences (all)	5	1	4
Constipation			
subjects affected / exposed	4 / 133 (3.01%)	1 / 51 (1.96%)	6 / 132 (4.55%)
occurrences (all)	4	1	11
Crohn's Disease			
subjects affected / exposed	12 / 133 (9.02%)	5 / 51 (9.80%)	12 / 132 (9.09%)
occurrences (all)	12	5	12
Diarrhoea			
subjects affected / exposed	7 / 133 (5.26%)	2 / 51 (3.92%)	11 / 132 (8.33%)
occurrences (all)	11	2	11
Gastrooesophageal Reflux Disease			
subjects affected / exposed	2 / 133 (1.50%)	2 / 51 (3.92%)	1 / 132 (0.76%)
occurrences (all)	2	2	1
Nausea			
subjects affected / exposed	9 / 133 (6.77%)	3 / 51 (5.88%)	10 / 132 (7.58%)
occurrences (all)	12	3	10
Vomiting			
subjects affected / exposed	9 / 133 (6.77%)	3 / 51 (5.88%)	5 / 132 (3.79%)
occurrences (all)	11	4	7
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 133 (2.26%)	1 / 51 (1.96%)	4 / 132 (3.03%)
occurrences (all)	4	1	5
Oropharyngeal Pain			
subjects affected / exposed	4 / 133 (3.01%)	2 / 51 (3.92%)	2 / 132 (1.52%)
occurrences (all)	4	3	3
Skin and subcutaneous tissue disorders			

Acne			
subjects affected / exposed	1 / 133 (0.75%)	3 / 51 (5.88%)	1 / 132 (0.76%)
occurrences (all)	2	4	2
Rash			
subjects affected / exposed	5 / 133 (3.76%)	2 / 51 (3.92%)	4 / 132 (3.03%)
occurrences (all)	5	2	4
Urticaria			
subjects affected / exposed	1 / 133 (0.75%)	0 / 51 (0.00%)	2 / 132 (1.52%)
occurrences (all)	1	0	2
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 133 (0.75%)	1 / 51 (1.96%)	2 / 132 (1.52%)
occurrences (all)	1	1	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	18 / 133 (13.53%)	6 / 51 (11.76%)	22 / 132 (16.67%)
occurrences (all)	24	7	25
Arthritis			
subjects affected / exposed	3 / 133 (2.26%)	0 / 51 (0.00%)	3 / 132 (2.27%)
occurrences (all)	3	0	3
Back Pain			
subjects affected / exposed	6 / 133 (4.51%)	2 / 51 (3.92%)	5 / 132 (3.79%)
occurrences (all)	6	2	5
Pain in Extremity			
subjects affected / exposed	0 / 133 (0.00%)	1 / 51 (1.96%)	0 / 132 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	4 / 133 (3.01%)	3 / 51 (5.88%)	1 / 132 (0.76%)
occurrences (all)	4	4	1
Gastroenteritis			
subjects affected / exposed	5 / 133 (3.76%)	1 / 51 (1.96%)	3 / 132 (2.27%)
occurrences (all)	6	1	3
Gastroenteritis Viral			
subjects affected / exposed	1 / 133 (0.75%)	3 / 51 (5.88%)	4 / 132 (3.03%)
occurrences (all)	1	4	4

Influenza			
subjects affected / exposed	4 / 133 (3.01%)	1 / 51 (1.96%)	8 / 132 (6.06%)
occurrences (all)	4	1	9
Nasopharyngitis			
subjects affected / exposed	10 / 133 (7.52%)	4 / 51 (7.84%)	17 / 132 (12.88%)
occurrences (all)	11	8	24
Pharyngitis Streptococcal			
subjects affected / exposed	2 / 133 (1.50%)	0 / 51 (0.00%)	0 / 132 (0.00%)
occurrences (all)	2	0	0
Sinusitis			
subjects affected / exposed	2 / 133 (1.50%)	0 / 51 (0.00%)	6 / 132 (4.55%)
occurrences (all)	2	0	8
Upper Respiratory Tract Infection			
subjects affected / exposed	21 / 133 (15.79%)	1 / 51 (1.96%)	9 / 132 (6.82%)
occurrences (all)	25	1	12
Urinary Tract Infection			
subjects affected / exposed	3 / 133 (2.26%)	1 / 51 (1.96%)	9 / 132 (6.82%)
occurrences (all)	3	1	11

Non-serious adverse events	UST-I-Rsp-UST 90 mg SC Q12W/Q8W Maintenance	UST-I-Rsp-UST-90 mg Q8W Maintenance	UST IV-I-Rsp-UST-90mg Maintenance-UST-90mg SC Q8W Maintenance
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 29 (68.97%)	84 / 131 (64.12%)	18 / 29 (62.07%)
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 29 (6.90%)	1 / 131 (0.76%)	0 / 29 (0.00%)
occurrences (all)	2	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 29 (6.90%)	15 / 131 (11.45%)	2 / 29 (6.90%)
occurrences (all)	2	23	2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 29 (3.45%)	3 / 131 (2.29%)	0 / 29 (0.00%)
occurrences (all)	1	4	0
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	1 / 29 (3.45%)	6 / 131 (4.58%)	0 / 29 (0.00%)
occurrences (all)	1	6	0
Injection Site Erythema			
subjects affected / exposed	1 / 29 (3.45%)	7 / 131 (5.34%)	1 / 29 (3.45%)
occurrences (all)	1	14	2
Pyrexia			
subjects affected / exposed	3 / 29 (10.34%)	9 / 131 (6.87%)	1 / 29 (3.45%)
occurrences (all)	8	11	1
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	5 / 29 (17.24%)	11 / 131 (8.40%)	1 / 29 (3.45%)
occurrences (all)	7	13	1
Abdominal Pain Upper			
subjects affected / exposed	1 / 29 (3.45%)	2 / 131 (1.53%)	2 / 29 (6.90%)
occurrences (all)	1	2	3
Constipation			
subjects affected / exposed	2 / 29 (6.90%)	3 / 131 (2.29%)	0 / 29 (0.00%)
occurrences (all)	2	3	0
Crohn's Disease			
subjects affected / exposed	3 / 29 (10.34%)	12 / 131 (9.16%)	2 / 29 (6.90%)
occurrences (all)	4	13	2
Diarrhoea			
subjects affected / exposed	1 / 29 (3.45%)	5 / 131 (3.82%)	0 / 29 (0.00%)
occurrences (all)	1	9	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 29 (0.00%)	1 / 131 (0.76%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	3 / 29 (10.34%)	4 / 131 (3.05%)	1 / 29 (3.45%)
occurrences (all)	4	4	1
Vomiting			
subjects affected / exposed	2 / 29 (6.90%)	4 / 131 (3.05%)	2 / 29 (6.90%)
occurrences (all)	2	4	2
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 29 (0.00%)	7 / 131 (5.34%)	0 / 29 (0.00%)
occurrences (all)	0	7	0
Oropharyngeal Pain			
subjects affected / exposed	2 / 29 (6.90%)	3 / 131 (2.29%)	1 / 29 (3.45%)
occurrences (all)	2	4	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 29 (0.00%)	2 / 131 (1.53%)	1 / 29 (3.45%)
occurrences (all)	0	2	1
Rash			
subjects affected / exposed	1 / 29 (3.45%)	7 / 131 (5.34%)	2 / 29 (6.90%)
occurrences (all)	2	7	3
Urticaria			
subjects affected / exposed	0 / 29 (0.00%)	0 / 131 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 29 (6.90%)	0 / 131 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 29 (17.24%)	18 / 131 (13.74%)	3 / 29 (10.34%)
occurrences (all)	5	20	3
Arthritis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 131 (0.76%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Back Pain			
subjects affected / exposed	1 / 29 (3.45%)	6 / 131 (4.58%)	3 / 29 (10.34%)
occurrences (all)	1	8	3
Pain in Extremity			
subjects affected / exposed	1 / 29 (3.45%)	5 / 131 (3.82%)	1 / 29 (3.45%)
occurrences (all)	1	5	1
Infections and infestations			
Bronchitis			

subjects affected / exposed	0 / 29 (0.00%)	6 / 131 (4.58%)	0 / 29 (0.00%)
occurrences (all)	0	8	0
Gastroenteritis			
subjects affected / exposed	0 / 29 (0.00%)	4 / 131 (3.05%)	0 / 29 (0.00%)
occurrences (all)	0	5	0
Gastroenteritis Viral			
subjects affected / exposed	0 / 29 (0.00%)	4 / 131 (3.05%)	2 / 29 (6.90%)
occurrences (all)	0	5	2
Influenza			
subjects affected / exposed	1 / 29 (3.45%)	5 / 131 (3.82%)	1 / 29 (3.45%)
occurrences (all)	1	7	1
Nasopharyngitis			
subjects affected / exposed	4 / 29 (13.79%)	14 / 131 (10.69%)	0 / 29 (0.00%)
occurrences (all)	5	22	0
Pharyngitis Streptococcal			
subjects affected / exposed	1 / 29 (3.45%)	0 / 131 (0.00%)	2 / 29 (6.90%)
occurrences (all)	1	0	2
Sinusitis			
subjects affected / exposed	2 / 29 (6.90%)	4 / 131 (3.05%)	2 / 29 (6.90%)
occurrences (all)	2	4	2
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 29 (0.00%)	13 / 131 (9.92%)	1 / 29 (3.45%)
occurrences (all)	0	14	1
Urinary Tract Infection			
subjects affected / exposed	1 / 29 (3.45%)	4 / 131 (3.05%)	1 / 29 (3.45%)
occurrences (all)	1	4	1

Non-serious adverse events	Placebo (PBO)-I-Rsp PBO Maintenance	PBO-I-nonRsp- UST-130mg Intravenous/90mg SC Q12W Maintenance	UST IV-I-nonRsp - UST-90 mg SC Q8W Maintenance
Total subjects affected by non-serious adverse events			
subjects affected / exposed	82 / 123 (66.67%)	160 / 285 (56.14%)	275 / 476 (57.77%)
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 123 (1.63%)	1 / 285 (0.35%)	5 / 476 (1.05%)
occurrences (all)	2	1	6

Nervous system disorders			
Headache			
subjects affected / exposed	16 / 123 (13.01%)	21 / 285 (7.37%)	41 / 476 (8.61%)
occurrences (all)	20	23	58
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 123 (4.07%)	6 / 285 (2.11%)	11 / 476 (2.31%)
occurrences (all)	6	6	11
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	9 / 123 (7.32%)	11 / 285 (3.86%)	15 / 476 (3.15%)
occurrences (all)	10	14	16
Injection Site Erythema			
subjects affected / exposed	2 / 123 (1.63%)	5 / 285 (1.75%)	7 / 476 (1.47%)
occurrences (all)	2	5	11
Pyrexia			
subjects affected / exposed	12 / 123 (9.76%)	16 / 285 (5.61%)	25 / 476 (5.25%)
occurrences (all)	25	16	30
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	15 / 123 (12.20%)	23 / 285 (8.07%)	38 / 476 (7.98%)
occurrences (all)	16	27	44
Abdominal Pain Upper			
subjects affected / exposed	5 / 123 (4.07%)	8 / 285 (2.81%)	15 / 476 (3.15%)
occurrences (all)	8	9	17
Constipation			
subjects affected / exposed	0 / 123 (0.00%)	6 / 285 (2.11%)	10 / 476 (2.10%)
occurrences (all)	0	7	10
Crohn's Disease			
subjects affected / exposed	13 / 123 (10.57%)	17 / 285 (5.96%)	40 / 476 (8.40%)
occurrences (all)	20	19	54
Diarrhoea			
subjects affected / exposed	11 / 123 (8.94%)	10 / 285 (3.51%)	12 / 476 (2.52%)
occurrences (all)	12	11	13
Gastrooesophageal Reflux Disease			

subjects affected / exposed	2 / 123 (1.63%)	4 / 285 (1.40%)	7 / 476 (1.47%)
occurrences (all)	3	4	7
Nausea			
subjects affected / exposed	12 / 123 (9.76%)	15 / 285 (5.26%)	46 / 476 (9.66%)
occurrences (all)	16	18	53
Vomiting			
subjects affected / exposed	5 / 123 (4.07%)	6 / 285 (2.11%)	33 / 476 (6.93%)
occurrences (all)	5	6	46
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 123 (4.88%)	9 / 285 (3.16%)	26 / 476 (5.46%)
occurrences (all)	7	10	28
Oropharyngeal Pain			
subjects affected / exposed	2 / 123 (1.63%)	8 / 285 (2.81%)	13 / 476 (2.73%)
occurrences (all)	2	8	13
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 123 (0.00%)	5 / 285 (1.75%)	7 / 476 (1.47%)
occurrences (all)	0	5	7
Rash			
subjects affected / exposed	5 / 123 (4.07%)	5 / 285 (1.75%)	22 / 476 (4.62%)
occurrences (all)	5	5	24
Urticaria			
subjects affected / exposed	2 / 123 (1.63%)	2 / 285 (0.70%)	3 / 476 (0.63%)
occurrences (all)	2	2	3
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 123 (0.00%)	4 / 285 (1.40%)	3 / 476 (0.63%)
occurrences (all)	0	6	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	23 / 123 (18.70%)	29 / 285 (10.18%)	49 / 476 (10.29%)
occurrences (all)	34	38	55
Arthritis			
subjects affected / exposed	8 / 123 (6.50%)	7 / 285 (2.46%)	3 / 476 (0.63%)
occurrences (all)	9	8	3

Back Pain			
subjects affected / exposed	2 / 123 (1.63%)	12 / 285 (4.21%)	15 / 476 (3.15%)
occurrences (all)	2	12	21
Pain in Extremity			
subjects affected / exposed	0 / 123 (0.00%)	4 / 285 (1.40%)	6 / 476 (1.26%)
occurrences (all)	0	4	7
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 123 (2.44%)	5 / 285 (1.75%)	7 / 476 (1.47%)
occurrences (all)	3	5	7
Gastroenteritis			
subjects affected / exposed	4 / 123 (3.25%)	8 / 285 (2.81%)	18 / 476 (3.78%)
occurrences (all)	4	11	22
Gastroenteritis Viral			
subjects affected / exposed	5 / 123 (4.07%)	6 / 285 (2.11%)	6 / 476 (1.26%)
occurrences (all)	6	7	8
Influenza			
subjects affected / exposed	4 / 123 (3.25%)	9 / 285 (3.16%)	8 / 476 (1.68%)
occurrences (all)	4	9	8
Nasopharyngitis			
subjects affected / exposed	15 / 123 (12.20%)	32 / 285 (11.23%)	52 / 476 (10.92%)
occurrences (all)	20	44	70
Pharyngitis Streptococcal			
subjects affected / exposed	2 / 123 (1.63%)	3 / 285 (1.05%)	1 / 476 (0.21%)
occurrences (all)	2	3	1
Sinusitis			
subjects affected / exposed	5 / 123 (4.07%)	12 / 285 (4.21%)	17 / 476 (3.57%)
occurrences (all)	6	13	22
Upper Respiratory Tract Infection			
subjects affected / exposed	7 / 123 (5.69%)	25 / 285 (8.77%)	33 / 476 (6.93%)
occurrences (all)	9	28	40
Urinary Tract Infection			
subjects affected / exposed	7 / 123 (5.69%)	5 / 285 (1.75%)	17 / 476 (3.57%)
occurrences (all)	8	7	18

Non-serious adverse events	Placebo Long Term Extension (LTE)	UST 90 mg SC Q12W LTE	UST 90 mg SC Q8W LTE

Total subjects affected by non-serious adverse events			
subjects affected / exposed	83 / 151 (54.97%)	162 / 213 (76.06%)	293 / 354 (82.77%)
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	5 / 151 (3.31%)	5 / 213 (2.35%)	5 / 354 (1.41%)
occurrences (all)	5	5	5
Nervous system disorders			
Headache			
subjects affected / exposed	12 / 151 (7.95%)	19 / 213 (8.92%)	40 / 354 (11.30%)
occurrences (all)	14	25	62
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 151 (1.32%)	15 / 213 (7.04%)	17 / 354 (4.80%)
occurrences (all)	2	23	21
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 151 (5.30%)	13 / 213 (6.10%)	29 / 354 (8.19%)
occurrences (all)	8	14	34
Injection Site Erythema			
subjects affected / exposed	1 / 151 (0.66%)	7 / 213 (3.29%)	7 / 354 (1.98%)
occurrences (all)	1	7	17
Pyrexia			
subjects affected / exposed	9 / 151 (5.96%)	19 / 213 (8.92%)	19 / 354 (5.37%)
occurrences (all)	10	25	26
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	16 / 151 (10.60%)	38 / 213 (17.84%)	68 / 354 (19.21%)
occurrences (all)	17	51	111
Abdominal Pain Upper			
subjects affected / exposed	8 / 151 (5.30%)	11 / 213 (5.16%)	22 / 354 (6.21%)
occurrences (all)	10	11	25
Constipation			
subjects affected / exposed	0 / 151 (0.00%)	9 / 213 (4.23%)	22 / 354 (6.21%)
occurrences (all)	0	9	30
Crohn's Disease			

subjects affected / exposed	25 / 151 (16.56%)	44 / 213 (20.66%)	80 / 354 (22.60%)
occurrences (all)	34	62	113
Diarrhoea			
subjects affected / exposed	11 / 151 (7.28%)	30 / 213 (14.08%)	50 / 354 (14.12%)
occurrences (all)	14	42	67
Gastrooesophageal Reflux Disease			
subjects affected / exposed	2 / 151 (1.32%)	11 / 213 (5.16%)	15 / 354 (4.24%)
occurrences (all)	4	11	15
Nausea			
subjects affected / exposed	12 / 151 (7.95%)	23 / 213 (10.80%)	34 / 354 (9.60%)
occurrences (all)	13	32	43
Vomiting			
subjects affected / exposed	2 / 151 (1.32%)	14 / 213 (6.57%)	26 / 354 (7.34%)
occurrences (all)	2	26	34
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	8 / 151 (5.30%)	13 / 213 (6.10%)	24 / 354 (6.78%)
occurrences (all)	8	17	31
Oropharyngeal Pain			
subjects affected / exposed	0 / 151 (0.00%)	10 / 213 (4.69%)	12 / 354 (3.39%)
occurrences (all)	0	11	19
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	2 / 151 (1.32%)	6 / 213 (2.82%)	9 / 354 (2.54%)
occurrences (all)	2	6	9
Rash			
subjects affected / exposed	5 / 151 (3.31%)	12 / 213 (5.63%)	20 / 354 (5.65%)
occurrences (all)	5	16	29
Urticaria			
subjects affected / exposed	0 / 151 (0.00%)	1 / 213 (0.47%)	2 / 354 (0.56%)
occurrences (all)	0	1	2
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 151 (0.66%)	6 / 213 (2.82%)	12 / 354 (3.39%)
occurrences (all)	1	6	12
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	11 / 151 (7.28%)	27 / 213 (12.68%)	40 / 354 (11.30%)
occurrences (all)	12	37	76
Arthritis			
subjects affected / exposed	1 / 151 (0.66%)	1 / 213 (0.47%)	4 / 354 (1.13%)
occurrences (all)	2	1	4
Back Pain			
subjects affected / exposed	13 / 151 (8.61%)	18 / 213 (8.45%)	48 / 354 (13.56%)
occurrences (all)	13	23	53
Pain in Extremity			
subjects affected / exposed	1 / 151 (0.66%)	9 / 213 (4.23%)	18 / 354 (5.08%)
occurrences (all)	2	9	21
Infections and infestations			
Bronchitis			
subjects affected / exposed	4 / 151 (2.65%)	13 / 213 (6.10%)	30 / 354 (8.47%)
occurrences (all)	4	17	39
Gastroenteritis			
subjects affected / exposed	7 / 151 (4.64%)	21 / 213 (9.86%)	41 / 354 (11.58%)
occurrences (all)	7	27	46
Gastroenteritis Viral			
subjects affected / exposed	2 / 151 (1.32%)	11 / 213 (5.16%)	12 / 354 (3.39%)
occurrences (all)	2	12	14
Influenza			
subjects affected / exposed	4 / 151 (2.65%)	25 / 213 (11.74%)	37 / 354 (10.45%)
occurrences (all)	5	44	44
Nasopharyngitis			
subjects affected / exposed	16 / 151 (10.60%)	54 / 213 (25.35%)	100 / 354 (28.25%)
occurrences (all)	21	130	209
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 151 (0.00%)	2 / 213 (0.94%)	3 / 354 (0.85%)
occurrences (all)	0	2	4
Sinusitis			
subjects affected / exposed	8 / 151 (5.30%)	19 / 213 (8.92%)	36 / 354 (10.17%)
occurrences (all)	9	24	53
Upper Respiratory Tract Infection			

subjects affected / exposed	14 / 151 (9.27%)	40 / 213 (18.78%)	62 / 354 (17.51%)
occurrences (all)	18	69	100
Urinary Tract Infection			
subjects affected / exposed	7 / 151 (4.64%)	15 / 213 (7.04%)	35 / 354 (9.89%)
occurrences (all)	7	23	47

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 December 2011	The overall reason of this amendment was to include clarification that the sponsor tracked all serious adverse events (SAEs) for 20 weeks following the last dose of study agent and correction of the time and events schedule to indicate that subjects should undergo a video ileocolonoscopy with biopsies for ribonucleic acid (RNA) analysis and histology at their early termination visit, as well as some minor editorial changes.
24 June 2014	The overall reason of this amendment was to include clarification of study-related procedures when subjects terminated participation in the study and to specify that subjects discontinuing study agent administration on or after Week 36 should complete the Week 44 visit in addition to a final safety visit.
06 August 2015	The overall reason of this amendment was to extend the long-term extension by 1 year to a total of 4 years after the Week 44 primary endpoint of this study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported