Clinical trial results:
A Phase 3, Randomized, Double-Blind, Study Comparing Upadacitinib (ABT-494) to Placebo and to Adalimumab in Subjects with Active Psoriatic Arthritis Who Have a History of Inadequate Response to at Least One Non-Biologic Disease Modifying Anti-Rheumatic Drug (DMARD) - SELECT - PsA 1

Summary

EudraCT number	2016-004130-24
Trial protocol	SK BE DE CZ GB GR NL PT EE LV LT SI HU ES HR BG IT
Global end of trial date	09 September 2024

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	M15-572

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03104400
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co. KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6 4UB
Public contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.com
Scientific contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.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	09 September 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study includes two periods. The main objective of Period 1 is to compare the efficacy of upadacitinib 15 mg once daily (QD) and 30 mg QD versus placebo and versus adalimumab (Humira®) in participants with moderately to severely active psoriatic arthritis (PsA) who have had an inadequate response to non-biologic DMARDs (DMARD-IR). Period 1 is also designed to compare the efficacy of upadacitinib 15 mg and 30 mg QD versus placebo for the prevention of structural progression.

The objective of Period 2 is to evaluate the long-term safety, tolerability and efficacy of upadacitinib 15 mg and 30 mg QD in participants who have completed Period 1.

The study includes a 35-day screening period, a 56-week blinded period (Period 1), a long-term extension period of up to a total treatment duration of approximately 5 years (Period 2), a 30-day follow-up call or visit, and a 70-day follow-up call.

Protection of trial subjects:

Subjects must voluntarily sign and date an informed consent, approved by an Independent Ethics Committee (IEC)/Institutional Review Board (IRB), prior to the initiation of any screening or study-specific procedures. For subjects in Japan only: if a subject is under 20 years of age, then the subject and their parent or legal guardian must voluntarily sign and date an informed consent.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 April 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 15
Country: Number of subjects enrolled	Argentina: 50
Country: Number of subjects enrolled	Belarus: 15
Country: Number of subjects enrolled	Belgium: 7
Country: Number of subjects enrolled	Bosnia and Herzegovina: 12
Country: Number of subjects enrolled	Brazil: 50
Country: Number of subjects enrolled	Bulgaria: 83
Country: Number of subjects enrolled	Canada: 39
Country: Number of subjects enrolled	Chile: 45
Country: Number of subjects enrolled	Colombia: 16
Country: Number of subjects enrolled	Estonia: 23

Country: Number of subjects enrolled	Greece: 9
Country: Number of subjects enrolled	Hong Kong: 11
Country: Number of subjects enrolled	Hungary: 78
Country: Number of subjects enrolled	Ireland: 1
Country: Number of subjects enrolled	Italy: 15
Country: Number of subjects enrolled	Japan: 15
Country: Number of subjects enrolled	Lithuania: 23
Country: Number of subjects enrolled	Malaysia: 10
Country: Number of subjects enrolled	Netherlands: 9
Country: Number of subjects enrolled	New Zealand: 36
Country: Number of subjects enrolled	Poland: 170
Country: Number of subjects enrolled	Portugal: 21
Country: Number of subjects enrolled	Puerto Rico: 4
Country: Number of subjects enrolled	Russian Federation: 54
Country: Number of subjects enrolled	Slovakia: 39
Country: Number of subjects enrolled	Slovenia: 4
Country: Number of subjects enrolled	South Africa: 66
Country: Number of subjects enrolled	Korea, Republic of: 4
Country: Number of subjects enrolled	Spain: 15
Country: Number of subjects enrolled	Taiwan: 20
Country: Number of subjects enrolled	United Kingdom: 26
Country: Number of subjects enrolled	Ukraine: 134
Country: Number of subjects enrolled	United States: 261
Country: Number of subjects enrolled	Czechia: 52
Country: Number of subjects enrolled	Germany: 45
Country: Number of subjects enrolled	Israel: 12
Country: Number of subjects enrolled	China: 61
Country: Number of subjects enrolled	Croatia: 18
Country: Number of subjects enrolled	Latvia: 26
Country: Number of subjects enrolled	Mexico: 37
Country: Number of subjects enrolled	Serbia: 51
Country: Number of subjects enrolled	Singapore: 10
Country: Number of subjects enrolled	Switzerland: 2
Country: Number of subjects enrolled	Türkiye: 11
Worldwide total number of subjects	1705
EEA total number of subjects	638

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)	1468
From 65 to 84 years	237
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study included a 35-day Screening Period.

Period 1

Period 1 title	Period 1 (Week 1 – 56)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo / Upadacitinib 15 mg

Arm description:

Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks followed by upadacitinib 15 mg once daily for 32 weeks (Weeks 24 to 56), as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 56.

Arm type	Experimental
Investigational medicinal product name	Placebo to Upadacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet

Investigational medicinal product name	Upadacitinib
Investigational medicinal product code	
Other name	ABT 494, RINVOQ®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet

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

Dosage and administration details:

Administered by subcutaneous injection

Arm title	Placebo / Upadacitinib 30 mg

Arm description:

Participants randomized to receive matching placebo to upadacitinib orally QD for 24 weeks followed by upadacitinib 30 mg once daily for 32 weeks (Weeks 24 to 56), in addition to matching placebo to adalimumab administered by subcutaneous injection EOW from Weeks 1 to 56.

Arm type	Experimental

Investigational medicinal product name	Placebo to Upadacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet

Investigational medicinal product name	Upadacitinib
Investigational medicinal product code	
Other name	ABT 494, RINVOQ®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet

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

Dosage and administration details:

Administered by subcutaneous injection

Arm title	Adalimumab 40 mg

Arm description:

Participants randomized to receive adalimumab 40 mg by subcutaneous injection EOW and matching placebo to upadacitinib orally QD for 56 weeks.

Arm type	Experimental
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	Humira®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Placebo to Upadacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet

Arm title	Upadacitinib 15 mg

Arm description:

Participants randomized to receive upadacitinib 15 mg orally QD and matching placebo to adalimumab by subcutaneous injection EOW for 56 weeks.

Arm type	Experimental
Investigational medicinal product name	Upadacitinib
Investigational medicinal product code	
Other name	ABT 494, RINVOQ®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet

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

Dosage and administration details:

Administered by subcutaneous injection

Arm title	Upadacitinib 30 mg

Arm description:

Participants randomized to receive upadacitinib 30 mg orally QD and matching placebo to adalimumab by subcutaneous injection EOW for 56 weeks.

Arm type	Experimental
Investigational medicinal product name	Upadacitinib
Investigational medicinal product code	
Other name	ABT 494, RINVOQ®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet

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

Dosage and administration details:

Administered by subcutaneous injection

Number of subjects in period 1	Placebo / Upadacitinib 15 mg	Placebo / Upadacitinib 30 mg	Adalimumab 40 mg
Started	211	212	429
Completed	177	178	370
Not completed	34	34	59
Adverse event, non-fatal	5	7	11
COVID-19 Logistical Restrictions	-	-	-
Other, not specified	2	3	7
Did not receive study drug	-	-	-
Lost to follow-up	4	1	4
Withdrawal by subject	17	20	29
Lack of efficacy	6	3	8

Number of subjects in period 1	Upadacitinib 15 mg	Upadacitinib 30 mg
Started	430	423
Completed	379	366
Not completed	51	57
Adverse event, non-fatal	9	21

COVID-19 Logistical Restrictions	1	-
Other, not specified	6	4
Did not receive study drug	1	-
Lost to follow-up	8	7
Withdrawal by subject	24	24
Lack of efficacy	2	1

Period 2

Period 2 title	Period 2 (Week 56 - 260)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo / Upadacitinib 15 mg Period 2 (Weeks 56 to 260)

Arm description:

Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks followed by upadacitinib 15 mg orally once a day (QD) for 32 weeks (Weeks 24 to 56), as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 56 in Period 1. During Period 2 (Weeks 56 to 260) participants continued to receive upadacitinib 15 mg orally once a day (QD).

Arm type	Experimental
Investigational medicinal product name	Upadacitinib
Investigational medicinal product code	
Other name	ABT 494, RINVOQ®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet

Arm title	Placebo / Upadacitinib 30 mg Period 2 (Weeks 56 to 260)

Arm description:

Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks followed by upadacitinib 30 mg orally once a day (QD) for 32 weeks (Weeks 24 to 56), as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 56 in Period 1. During Period 2 (Weeks 56 to 260) participants continued to receive upadacitinib 30 mg orally once a day (QD).

Arm type	Experimental
Investigational medicinal product name	Upadacitinib
Investigational medicinal product code	
Other name	ABT 494, RINVOQ®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet

Arm title	Adalimumab 40 mg Period 2 (Weeks 56 to 260)

Arm description:	
Participants randomized to receive adalimumab 40 mg by subcutaneous injection every other week (EOW) and matching placebo to upadacitinib orally once a day (QD) for 56 weeks in Period 1 who continued to receive 40 mg adalimumab EOW in Period 2 (Weeks 56 to 260).	
Arm type	Experimental
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	Humira®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered by subcutaneous injection	
Arm title	Upadacitinib 15 mg Period 2 (Weeks 56 to 260)
Arm description:	
Participants randomized to receive upadacitinib 15 mg orally once a day (QD) and matching placebo to adalimumab by subcutaneous injection EOW for 56 weeks in Period 1 who continued to receive 15 mg upadacitinib QD in Period 2 (Weeks 56 to 260).	
Arm type	Experimental
Investigational medicinal product name	Upadacitinib
Investigational medicinal product code	
Other name	ABT 494, RINVOQ®
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Oral tablet	
Arm title	Upadacitinib 30 mg Period 2 (Weeks 56 to 260)
Arm description:	
Participants randomized to receive upadacitinib 30 mg orally once a day (QD) and matching placebo to adalimumab by subcutaneous injection every other week (EOW) for 56 weeks in Period 1 who continued to receive 30 mg upadacitinib QD in Period 2 (Weeks 56 to 260).	
Arm type	Experimental
Investigational medicinal product name	Upadacitinib
Investigational medicinal product code	
Other name	ABT 494, RINVOQ®
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Oral tablet	

Number of subjects in period 2[1]	Placebo / Upadacitinib 15 mg Period 2 (Weeks 56 to 260)	Placebo / Upadacitinib 30 mg Period 2 (Weeks 56 to 260)	Adalimumab 40 mg Period 2 (Weeks 56 to 260)
Started	177	178	366
Completed	131	121	268
Not completed	46	57	98
Adverse event, non-fatal	14	17	14
COVID-19 Logistical Restrictions	-	-	1
Other, not specified	10	7	17

Unknown	-	-	-
Lost to follow-up	7	6	12
COVID-19 infection	-	2	-
Withdrawal by subject	11	21	45
Lack of efficacy	4	4	9

Number of subjects in period 2[1]	Upadacitinib 15 mg Period 2 (Weeks 56 to 260)	Upadacitinib 30 mg Period 2 (Weeks 56 to 260)
Started	378	365
Completed	272	269
Not completed	106	96
Adverse event, non-fatal	28	28
COVID-19 Logistical Restrictions	1	-
Other, not specified	12	18
Unknown	1	1
Lost to follow-up	12	7
COVID-19 infection	2	3
Withdrawal by subject	44	32
Lack of efficacy	6	7

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: 1,470 subjects completed study Period 1, and 1,464 subjects entered study Period 2.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo / Upadacitinib 15 mg
Reporting group description:	
Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks followed by upadacitinib 15 mg once daily for 32 weeks (Weeks 24 to 56), as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 56.	
Reporting group title	Placebo / Upadacitinib 30 mg
Reporting group description:	
Participants randomized to receive matching placebo to upadacitinib orally QD for 24 weeks followed by upadacitinib 30 mg once daily for 32 weeks (Weeks 24 to 56), in addition to matching placebo to adalimumab administered by subcutaneous injection EOW from Weeks 1 to 56.	
Reporting group title	Adalimumab 40 mg
Reporting group description:	
Participants randomized to receive adalimumab 40 mg by subcutaneous injection EOW and matching placebo to upadacitinib orally QD for 56 weeks.	
Reporting group title	Upadacitinib 15 mg
Reporting group description:	
Participants randomized to receive upadacitinib 15 mg orally QD and matching placebo to adalimumab by subcutaneous injection EOW for 56 weeks.	
Reporting group title	Upadacitinib 30 mg
Reporting group description:	
Participants randomized to receive upadacitinib 30 mg orally QD and matching placebo to adalimumab by subcutaneous injection EOW for 56 weeks.	

Reporting group values	Placebo / Upadacitinib 15 mg	Placebo / Upadacitinib 30 mg	Adalimumab 40 mg
Number of subjects	211	212	429
Age categorical Units: Subjects			
< 65 years	185	182	362
65 - < 75 years	24	28	61
≥75 years	2	2	6
Age continuous Units: years			
arithmetic mean	50.0	50.8	51.4
standard deviation	± 12.25	± 12.18	± 12.04
Gender categorical Units: Subjects			
Female	98	113	222
Male	113	99	207
Ethnicity Units: Subjects			
Hispanic or Latino	29	37	65
Not Hispanic or Latino	182	175	364
Unknown or Not Reported	0	0	0
Race/Ethnicity Units: Subjects			
White	190	187	375
Black or African American	2	1	2
American Indian/ Alaska Native	1	1	2

Native Hawaiian or other Pacific Islander	0	1	2
Asian	16	21	41
Multiple	2	1	7
Extent of Psoriasis			
The extent of psoriasis was measured by the physician as the total body surface area (BSA) involved with psoriasis. For purposes of clinical estimation, the total surface of the participant's palm and five digits was assumed to be approximately equivalent to 1% of BSA.			
Units: Subjects			
< 3% BSA	108	104	218
≥3% BSA	103	108	211
Missing	0	0	0
Current Use of at Least 1 Non- Biologic DMARD Units: Subjects			
Yes	174	173	346
No	37	39	83
Presence of Dactylitis			
Dactylitis is characterized by swelling of the fingers or toes. The Leeds dactylitis index (LDI) is a score based on finger circumference and tenderness, assessed across all digits. The presence of a dactylitic digit is defined as at least 1 affected AND tender digit with circumference increase over reference digit ≥10%. Digit scores are calculated from the ratio of circumference between an affected digit and control digit and the tenderness score; unaffected digits have score = 0. Scores from each digit are summed to provide the final LDI. The presence of dactylitis is defined as LDI > 0.			
Units: Subjects			
Yes	65	61	127
No	146	151	302
Missing	0	0	0
Presence of Enthesitis			
Enthesitis is inflammation of the entheses, the specific point where tendons or ligaments attach to bone. Tenderness at 9 bilateral sites was assessed as present (1) or absent (0). The total enthesitis count is calculated by summing the tenderness scores from all 18 sites (range 0 - 18). Presence of enthesitis is defined as Total Enthesitis Count > 0.			
Units: Subjects			
Yes	161	161	331
No	50	51	98
Missing	0	0	0
Duration of Psoriatic Arthritis Symptoms			
Analysis Population Description: Participants with available data Number of participants analyzed = 428 for the Adalimumab 40 mg group and 429 for the Upadacitinib 15 mg group			
Units: years			
arithmetic mean	9.6	9.0	9.1
standard deviation	± 9.00	± 8.15	± 8.78
Duration of PsA Diagnosis			
Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: years			
arithmetic mean	6.4	6.1	5.9
standard deviation	± 7.39	± 6.63	± 7.06
Tender Joint Count (TJC)			
A total of 68 joints were assessed for the presence or absence of tenderness.			

Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: joints arithmetic mean standard deviation	 20.7 ± 15.67	 19.3 ± 12.89	 20.1 ± 13.82
Swollen Joint Count (SJC)			
A total of 66 joints were assessed for the presence or absence of swelling. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: joints arithmetic mean standard deviation	 11.4 ± 8.47	 10.7 ± 7.85	 11.6 ± 8.75
Patient's Assessment of Pain			
Participants were asked to indicate the severity of their arthritis pain within the previous week on a numeric rating scale (NRS) from 0 to 10. A score of 0 indicates "no pain" and a score of 10 indicates "worst possible pain." Analysis Population Description: Participants with available data; Placebo / Upadacitinib 30 mg (n=210); Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale arithmetic mean standard deviation	 6.0 ± 2.21	 6.2 ± 2.07	 6.0 ± 2.08
Patient's Global Assessment of Disease Activity			
The participant was asked to rate their current psoriatic arthritis disease activity on a 0 to 10 NRS, where 0 indicates very low disease activity and 10 indicates very high disease activity. Analysis Population Description: Participants with available data; Placebo / Upadacitinib 30 mg (n=210); Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale arithmetic mean standard deviation	 6.2 ± 2.17	 6.4 ± 1.89	 6.3 ± 2.03
Physician's Global Assessment of Disease Activity			
The physician rated the participant's current global psoriatic arthritis disease activity (independently from the participant's assessment) on a 0 to 10 NRS where 0 indicates very low disease activity and 10 indicates very high disease activity. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: units on a scale arithmetic mean standard deviation	 6.6 ± 1.65	 6.4 ± 1.62	 6.6 ± 1.65
Health Assessment Questionnaire - Disability Index (HAQ-DI)			
HAQ DI is a patient-reported questionnaire measuring difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and errands and chores) over the past week. Subjects assessed ability to do each task on a scale from 0 to 3). Scores were averaged to provide an overall score ranging from 0 to 3, where 0 = no disability and 3= very severe, high-dependency disability. Analysis Population: Subjects w/available data; Pbo / Upa 30 mg (n=210); Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale arithmetic mean standard deviation	 1.08 ± 0.638	 1.15 ± 0.640	 1.12 ± 0.626

High-sensitivity C- reactive Protein (hsCRP)			
C-reactive protein (CRP) is a protein found in blood. CRP levels rise in response to inflammation. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: mg/mL			
arithmetic mean	12.00	10.96	10.91
standard deviation	± 17.146	± 14.357	± 15.462

Reporting group values	Upadacitinib 15 mg	Upadacitinib 30 mg	Total
Number of subjects	430	423	1705
Age categorical Units: Subjects			
< 65 years	368	371	1468
65 - < 75 years	52	46	211
≥75 years	10	6	26
Age continuous Units: years			
arithmetic mean	51.6	49.9	
standard deviation	± 12.18	± 12.41	-
Gender categorical Units: Subjects			
Female	239	236	908
Male	191	187	797
Ethnicity Units: Subjects			
Hispanic or Latino	60	53	244
Not Hispanic or Latino	370	370	1461
Unknown or Not Reported	0	0	0
Race/Ethnicity Units: Subjects			
White	387	377	1516
Black or African American	1	3	9
American Indian/ Alaska Native	0	2	6
Native Hawaiian or other Pacific Islander	0	1	4
Asian	37	34	149
Multiple	5	6	21
Extent of Psoriasis			
The extent of psoriasis was measured by the physician as the total body surface area (BSA) involved with psoriasis. For purposes of clinical estimation, the total surface of the participant's palm and five digits was assumed to be approximately equivalent to 1% of BSA.			
Units: Subjects			
< 3% BSA	215	213	858
≥3% BSA	214	210	846
Missing	1	0	1
Current Use of at Least 1 Non- Biologic DMARD Units: Subjects			
Yes	353	345	1391
No	77	78	314

Presence of Dactylitis			
Dactylitis is characterized by swelling of the fingers or toes. The Leeds dactylitis index (LDI) is a score based on finger circumference and tenderness, assessed across all digits. The presence of a dactylitic digit is defined as at least 1 affected AND tender digit with circumference increase over reference digit ≥10%. Digit scores are calculated from the ratio of circumference between an affected digit and control digit and the tenderness score; unaffected digits have score = 0. Scores from each digit are summed to provide the final LDI. The presence of dactylitis is defined as LDI > 0.			
Units: Subjects			
Yes	136	127	516
No	293	296	1188
Missing	1	0	1
Presence of Enthesitis			
Enthesitis is inflammation of the entheses, the specific point where tendons or ligaments attach to bone. Tenderness at 9 bilateral sites was assessed as present (1) or absent (0). The total enthesitis count is calculated by summing the tenderness scores from all 18 sites (range 0 - 18). Presence of enthesitis is defined as Total Enthesitis Count > 0.			
Units: Subjects			
Yes	333	331	1317
No	96	92	387
Missing	1	0	1
Duration of Psoriatic Arthritis Symptoms			
Analysis Population Description: Participants with available data Number of participants analyzed = 428 for the Adalimumab 40 mg group and 429 for the Upadacitinib 15 mg group			
Units: years			
arithmetic mean	9.2	9.2	
standard deviation	± 8.63	± 8.28	-
Duration of PsA Diagnosis			
Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: years			
arithmetic mean	6.2	5.9	
standard deviation	± 7.41	± 6.37	-
Tender Joint Count (TJC)			
A total of 68 joints were assessed for the presence or absence of tenderness. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: joints			
arithmetic mean	20.4	19.4	
standard deviation	± 14.72	± 13.32	-
Swollen Joint Count (SJC)			
A total of 66 joints were assessed for the presence or absence of swelling. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: joints			
arithmetic mean	11.6	10.6	
standard deviation	± 9.31	± 7.06	-
Patient's Assessment of Pain			
Participants were asked to indicate the severity of their arthritis pain within the previous week on a numeric rating scale (NRS) from 0 to 10. A score of 0 indicates "no pain" and a score of 10 indicates			

"worst possible pain." Analysis Population Description: Participants with available data; Placebo / Upadacitinib 30 mg (n=210); Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale arithmetic mean standard deviation	 6.2 ± 2.07	 5.9 ± 2.05	 -
Patient's Global Assessment of Disease Activity			
The participant was asked to rate their current psoriatic arthritis disease activity on a 0 to 10 NRS, where 0 indicates very low disease activity and 10 indicates very high disease activity. Analysis Population Description: Participants with available data; Placebo / Upadacitinib 30 mg (n=210); Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale arithmetic mean standard deviation	 6.6 ± 2.03	 6.4 ± 2.07	 -
Physician's Global Assessment of Disease Activity			
The physician rated the participant's current global psoriatic arthritis disease activity (independently from the participant's assessment) on a 0 to 10 NRS where 0 indicates very low disease activity and 10 indicates very high disease activity. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: units on a scale arithmetic mean standard deviation	 6.7 ± 1.62	 6.5 ± 1.68	 -
Health Assessment Questionnaire - Disability Index (HAQ-DI)			
HAQ DI is a patient-reported questionnaire measuring difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and errands and chores) over the past week. Subjects assessed ability to do each task on a scale from 0 to 3). Scores were averaged to provide an overall score ranging from 0 to 3, where 0 = no disability and 3= very severe, high-dependency disability. Analysis Population: Subjects w/available data; Pbo / Upa 30 mg (n=210); Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale arithmetic mean standard deviation	 1.15 ± 0.653	 1.09 ± 0.630	 -
High-sensitivity C- reactive Protein (hsCRP)			
C-reactive protein (CRP) is a protein found in blood. CRP levels rise in response to inflammation. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: mg/mL arithmetic mean standard deviation	 11.00 ± 14.910	 11.49 ± 15.355	 -

Subject analysis sets

Subject analysis set title	Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received matching placebo to upadacitinib orally QD and matching placebo to adalimumab

by subcutaneous (SC) injection EOW.

Subject analysis set title	Adalimumab 40 mg
Subject analysis set type	Full analysis
Subject analysis set description: Participants received adalimumab 40 mg SC EOW and matching placebo to upadacitinib orally QD.	
Subject analysis set title	Upadacitinib 15 mg
Subject analysis set type	Full analysis
Subject analysis set description: Participants received upadacitinib 15 mg orally QD and matching placebo to adalimumab SC EOW.	
Subject analysis set title	Upadacitinib 30 mg
Subject analysis set type	Full analysis
Subject analysis set description: Participants received upadacitinib 30 mg orally QD and matching placebo to adalimumab SC EOW.	

Reporting group values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg
Number of subjects	423	429	429
Age categorical Units: Subjects			
< 65 years	367	362	367
65 - < 75 years	52	61	52
≥75 years	4	6	10
Age continuous Units: years			
arithmetic mean	50.4	51.4	51.6
standard deviation	± 12.21	± 12.04	± 12.19
Gender categorical Units: Subjects			
Female	211	222	238
Male	212	207	191
Ethnicity Units: Subjects			
Hispanic or Latino	66	65	59
Not Hispanic or Latino	357	364	370
Unknown or Not Reported	0	0	0
Race/Ethnicity Units: Subjects			
White	377	375	386
Black or African American	3	2	1
American Indian/ Alaska Native	2	2	0
Native Hawaiian or other Pacific Islander	1	2	0
Asian	37	41	37
Multiple	3	7	5
Extent of Psoriasis			
The extent of psoriasis was measured by the physician as the total body surface area (BSA) involved with psoriasis. For purposes of clinical estimation, the total surface of the participant's palm and five digits was assumed to be approximately equivalent to 1% of BSA.			
Units: Subjects			
< 3% BSA	212	218	215
≥3% BSA	211	211	214
Missing	0	0	0
Current Use of at Least 1 Non- Biologic			

DMARD			
Units: Subjects			
Yes	347	347	353
No	76	82	76
Presence of Dactylitis			
Dactylitis is characterized by swelling of the fingers or toes. The Leeds dactylitis index (LDI) is a score based on finger circumference and tenderness, assessed across all digits. The presence of a dactylitic digit is defined as at least 1 affected AND tender digit with circumference increase over reference digit ≥10%. Digit scores are calculated from the ratio of circumference between an affected digit and control digit and the tenderness score; unaffected digits have score = 0. Scores from each digit are summed to provide the final LDI. The presence of dactylitis is defined as LDI > 0.			
Units: Subjects			
Yes	126	127	136
No	297	302	293
Missing	0	0	0
Presence of Enthesitis			
Enthesitis is inflammation of the entheses, the specific point where tendons or ligaments attach to bone. Tenderness at 9 bilateral sites was assessed as present (1) or absent (0). The total enthesitis count is calculated by summing the tenderness scores from all 18 sites (range 0 - 18). Presence of enthesitis is defined as Total Enthesitis Count > 0.			
Units: Subjects			
Yes	322	330	333
No	101	99	96
Missing	0	0	0
Duration of Psoriatic Arthritis Symptoms			
Analysis Population Description: Participants with available data Number of participants analyzed = 428 for the Adalimumab 40 mg group and 429 for the Upadacitinib 15 mg group			
Units: years			
arithmetic mean	9.3	9.1	9.2
standard deviation	± 8.58	± 8.78	± 8.63
Duration of PsA Diagnosis			
Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: years			
arithmetic mean	6.2	5.9	6.2
standard deviation	± 7.01	± 7.06	± 7.41
Tender Joint Count (TJC)			
A total of 68 joints were assessed for the presence or absence of tenderness. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: joints			
arithmetic mean	20.0	20.1	20.4
standard deviation	± 14.34	± 13.82	± 14.72
Swollen Joint Count (SJC)			
A total of 66 joints were assessed for the presence or absence of swelling. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: joints			

arithmetic mean	11.0	11.6	11.6
standard deviation	± 8.16	± 8.75	± 9.31
Patient's Assessment of Pain			
Participants were asked to indicate the severity of their arthritis pain within the previous week on a numeric rating scale (NRS) from 0 to 10. A score of 0 indicates "no pain" and a score of 10 indicates "worst possible pain." Analysis Population Description: Participants with available data; Placebo / Upadacitinib 30 mg (n=210); Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale			
arithmetic mean	6.1	6.0	6.2
standard deviation	± 2.04	± 2.08	± 2.07
Patient's Global Assessment of Disease Activity			
The participant was asked to rate their current psoriatic arthritis disease activity on a 0 to 10 NRS, where 0 indicates very low disease activity and 10 indicates very high disease activity. Analysis Population Description: Participants with available data; Placebo / Upadacitinib 30 mg (n=210); Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale			
arithmetic mean	6.3	6.3	6.6
standard deviation	± 2.04	± 2.03	± 2.03
Physician's Global Assessment of Disease Activity			
The physician rated the participant's current global psoriatic arthritis disease activity (independently from the participant's assessment) on a 0 to 10 NRS where 0 indicates very low disease activity and 10 indicates very high disease activity. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: units on a scale			
arithmetic mean	6.5	6.6	6.7
standard deviation	± 1.64	± 1.65	± 1.62
Health Assessment Questionnaire - Disability Index (HAQ-DI)			
HAQ DI is a patient-reported questionnaire measuring difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and errands and chores) over the past week. Subjects assessed ability to do each task on a scale from 0 to 3). Scores were averaged to provide an overall score ranging from 0 to 3, where 0 = no disability and 3= very severe, high-dependency disability. Analysis Population: Subjects w/available data; Pbo / Upa 30 mg (n=210); Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale			
arithmetic mean	1.12	1.12	1.15
standard deviation	± 0.639	± 0.626	± 0.653
High-sensitivity C- reactive Protein (hsCRP)			
C-reactive protein (CRP) is a protein found in blood. CRP levels rise in response to inflammation. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: mg/mL			
arithmetic mean	11.48	10.91	11.00
standard deviation	± 15.800	± 15.462	± 14.910

Reporting group values	Upadacitinib 30 mg		

Number of subjects	423		
Age categorical Units: Subjects			
< 65 years	371		
65 - < 75 years	46		
≥75 years	6		
Age continuous Units: years			
arithmetic mean	49.9		
standard deviation	± 12.41		
Gender categorical Units: Subjects			
Female	236		
Male	187		
Ethnicity Units: Subjects			
Hispanic or Latino	53		
Not Hispanic or Latino	370		
Unknown or Not Reported	0		
Race/Ethnicity Units: Subjects			
White	377		
Black or African American	3		
American Indian/ Alaska Native	2		
Native Hawaiian or other Pacific Islander	1		
Asian	34		
Multiple	6		
Extent of Psoriasis			
The extent of psoriasis was measured by the physician as the total body surface area (BSA) involved with psoriasis. For purposes of clinical estimation, the total surface of the participant's palm and five digits was assumed to be approximately equivalent to 1% of BSA.			
Units: Subjects			
< 3% BSA	213		
≥3% BSA	210		
Missing	0		
Current Use of at Least 1 Non- Biologic DMARD Units: Subjects			
Yes	346		
No	77		
Presence of Dactylitis			
Dactylitis is characterized by swelling of the fingers or toes. The Leeds dactylitis index (LDI) is a score based on finger circumference and tenderness, assessed across all digits. The presence of a dactylitic digit is defined as at least 1 affected AND tender digit with circumference increase over reference digit ≥10%. Digit scores are calculated from the ratio of circumference between an affected digit and control digit and the tenderness score; unaffected digits have score = 0. Scores from each digit are summed to provide the final LDI. The presence of dactylitis is defined as LDI > 0.			
Units: Subjects			
Yes	127		
No	296		
Missing	0		

Presence of Enthesitis			
Enthesitis is inflammation of the entheses, the specific point where tendons or ligaments attach to bone. Tenderness at 9 bilateral sites was assessed as present (1) or absent (0). The total enthesitis count is calculated by summing the tenderness scores from all 18 sites (range 0 - 18). Presence of enthesitis is defined as Total Enthesitis Count > 0.			
Units: Subjects			
Yes	331		
No	92		
Missing	0		
Duration of Psoriatic Arthritis Symptoms			
Analysis Population Description: Participants with available data Number of participants analyzed = 428 for the Adalimumab 40 mg group and 429 for the Upadacitinib 15 mg group			
Units: years			
arithmetic mean	9.2		
standard deviation	± 8.28		
Duration of PsA Diagnosis			
Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: years			
arithmetic mean	5.9		
standard deviation	± 6.37		
Tender Joint Count (TJC)			
A total of 68 joints were assessed for the presence or absence of tenderness. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: joints			
arithmetic mean	19.4		
standard deviation	± 13.32		
Swollen Joint Count (SJC)			
A total of 66 joints were assessed for the presence or absence of swelling. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: joints			
arithmetic mean	10.6		
standard deviation	± 7.06		
Patient's Assessment of Pain			
Participants were asked to indicate the severity of their arthritis pain within the previous week on a numeric rating scale (NRS) from 0 to 10. A score of 0 indicates "no pain" and a score of 10 indicates "worst possible pain." Analysis Population Description: Participants with available data; Placebo / Upadacitinib 30 mg (n=210); Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale			
arithmetic mean	5.9		
standard deviation	± 2.05		
Patient's Global Assessment of Disease Activity			
The participant was asked to rate their current psoriatic arthritis disease activity on a 0 to 10 NRS, where 0 indicates very low disease activity and 10 indicates very high disease activity. Analysis Population Description: Participants with available data; Placebo / Upadacitinib 30 mg (n=210);			

Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale arithmetic mean standard deviation	 6.4 ± 2.07		
Physician's Global Assessment of Disease Activity			
The physician rated the participant's current global psoriatic arthritis disease activity (independently from the participant's assessment) on a 0 to 10 NRS where 0 indicates very low disease activity and 10 indicates very high disease activity. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: units on a scale arithmetic mean standard deviation	 6.5 ± 1.68		
Health Assessment Questionnaire - Disability Index (HAQ-DI)			
HAQ DI is a patient-reported questionnaire measuring difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and errands and chores) over the past week. Subjects assessed ability to do each task on a scale from 0 to 3). Scores were averaged to provide an overall score ranging from 0 to 3, where 0 = no disability and 3= very severe, high-dependency disability. Analysis Population: Subjects w/available data; Pbo / Upa 30 mg (n=210); Adalimumab 40 mg (n=428); Upadacitinib 15 mg (n=425); Upadacitinib 30 mg (n=421)			
Units: units on a scale arithmetic mean standard deviation	 1.09 ± 0.630		
High-sensitivity C- reactive Protein (hsCRP)			
C-reactive protein (CRP) is a protein found in blood. CRP levels rise in response to inflammation. Analysis Population Description: Participants with available data Number of participants analyzed = 429 for the Upadacitinib 15 mg group			
Units: mg/mL arithmetic mean standard deviation	 11.49 ± 15.355		

End points reporting groups

Reporting group title	Placebo / Upadacitinib 15 mg
Reporting group description:	
Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks followed by upadacitinib 15 mg once daily for 32 weeks (Weeks 24 to 56), as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 56.	
Reporting group title	Placebo / Upadacitinib 30 mg
Reporting group description:	
Participants randomized to receive matching placebo to upadacitinib orally QD for 24 weeks followed by upadacitinib 30 mg once daily for 32 weeks (Weeks 24 to 56), in addition to matching placebo to adalimumab administered by subcutaneous injection EOW from Weeks 1 to 56.	
Reporting group title	Adalimumab 40 mg
Reporting group description:	
Participants randomized to receive adalimumab 40 mg by subcutaneous injection EOW and matching placebo to upadacitinib orally QD for 56 weeks.	
Reporting group title	Upadacitinib 15 mg
Reporting group description:	
Participants randomized to receive upadacitinib 15 mg orally QD and matching placebo to adalimumab by subcutaneous injection EOW for 56 weeks.	
Reporting group title	Upadacitinib 30 mg
Reporting group description:	
Participants randomized to receive upadacitinib 30 mg orally QD and matching placebo to adalimumab by subcutaneous injection EOW for 56 weeks.	
Reporting group title	Placebo / Upadacitinib 15 mg Period 2 (Weeks 56 to 260)
Reporting group description:	
Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks followed by upadacitinib 15 mg orally once a day (QD) for 32 weeks (Weeks 24 to 56), as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 56 in Period 1. During Period 2 (Weeks 56 to 260) participants continued to receive upadacitinib 15 mg orally once a day (QD).	
Reporting group title	Placebo / Upadacitinib 30 mg Period 2 (Weeks 56 to 260)
Reporting group description:	
Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks followed by upadacitinib 30 mg orally once a day (QD) for 32 weeks (Weeks 24 to 56), as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 56 in Period 1. During Period 2 (Weeks 56 to 260) participants continued to receive upadacitinib 30 mg orally once a day (QD).	
Reporting group title	Adalimumab 40 mg Period 2 (Weeks 56 to 260)
Reporting group description:	
Participants randomized to receive adalimumab 40 mg by subcutaneous injection every other week (EOW) and matching placebo to upadacitinib orally once a day (QD) for 56 weeks in Period 1 who continued to receive 40 mg adalimumab EOW in Period 2 (Weeks 56 to 260).	
Reporting group title	Upadacitinib 15 mg Period 2 (Weeks 56 to 260)
Reporting group description:	
Participants randomized to receive upadacitinib 15 mg orally once a day (QD) and matching placebo to adalimumab by subcutaneous injection EOW for 56 weeks in Period 1 who continued to receive 15 mg upadacitinib QD in Period 2 (Weeks 56 to 260).	

Reporting group title	Upadacitinib 30 mg Period 2 (Weeks 56 to 260)
Reporting group description:	
Participants randomized to receive upadacitinib 30 mg orally once a day (QD) and matching placebo to adalimumab by subcutaneous injection every other week (EOW) for 56 weeks in Period 1 who continued to receive 30 mg upadacitinib QD in Period 2 (Weeks 56 to 260).	

Subject analysis set title	Placebo
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants received matching placebo to upadacitinib orally QD and matching placebo to adalimumab by subcutaneous (SC) injection EOW.	
Subject analysis set title	Adalimumab 40 mg
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants received adalimumab 40 mg SC EOW and matching placebo to upadacitinib orally QD.	
Subject analysis set title	Upadacitinib 15 mg
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants received upadacitinib 15 mg orally QD and matching placebo to adalimumab SC EOW.	
Subject analysis set title	Upadacitinib 30 mg
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants received upadacitinib 30 mg orally QD and matching placebo to adalimumab SC EOW.	

Primary: Percentage of Participants With an American College of Rheumatology 20% (ACR20) Response at Week 12

End point title	Percentage of Participants With an American College of Rheumatology 20% (ACR20) Response at Week 12
End point description:	
Participants who met the following 3 conditions for improvement from Baseline were classified as meeting the ACR20 response criteria: 1. ≥20% improvement in 68-tender joint count; 2. ≥20% improvement in 66-swollen joint count; and 3. ≥20% improvement in at least 3 of the 5 following parameters: •Physician global assessment of disease activity •Patient global assessment of disease activity •Patient assessment of pain •Health Assessment Questionnaire - Disability Index (HAQ-DI) •High-sensitivity C-reactive protein (hsCRP). Analysis population: Full analysis set; participants who prematurely discontinued from study drug prior to Week 12 or for whom ACR data were missing at Week 12 were considered non-responders.	
End point type	Primary
End point timeframe:	
Baseline and Week 12	

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	423	429	429	423
Units: percentage of participants				
number (confidence interval 95%)	36.2 (31.6 to 40.7)	65.0 (60.5 to 69.5)	70.6 (66.3 to 74.9)	78.5 (74.6 to 82.4)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	852
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [1]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	34.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.2
upper limit	40.7

Notes:

[1] - Cochran-Mantel-Haenszel (CMH) test adjusted for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Upadacitinib 30 mg v Placebo
Number of subjects included in analysis	846
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [2]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	42.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	36.3
upper limit	48.3

Notes:

[2] - Cochran-Mantel-Haenszel (CMH) test adjusted for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Secondary: Change From Baseline in Health Assessment Questionnaire Disability Index (HAQ-DI) at Week 12

End point title	Change From Baseline in Health Assessment Questionnaire Disability Index (HAQ-DI) at Week 12

End point description:

The Health Assessment Questionnaire - Disability Index is a patient-reported questionnaire that measures the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and errands and chores) over the past week.

Participants assessed their ability to do each task on a scale from 0 (without any difficulty) to 3 (unable to do). Scores were averaged to provide an overall score ranging from 0 to 3, where 0 represents no disability and 3 represents very severe, high-dependency disability.

A negative change from Baseline in the overall score indicates improvement.

Analysis popualation: Full analysis set participants with available data; a mixed effect model repeat measurement (MMRM) analysis with longitudinal data from observed cases up to Week 12 was used.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	392	406	404	398
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.14 (-0.18 to -0.09)	-0.34 (-0.38 to -0.29)	-0.42 (-0.47 to -0.37)	-0.47 (-0.52 to -0.42)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	796
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [3]
Method	[Mixed Effect Model Repeated Measurement
Parameter estimate	[Least Squares (LS) Mean Difference
Point estimate	-0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.35
upper limit	-0.22

Notes:

[3] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Treatment Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 30 mg
Number of subjects included in analysis	790
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [4]
Method	[Mixed Effect Model Repeated Measurement
Parameter estimate	[Least Squares (LS) Mean Difference
Point estimate	-0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	-0.27

Notes:

[4] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Treatment Difference = Upadacitinib - Placebo

Secondary: Percentage of Participants Achieving a Static Investigator Global Assessment (sIGA) of Psoriasis of 0 or 1 and at Least a 2-point Improvement From Baseline (sIGA 0/1) at Week 16

End point title	Percentage of Participants Achieving a Static Investigator Global Assessment (sIGA) of Psoriasis of 0 or 1 and at Least a 2-point Improvement From Baseline (sIGA 0/1) at Week 16

End point description:

The sIGA is a 5 point scale ranging from 0 to 4, based on the investigator's assessment of the average elevation, erythema, and scaling of all psoriatic lesions at the current visit. A lower score indicates less severe psoriasis (0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe).

Analysis population: Full analysis set participants with a Baseline sIGA score ≥2; participants who prematurely discontinued from study drug prior to Week 16 or for whom sIGA data were missing at Week 16 were considered non-responders.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	313	330	322	324
Units: percentage of participants				
number (confidence interval 95%)	10.9 (7.4 to 14.3)	38.5 (33.2 to 43.7)	41.9 (36.5 to 47.3)	54.0 (48.6 to 59.4)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2

for each dose followed by a prespecified gtransfer path.

Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	635
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [5]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	31.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.7
upper limit	37.5

Notes:

[5] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified gtransfer path.

Comparison groups	Placebo v Upadacitinib 30 mg
Number of subjects included in analysis	637
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [6]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	43.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	36.7
upper limit	49.6

Notes:

[6] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Secondary: Percentage of Participants Achieving Psoriasis Area Severity Index (PASI) 75 Response at Week 16

End point title	Percentage of Participants Achieving Psoriasis Area Severity Index (PASI) 75 Response at Week 16

End point description:

PASI is a composite score based on percentage of body surface area (BSA) affected by psoriasis and intensity of erythema (reddening), induration (thickening or hardening of the skin), and desquamation (peeling of the skin) of lesions assessed at 4 anatomic sites (head, upper extremities, trunk, and lower extremities). At each location, percentage of BSA involvement is assigned a score from 0 (no involvement) to 6 (90% to 100% involvement), and erythema, induration, and desquamation are scored on a scale from 0 (no symptoms) to 4 (very marked).

PASI score ranges from 0 (no psoriasis) to 72 (very severe psoriasis). PASI-75 response is percentage

of subjects who achieved at least a 75% reduction (improvement) from Baseline in PASI score.

Analysis population: FAS subjects w/ Baseline psoriasis BSA involvement ≥3%; those who prematurely discontinued from study drug prior to Week 16 or for whom PASI data were missing at Week 16 were considered non-responders.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	211	211	214	210
Units: percentage of participants				
number (confidence interval 95%)	21.3 (15.8 to 26.9)	53.1 (46.3 to 59.8)	62.6 (56.1 to 69.1)	62.4 (55.8 to 68.9)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	425
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [7]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	41.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.8
upper limit	49.8

Notes:

[7] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 30 mg

Number of subjects included in analysis	421
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [8]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	41.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.5
upper limit	49.6

Notes:

[8] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Secondary: Change From Baseline in Modified PsA Total Sharp/Van Der Heijde Score (mTSS) at Week 24

End point title	Change From Baseline in Modified PsA Total Sharp/Van Der Heijde Score (mTSS) at Week 24

End point description:

The Sharp–van der Heijde modified scoring method for PsA measures level of joint damage from radiographs of hands/feet, assessed by 2 readers.

Joint erosion severity assessed in 20 joints in each hand/wrist and 6 joints in each foot. Each joint scored from 0 (no erosion) to 5 for hands/wrists or to 10 for feet (complete collapse). Total erosion score ranges from 0 to 320 (worst).

Joint space narrowing (JSN) assessed in 20 joints of each hand/wrist, and 6 joints of each foot, from 0 (normal) to 4 (complete loss of joint space, bony ankylosis, or luxation). Total JSN score ranges from 0 to 208 (worst).

Joints with gross osteolysis/pencil in cup were assigned maximum score for both erosions and JSN. Total mTSS score is sum of joint erosion and JSN scores, ranging from 0 (normal) to 528 (worst).

A negative change from Baseline = improvement in joint damage. Analysis population: FAS w/available data at Baseline; linear extrapolation used for discontinued/rescued before Wk 24

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	372	384	391	383
Units: score on a scale				
least squares mean (confidence interval 95%)	0.25 (0.13 to 0.36)	0.01 (-0.11 to 0.13)	-0.04 (-0.16 to 0.07)	0.03 (-0.08 to 0.15)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	763
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002 [9]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.44
upper limit	-0.14

Notes:

[9] - ANCOVA model including treatment and the stratification factor current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Treatment Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 30 mg
Number of subjects included in analysis	755
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0069 [10]
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	-0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.36
upper limit	-0.06

Notes:

[10] - ANCOVA model including treatment and the stratification factor current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Treatment Difference = Upadacitinib - Placebo

Secondary: Percentage of Participants Achieving Minimal Disease Activity (MDA) at Week 24

End point title	Percentage of Participants Achieving Minimal Disease Activity (MDA) at Week 24

End point description:

A participant was classified as achieving MDA if 5 of the following 7 criteria were met:

•Tender joint count (out of 68 joints) ≤1

•Swollen joint count (out of 66 joints) ≤1
•PASI score ≤1 (score ranges from 0 - 72) or percent BSA involved with psoriasis ≤3%
•Patient's assessment of pain ≤1.5 (NRS from 0 to 10)
•Patient's Global Assessment of disease activity ≤2 (NRS from 0 to 10)
•HAQ-DI score ≤0.5 (index score ranges from 0 to 3)
•Leeds Enthesitis Index ≤1 (assesses the presence or absence of enthesitis at 3 bilateral sites, with an overall score range from 0 to 6)

Analysis population: Full analysis set; participants who prematurely discontinued from study drug prior to Week 24 or for whom data were missing at Week 24, or who met the rescue criteria at Week 16 were considered non-responders.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	423	429	429	423
Units: percentage of participants				
number (confidence interval 95%)	12.3 (9.2 to 15.4)	33.3 (28.9 to 37.8)	36.6 (32.0 to 41.2)	45.4 (40.6 to 50.1)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	852
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [11]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.8
upper limit	29.8

Notes:

[11] - Cochran-Mantel-Haenszel (CMH) test adjusted for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using

a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 30 mg
Number of subjects included in analysis	846
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [12]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	33.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	27.4
upper limit	38.8

Notes:

[12] - Cochran-Mantel-Haenszel (CMH) test adjusted for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Secondary: Percentage of Participants With Resolution of Enthesitis at Week 24

End point title	Percentage of Participants With Resolution of Enthesitis at Week 24

End point description:

Resolution of enthesitis is defined as a Leeds Enthesitis Index (LEI) score = 0.

LEI is an enthesitis measure developed specifically for PsA and assesses the presence or absence of tenderness at the following 3 bilateral enthesial sites: medial femoral condyles, lateral epicondyles of the humerus, and Achilles tendon insertions. Tenderness on examination is recorded as either present (coded as 1), absent (coded as 0), or not assessed for each of the 6 sites. The LEI is calculated by taking the sum of the scores from the 6 sites. The LEI ranges from 0 to 6 (worst).

Analysis population: Full analysis set participants with a Baseline LEI > 0; participants who prematurely discontinued from study drug prior to Week 24 or for whom data were missing at Week 24, or who met the rescue criteria at Week 16 were considered non-responders.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	241	265	270	267
Units: percentage of participants				
number (confidence interval 95%)	32.4 (26.5 to 38.3)	47.2 (41.2 to 53.2)	53.7 (47.8 to 59.7)	57.7 (51.8 to 63.6)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [13]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	21.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	13
upper limit	29.7

Notes:

[13] - Cochran-Mantel-Haenszel (CMH) test adjusted for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 30 mg
Number of subjects included in analysis	508
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [14]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	25.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.9
upper limit	33.7

Notes:

[14] - Cochran-Mantel-Haenszel (CMH) test adjusted for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Secondary: Percentage of Participants With an ACR20 Response at Week 12 - Non-inferiority Versus Adalimumab

End point title	Percentage of Participants With an ACR20 Response at Week 12 - Non-inferiority Versus Adalimumab

End point description:

Participants who met the following 3 conditions for improvement from Baseline were classified as meeting the ACR20 response criteria:
1. ≥20% improvement in 68-tender joint count;

2. ≥20% improvement in 66-swollen joint count; and
3. ≥20% improvement in at least 3 of the 5 following parameters:

•Physician global assessment of disease activity
•Patient global assessment of disease activity
•Patient assessment of pain
•Health Assessment Questionnaire - Disability Index (HAQ-DI)
•High-sensitivity C-reactive protein (hsCRP).

Analysis population: Full analysis set; participants who prematurely discontinued from study drug prior to Week 12 or for whom ACR data were missing at Week 12 were considered non-responders.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	423	429	429	423
Units: percentage of participants				
number (confidence interval 95%)	36.2 (31.6 to 40.7)	65.0 (60.5 to 69.5)	70.6 (66.3 to 74.9)	78.5 (74.6 to 82.4)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Adalimumab 40 mg

Statistical analysis description:

Non-inferiority of each upadacitinib dose versus adalimumab was assessed using Koch’s 3-arm approach; non-inferiority was achieved if upadacitinib preserved at least 50% of the placebo-subtracted adalimumab effect.

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Adalimumab 40 mg v Upadacitinib 15 mg
Number of subjects included in analysis	858
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.0001 [15]
Method	Koch 3-Arm Test
Parameter estimate	Percent Adalimumab Effect Preservation
Point estimate	119.381
Confidence interval	
level	95 %
sides	2-sided
lower limit	97.987
upper limit	147.942

Notes:

[15] - The percent of adalimumab effect preservation is the point estimate of 3-arm non-inferiority analysis, which is calculated by (Upadacitinib - Placebo) / (Adalimumab - Placebo) * 100.

Statistical analysis title	Upadacitinib 30 mg vs Adalimumab 40 mg

Statistical analysis description:

Non-inferiority of each upadacitinib dose versus adalimumab was assessed using Koch's 3-arm approach; non-inferiority was achieved if upadacitinib preserved at least 50% of the placebo-subtracted adalimumab effect.

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Adalimumab 40 mg v Upadacitinib 30 mg
Number of subjects included in analysis	852
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.0001 [16]
Method	Koch 3-Arm Test
Parameter estimate	Percent Adalimumab Effect Preservation
Point estimate	146.604
Confidence interval	
level	95 %
sides	2-sided
lower limit	122.817
upper limit	180.398

Notes:

[16] - The percent of adalimumab effect preservation is the point estimate of 3-arm non-inferiority analysis, which is calculated by (Upadacitinib - Placebo) / (Adalimumab - Placebo) * 100.

Secondary: Change From Baseline in Short-Form 36 (SF-36) Physical Component Score (PCS) at Week 12

End point title	Change From Baseline in Short-Form 36 (SF-36) Physical Component Score (PCS) at Week 12

End point description:

The Short Form 36-Item Health Survey (SF-36) Version 2 is a self-administered questionnaire that measures the impact of disease on overall quality of life during the past 4 weeks. The SF-36 consists of 36 questions in eight domains (physical function, pain, general and mental health, vitality, social function, physical and emotional health).

The physical component score is a weighted combination of the 8 subscales with positive weighting for physical functioning, role-physical, bodily pain, and general health. The PCS was calculated using norm-based scoring so that 50 is the average score and the standard deviation equals 10. Higher scores are associated with better functioning/ quality of life; a positive change from Baseline score indicates an improvement.

Analysis population: Full analysis set participants with available data; a mixed effect model repeat measurement (MMRM) analysis with longitudinal data from observed cases up to Week 12 was used.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	394	410	405	398
Units: score on a scale				
least squares mean (confidence interval 95%)	3.19 (2.41 to 3.96)	6.82 (6.07 to 7.58)	7.86 (7.09 to 8.63)	8.90 (8.13 to 9.68)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	799
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [17]
Method	Mixed Effect Model Repeated Measurement
Parameter estimate	LS Mean Difference
Point estimate	4.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.67
upper limit	5.67

Notes:

[17] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 30 mg
Number of subjects included in analysis	792
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [18]
Method	Mixed Effect Model Repeated Measurement
Parameter estimate	LS Mean Difference
Point estimate	5.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.71
upper limit	6.72

Notes:

[18] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Secondary: Change From Baseline in Functional Assessment of Chronic Illness

Therapy-Fatigue (FACIT-F) Score at Week 12

End point title	Change From Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Score at Week 12

End point description:

The FACIT-Fatigue questionnaire is a self-administered patient questionnaire that consists of 13 questions designed to measure the degree of fatigue experienced by participants in the previous 7 days, including physical fatigue (e.g., I feel tired), functional fatigue (e.g., trouble finishing things), emotional fatigue (e.g., frustration), and social consequences of fatigue (e.g., limits social activity). Participants respond to the questions on a scale from 0 'not at all' to 4 'very much'. The FACIT Fatigue score is computed by summing the item scores, after reversing those items that are worded in the negative direction. The FACIT-Fatigue subscale score ranges from 0 to 52, where higher scores represent less fatigue. A positive change from Baseline indicates improvement.

Analysis population: Full analysis set participants with available data; a mixed effect model repeat measurement (MMRM) analysis with longitudinal data from observed cases up to Week 12 was used.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	394	410	404	398
Units: score on a scale				
least squares mean (confidence interval 95%)	2.8 (1.9 to 3.7)	5.7 (4.8 to 6.6)	6.3 (5.4 to 7.2)	7.1 (6.2 to 8.0)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	798
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [19]
Method	Mixed Effect Model Repeated Measurement
Parameter estimate	LS Mean Difference
Point estimate	3.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.4
upper limit	4.7

Notes:

[19] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 30 mg
Number of subjects included in analysis	792
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [20]
Method	Mixed Effect Model Repeated Measurement
Parameter estimate	LS Mean Difference
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.1
upper limit	5.5

Notes:

[20] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Secondary: Percentage of Participants With an ACR20 Response at Week 12 - Superiority Versus Adalimumab

End point title	Percentage of Participants With an ACR20 Response at Week 12 - Superiority Versus Adalimumab

End point description:

Participants who met the following 3 conditions for improvement from Baseline were classified as meeting the ACR20 response criteria:

1. ≥20% improvement in 68-tender joint count;
2. ≥20% improvement in 66-swollen joint count; and
3. ≥20% improvement in at least 3 of the 5 following parameters:

•Physician global assessment of disease activity
•Patient global assessment of disease activity
•Patient assessment of pain
•Health Assessment Questionnaire - Disability Index (HAQ-DI)
•High-sensitivity C-reactive protein (hsCRP).

Analysis population: Full analysis set; participants who prematurely discontinued from study drug prior to Week 12 or for whom ACR data were missing at Week 12 were considered non-responders.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	423	429	429	423
Units: percentage of participants				
number (confidence interval 95%)	36.2 (31.6 to 40.7)	65.0 (60.5 to 69.5)	70.6 (66.3 to 74.9)	78.5 (74.6 to 82.4)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Adalimumab 40 mg

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Upadacitinib 15 mg v Adalimumab 40 mg
Number of subjects included in analysis	858
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0815 [21]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	5.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	11.8

Notes:

[21] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Statistical analysis title	Upadacitinib 30 mg vs Adalimumab 40 mg

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Upadacitinib 30 mg v Adalimumab 40 mg
Number of subjects included in analysis	852
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [22]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.5
upper limit	19.4

Notes:

[22] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Secondary: Percentage of Participants With Resolution of Dactylitis at Week 24

End point title	Percentage of Participants With Resolution of Dactylitis at Week 24

End point description:

Resolution of dactylitis is defined as Leeds Dactylitis Index (LDI) score = 0. LDI is a score based on finger circumference and tenderness, assessed and summed across all fingers and toes. The presence of a dactylitic digit is defined as at least one affected AND tender digit with circumference increase over reference digit ≥10%. Reference digit circumference is either the contralateral digit (unaffected digit on opposite hand or foot) if available, or from a standard reference table if otherwise. Tenderness of affected digits is assessed on a scale from 0 [none] to 3 [worst].

Ratio of circumference between an affected digit and reference digit is multiplied by tenderness score for each affected digit. Results from each involved digit are summed to provide final LDI. A higher LDI indicates worse dactylitis.

Analysis population: FAS w/ BL LDI > 0; those who stopped study drug prior to Wk 24, had missing data at Wk 24, or met rescue criteria at Wk 16 were considered nonresponders.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	126	127	136	127
Units: percentage of participants				
number (confidence interval 95%)	39.7 (31.1 to 48.2)	74.0 (66.4 to 81.6)	76.5 (69.3 to 83.6)	79.5 (72.5 to 86.5)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	262
Analysis specification	Pre-specified
Analysis type	other[23]
P-value	< 0.0001 [24]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	36.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.7
upper limit	47.9

Notes:

[23] - This comparison was not tested for statistical significance because the hierarchical testing procedures stopped at ACR 20 at Week 12 superiority test of upadacitinib 15 mg versus adalimumab 40 mg.

[24] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 30 mg
Number of subjects included in analysis	253
Analysis specification	Pre-specified
Analysis type	other[25]
P-value	< 0.0001 [26]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	39.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.8
upper limit	50.9

Notes:

[25] - This comparison was not tested for statistical significance because the hierarchical testing procedures stopped at ACR 20 at Week 12 superiority test of upadacitinib 15 mg versus adalimumab 40 mg.
[26] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Secondary: Change From Baseline in Patient's Assessment of Pain - Superiority Versus Adalimumab

End point title	Change From Baseline in Patient's Assessment of Pain - Superiority Versus Adalimumab

End point description:

Participants were asked to indicate the severity of their arthritis pain within the previous week on a numerical rating scale (NRS) from 0 to 10. A score of 0 indicates "no pain" and a score of 10 indicates "worst possible pain." A negative change from Baseline indicates improvement.

Analysis population: Full analysis set participants with available data; a mixed effect model repeat measurement (MMRM) analysis with longitudinal data from observed cases up to Week 12 was used.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	392	406	404	398
Units: units on a scale				
least squares mean (confidence interval 95%)	-0.9 (-1.2 to -0.7)	-2.3 (-2.5 to -2.1)	-2.3 (-2.5 to -2.0)	-2.7 (-2.9 to -2.5)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Adalimumab 40 mg

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Adalimumab 40 mg v Upadacitinib 15 mg
Number of subjects included in analysis	810
Analysis specification	Pre-specified
Analysis type	other[27]
P-value	= 0.897 [28]
Method	Mixed Effect Model Repeated Measurement
Parameter estimate	LS Mean Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.3

Notes:

[27] - This comparison was not tested for statistical significance because the hierarchical testing procedures stopped at ACR 20 at Week 12 superiority test of upadacitinib 15 mg versus adalimumab 40 mg.
[28] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Treatment Difference = Upadacitinib - Adalimumab

Statistical analysis title	Upadacitinib 30 mg vs Adalimumab 40 mg

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Adalimumab 40 mg v Upadacitinib 30 mg
Number of subjects included in analysis	804
Analysis specification	Pre-specified
Analysis type	other[29]
P-value	= 0.0028 [30]
Method	Mixed Effect Model Repeated Measurement
Parameter estimate	LS Mean Difference
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	-0.2

Notes:

[29] - This comparison was not tested for statistical significance because the hierarchical testing procedures stopped at ACR 20 at Week 12 superiority test of upadacitinib 15 mg versus adalimumab 40 mg.
[30] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Treatment Difference = Upadacitinib - Adalimumab

Secondary: Change From Baseline in HAQ-DI - Superiority Versus Adalimumab

End point title	Change From Baseline in HAQ-DI - Superiority Versus Adalimumab

End point description:

The Health Assessment Questionnaire - Disability Index is a patient-reported questionnaire that measures the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and errands and chores) over the past week. Participants assessed their ability to do each task on a scale from 0 (without any difficulty) to 3 (unable to do). Scores were averaged to provide an overall score ranging from 0 to 3, where 0 represents no disability and 3 represents very severe, high-dependency disability.

A negative change from Baseline in the overall score indicates improvement.

Analysis population: Full analysis set participants with available data; a mixed effect model repeat measurement (MMRM) analysis with longitudinal data from observed cases up to Week 12 was used.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	392	406	404	398
Units: score on a scale				
least squares mean (confidence interval 95%)	-0.14 (-0.18 to -0.09)	-0.34 (-0.38 to -0.29)	-0.42 (-0.47 to -0.37)	-0.47 (-0.52 to -0.42)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Adalimumab 40 mg

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Adalimumab 40 mg v Upadacitinib 15 mg
Number of subjects included in analysis	810
Analysis specification	Pre-specified
Analysis type	other[31]
P-value	= 0.0162 [32]
Method	Mixed Effect Model Repeated Measurement
Parameter estimate	LS Mean Difference
Point estimate	-0.08

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	-0.01

Notes:

[31] - This comparison was not tested for statistical significance because the hierarchical testing procedures stopped at ACR 20 at Week 12 superiority test of upadacitinib 15 mg versus adalimumab 40 mg.
[32] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Treatment Difference = Upadacitinib - Adalimumab

Statistical analysis title	Upadacitinib 30 mg vs Adalimumab 40 mg

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Upadacitinib 30 mg v Adalimumab 40 mg
Number of subjects included in analysis	804
Analysis specification	Pre-specified
Analysis type	other[33]
P-value	< 0.0001 [34]
Method	Mixed Effect Model Repeated Measurement
Parameter estimate	LS Mean Difference
Point estimate	-0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	-0.07

Notes:

[33] - This comparison was not tested for statistical significance because the hierarchical testing procedures stopped at ACR 20 at Week 12 superiority test of upadacitinib 15 mg versus adalimumab 40 mg.
[34] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Treatment Difference = Upadacitinib - Adalimumab

Secondary: Change From Baseline in Self-Assessment of Psoriasis Symptoms (SAPS) Questionnaire at Week 16

End point title	Change From Baseline in Self-Assessment of Psoriasis Symptoms (SAPS) Questionnaire at Week 16

End point description:

The SAPS is an 11-item self-assessment of psoriasis symptoms that includes questions on: pain, itching, redness, scaling, flaking, bleeding, burning, stinging, tenderness, pain due to skin cracking, and joint pain. Each item is scored from 0 to 10, with 0 being least severe and 10 being most severe. The total score is generated by summing the 11 items and ranges from 0 to 110 (worst). A negative change from Baseline in the total score indicates improvement.

Analysis population: Full analysis set participants with available data; a mixed effect model repeat measurement (MMRM) analysis with longitudinal data from observed cases up to Week 16 was used.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	388	407	396	395
Units: score on a scale				
least squares mean (confidence interval 95%)	-8.2 (-10.2 to -6.3)	-22.7 (-24.7 to -20.8)	-25.3 (-27.3 to -23.4)	-28.1 (-30.0 to -26.1)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Upadacitinib 15 mg v Placebo
Number of subjects included in analysis	784
Analysis specification	Pre-specified
Analysis type	other[35]
P-value	< 0.0001 [36]
Method	Mixed Effect Model Repeated Measurement
Parameter estimate	LS Mean Difference
Point estimate	-17.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.6
upper limit	-14.6

Notes:

[35] - This comparison was not tested for statistical significance because the hierarchical testing procedures stopped at ACR 20 at Week 12 superiority test of upadacitinib 15 mg versus adalimumab 40 mg.

[36] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Treatment Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

The overall type I error rate of the primary and the 14 ranked secondary endpoints was controlled using a two-part sequential graphical multiple testing procedure starting with the primary endpoint using α/2 for each dose followed by a prespecified αtransfer path.

Comparison groups	Placebo v Upadacitinib 30 mg

Number of subjects included in analysis	783
Analysis specification	Pre-specified
Analysis type	other[37]
P-value	< 0.0001 [38]
Method	Mixed Effect Model Repeated Measurement
Parameter estimate	LS Mean Difference
Point estimate	-19.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.3
upper limit	-17.3

Notes:

[37] - This comparison was not tested for statistical significance because the hierarchical testing procedures stopped at ACR 20 at Week 12 superiority test of upadacitinib 15 mg versus adalimumab 40 mg.
[38] - MMRM analysis including treatment, visit, treatment-by-visit interaction, current DMARD use (yes/no) as fixed factors and Baseline value as covariate.

Treatment Difference = Upadacitinib - Placebo

Secondary: Percentage of Participants With an American College of Rheumatology 50% (ACR50) Response at Week 12

End point title	Percentage of Participants With an American College of Rheumatology 50% (ACR50) Response at Week 12

End point description:

Participants who met the following 3 conditions for improvement from Baseline were classified as meeting the ACR50 response criteria:

1. ≥50% improvement in 68-tender joint count;
2. ≥50% improvement in 66-swollen joint count; and
3. ≥50% improvement in at least 3 of the 5 following parameters:

•Physician global assessment of disease activity
•Patient global assessment of disease activity
•Patient assessment of pain
•Health Assessment Questionnaire - Disability Index (HAQ-DI)
•High-sensitivity C-reactive protein (hsCRP).

Analysis population: Full analysis set; participants who prematurely discontinued from study drug prior to Week 12 or for whom ACR data were missing at Week 12 were considered non-responders.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	423	429	429	423
Units: percentage of participants				
number (confidence interval 95%)	13.2 (10.0 to 16.5)	37.5 (32.9 to 42.1)	37.5 (32.9 to 42.1)	51.8 (47.0 to 56.5)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo

Statistical analysis description:

This comparison was not part of the pre-specified multiplicity testing sequence.

Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	852
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001 [39]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	24.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.7
upper limit	29.9

Notes:

[39] - Cochran-Mantel-Haenszel (CMH) test adjusted for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo

Statistical analysis description:

This comparison was not part of the pre-specified multiplicity testing sequence.

Comparison groups	Placebo v Upadacitinib 30 mg
Number of subjects included in analysis	846
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001 [40]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	38.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.8
upper limit	44.3

Notes:

[40] - Cochran-Mantel-Haenszel (CMH) test adjusted for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Secondary: Percentage of Participants With an American College of Rheumatology 70% (ACR70) Response at Week 12

End point title	Percentage of Participants With an American College of Rheumatology 70% (ACR70) Response at Week 12

End point description:

Participants who met the following 3 conditions for improvement from baseline were classified as meeting the ACR70 response criteria:

1. ≥70% improvement in 68-tender joint count;
2. ≥70% improvement in 66-swollen joint count; and

3. ≥70% improvement in at least 3 of the 5 following parameters:

•Physician global assessment of disease activity
•Patient global assessment of disease activity
•Patient assessment of pain
•Health Assessment Questionnaire - Disability Index (HAQ-DI)
•High-sensitivity C-reactive protein (hsCRP).

Analysis population: Full analysis set; participants who prematurely discontinued from study drug prior to Week 12 or for whom ACR data were missing at Week 12 were considered non-responders.

End point type	Secondary
End point timeframe:	
Baseline and Week 12	

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	423	429	429	423
Units: percentage of participants				
number (confidence interval 95%)	2.4 (0.9 to 3.8)	13.8 (10.5 to 17.0)	15.6 (12.2 to 19.1)	25.3 (21.2 to 29.4)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo
Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	852
Analysis specification	Pre-specified
Analysis type	other[41]
P-value	< 0.0001 [42]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	13.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.5
upper limit	17

Notes:

[41] - This comparison was not part of the pre-specified multiplicity testing sequence.

[42] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo
Comparison groups	Placebo v Upadacitinib 30 mg

Number of subjects included in analysis	846
Analysis specification	Pre-specified
Analysis type	other[43]
P-value	< 0.0001 [44]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	22.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.5
upper limit	27.3

Notes:

[43] - This comparison was not part of the pre-specified multiplicity testing sequence.

[44] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Secondary: Percentage of Participants With an American College of Rheumatology 20% (ACR20) Response at Week 2

End point title	Percentage of Participants With an American College of Rheumatology 20% (ACR20) Response at Week 2

End point description:

Participants who met the following 3 conditions for improvement from baseline were classified as meeting the ACR20 response criteria:

1. ≥20% improvement in 68-tender joint count;
2. ≥20% improvement in 66-swollen joint count; and
3. ≥20% improvement in at least 3 of the 5 following parameters:

•Physician global assessment of disease activity
•Patient global assessment of disease activity
•Patient assessment of pain
•Health Assessment Questionnaire - Disability Index (HAQ-DI)
•High-sensitivity C-reactive protein (hsCRP).

Analysis population: Full analysis set; participants who prematurely discontinued from study drug prior to Week 2 or for whom ACR data were missing at Week 2 were considered non-responders.

End point type	Secondary

End point timeframe:

Baseline and Week 2

End point values	Placebo	Adalimumab 40 mg	Upadacitinib 15 mg	Upadacitinib 30 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	423	429	429	423
Units: percentage of participants				
number (confidence interval 95%)	12.1 (9.0 to 15.2)	30.3 (26.0 to 34.7)	28.2 (23.9 to 32.5)	38.3 (33.7 to 42.9)

Statistical analyses

Statistical analysis title	Upadacitinib 15 mg vs Placebo
Comparison groups	Placebo v Upadacitinib 15 mg
Number of subjects included in analysis	852
Analysis specification	Pre-specified
Analysis type	other[45]
P-value	< 0.0001 [46]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	16.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.9
upper limit	21.4

Notes:

[45] - This comparison was not part of the pre-specified multiplicity testing sequence.

[46] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Statistical analysis title	Upadacitinib 30 mg vs Placebo
Comparison groups	Placebo v Upadacitinib 30 mg
Number of subjects included in analysis	846
Analysis specification	Pre-specified
Analysis type	other[47]
P-value	< 0.0001 [48]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	26.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.7
upper limit	31.8

Notes:

[47] - This comparison was not part of the pre-specified multiplicity testing sequence.

[48] - Cochran-Mantel-Haenszel test adjusting for the main stratification factor of current DMARD use (yes/no).

Response Rate Difference = Upadacitinib - Placebo

Adverse events information

Timeframe for reporting adverse events:

Median time on follow-up in Period 1 (days): Upa 15 mg (415); Upa 30 mg (414); Ada 40 mg (194); Pbo up to Wk 24 (418); Pbo/Upa 15 mg Wk 24-56 (419); and Pbo/Upa 30 mg Wk 24-56 (776.5).

Adverse event reporting additional description:

Median time on follow-up in Period 2 (days): Upa 15 mg (1458); Upa 30 mg (796.5); Ada 40 mg (1486); Pbo/Upa 15 mg (1459); Pbo/Upa 30 mg (790.5); and Upa 30 mg/Upa 15 mg (842).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Upadacitinib 30 mg Period 1 (Weeks 1 to 56)

Reporting group description:

Participants randomized to receive upadacitinib 30 mg orally once a day (QD) and matching placebo to adalimumab by subcutaneous injection every other week (EOW) for 56 weeks in Period 1.

Reporting group title	Upadacitinib 15 mg Period 1 (Weeks 1 to 56)

Reporting group description:

Participants randomized to receive upadacitinib 15 mg orally once a day (QD) and matching placebo to adalimumab by subcutaneous injection every other week (EOW) for 56 weeks in Period 1.

Reporting group title	Adalimumab 40 mg Period 1 (Weeks 1 to 56)

Reporting group description:

Participants randomized to receive adalimumab 40 mg by subcutaneous injection every other week (EOW) and matching placebo to upadacitinib orally once a day (QD) for 56 weeks in Period 1.

Reporting group title	Upadacitinib 15 mg Period 2 (Weeks 56 to 260)

Reporting group description:

Participants randomized to receive upadacitinib 15 mg orally once a day (QD) and matching placebo to adalimumab by subcutaneous injection EOW for 56 weeks in Period 1 who continued to receive 15 mg upadacitinib QD in Period 2 (Weeks 56 to 260).

Reporting group title	Upadacitinib 30 mg Period 2 (Weeks 56 to 260)

Reporting group description:

Participants randomized to receive upadacitinib 30 mg orally once a day (QD) and matching placebo to adalimumab by subcutaneous injection every other week (EOW) for 56 weeks in Period 1 who continued to receive 30 mg upadacitinib QD in Period 2 (Weeks 56 to 260).

Reporting group title	Adalimumab 40 mg Period 2 (Weeks 56 to 260)

Reporting group description:

Participants randomized to receive adalimumab 40 mg by subcutaneous injection every other week (EOW) and matching placebo to upadacitinib orally once a day (QD) for 56 weeks in Period 1 who continued to receive 40 mg adalimumab EOW in Period 2 (Weeks 56 to 260).

Reporting group title	Placebo / Upadacitinib 15 mg Period 2 (Weeks 56 to 260)

Reporting group description:

Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks followed by upadacitinib 15 mg orally once a day (QD) for 32 weeks (Weeks 24 to 56), as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 56 in Period 1. During Period 2 (Weeks 56 to 260) participants continued to receive upadacitinib 15 mg orally once a day (QD).

Reporting group title	Placebo / Upadacitinib 30 mg Period 2 (Weeks 56 to 260)

Reporting group description:

Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks followed by upadacitinib 30 mg orally once a day (QD) for 32 weeks (Weeks 24 to 56), as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 56 in Period 1. During Period 2 (Weeks 56 to 260) participants continued to receive upadacitinib 30 mg orally once a day (QD).

Reporting group title	Upadacitinib 30 mg / Upadacitinib 15 mg Period 2 (Wks 56

	-260)

Reporting group description:

Participants randomized to receive upadacitinib 30 mg orally once a day (QD) who were switched to upadacitinib 15 mg orally once a day (QD) at their next scheduled study visit in Period 2 after Protocol Amendment 7 was approved (30 January 2021).

Reporting group title	Placebo / Upadacitinib 15 mg Period 1 (Weeks 24 to 56)

Reporting group description:

Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks followed by upadacitinib 15 mg orally once a day (QD) for 32 weeks (Weeks 24 to 56), as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 56 in Period 1.

Reporting group title	Placebo Period 1 (Weeks 1 to 24)

Reporting group description:

Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks, as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 24 in Period 1.

Reporting group title	Placebo / Upadacitinib 30 mg Period 1 (Weeks 24 to 56)

Reporting group description:

Participants randomized to receive matching placebo to upadacitinib orally once a day (QD) for 24 weeks followed by upadacitinib 30 mg orally once a day (QD) for 32 weeks (Weeks 24 to 56), as well as matching placebo to adalimumab administered by subcutaneous injection every other week (EOW) from Weeks 1 to 56 in Period 1.

Serious adverse events	Upadacitinib 30 mg Period 1 (Weeks 1 to 56)	Upadacitinib 15 mg Period 1 (Weeks 1 to 56)	Adalimumab 40 mg Period 1 (Weeks 1 to 56)
Total subjects affected by serious adverse events			
subjects affected / exposed	46 / 423 (10.87%)	28 / 430 (6.51%)	35 / 429 (8.16%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA GASTRIC			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA OF COLON			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL CELL CARCINOMA			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER STAGE II			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLEAR CELL RENAL CELL CARCINOMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HORMONE RECEPTOR POSITIVE HER2 NEGATIVE BREAST CANCER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMANGIOMA OF LIVER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLON CANCER METASTATIC			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ADENOCARCINOMA			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
LARYNGEAL NEOPLASM			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INVASIVE DUCTAL BREAST CARCINOMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INVASIVE BREAST CARCINOMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ADENOCARCINOMA STAGE IV			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
MALIGNANT MELANOMA IN SITU			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYELOFIBROSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CANCER			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROENDOCRINE CARCINOMA OF THE SKIN			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 METASTATIC			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 NEOPLASM			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLASMA CELL MYELOMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POORLY DIFFERENTIATED THYROID CARCINOMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL CANCER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SCHWANNOMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF THE CERVIX			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF SKIN			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THYROID ADENOMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
UTERINE CANCER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

AORTIC STENOSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CIRCULATORY COLLAPSE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPERFICIAL VEIN THROMBOSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICOSE VEIN			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

UNINTENDED PREGNANCY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
CHEST PAIN			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
CYST RUPTURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DROWNING			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	2 / 423 (0.47%)	1 / 430 (0.23%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

RETENTION CYST			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
BENIGN PROSTATIC HYPERPLASIA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALLOPIAN TUBE CYST			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL HYPERTROPHY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 HYPERPLASIA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CERVICAL POLYP			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FIBROCYSTIC BREAST DISEASE			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
HAEMORRHAGIC OVARIAN CYST			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEAVY MENSTRUAL BLEEDING			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN STROMAL HYPERPLASIA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UTERINE HAEMORRHAGE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UTERINE POLYP			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL PROLAPSE			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPHYXIA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 RESPIRATORY FAILURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
DYSPNOEA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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

EPISTAXIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERVENTILATION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE SLEEP APNOEA SYNDROME			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX SPONTANEOUS			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY FIBROSIS			

subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	1 / 423 (0.24%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY DISTRESS			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (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
TONSILLAR HYPERTROPHY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TONSILLAR HAEMORRHAGE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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			
BIPOLAR DISORDER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BIPOLAR I DISORDER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANXIETY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MAJOR DEPRESSION			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEPRESSION			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (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
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORTISOL ABNORMAL			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WEIGHT INCREASED			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
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			
ANKLE FRACTURE			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
CHEST INJURY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CLAVICLE FRACTURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMMINUTED FRACTURE			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
CONCUSSION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE DISPLACEMENT			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOT FRACTURE			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAND FRACTURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCISIONAL HERNIA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT DISLOCATION			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT INJURY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 FOREIGN BODY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OPTIC NERVE INJURY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATELLA FRACTURE			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX TRAUMATIC			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RADIUS FRACTURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE FOREIGN BODY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 FRACTURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS FRACTURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER LIMB FRACTURE			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRAUMATIC LIVER INJURY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENDON RUPTURE			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
WOUND DEHISCENCE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
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			
HYDROCELE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANGINA PECTORIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 STENOSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIOSCLEROSIS CORONARY ARTERY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 FLUTTER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK SECOND DEGREE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 ARREST			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE ACUTE			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC CORONARY SYNDROME			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIOGENIC SHOCK			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORONARY ARTERY DISEASE			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	2 / 423 (0.47%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROXYSMAL ATRIOVENTRICULAR BLOCK			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL ISCHAEMIA			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDITIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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			
AMYOTROPHIC LATERAL SCLEROSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEMYELINATION			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL RADICULOPATHY			

subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETIC NEUROPATHY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ISCHAEMIC STROKE			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC ENCEPHALOPATHY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACUNAR STROKE			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (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
LUMBAR RADICULOPATHY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVE COMPRESSION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SCIATICA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VITH NERVE PARALYSIS			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
VERTEBROBASILAR INSUFFICIENCY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHADENOPATHY			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
ANAEMIA MACROCYTIC			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NORMOCHROMIC NORMOCYTIC ANAEMIA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOID TISSUE HYPERPLASIA			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
Ear and labyrinth disorders			
SUDDEN HEARING LOSS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VERTIGO POSITIONAL			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VERTIGO			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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			

EYELID PTOSIS			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIPLOPIA			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CATARACT			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
RETINAL DETACHMENT			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VISUAL ACUITY REDUCED			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 STRANGULATED HERNIA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 ADHESIONS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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

ASCITES			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL ULCER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL ULCER HAEMORRHAGE			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
DYSPEPSIA			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAECALOMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOD POISONING			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
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 EROSIVE			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (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
GASTRODUODENAL HAEMORRHAGE			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 PERFORATION			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (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
HAEMATEMESIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INGUINAL HERNIA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIATUS HERNIA			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHOIDS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
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 POLYP			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MESENTERIC VEIN THROMBOSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 SPASM			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETROPERITONEAL HAEMATOMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETROPERITONEAL HAEMORRHAGE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
BILE DUCT STONE			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY COLIC			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 FAILURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 ACUTE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC STEATOSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL VEIN THROMBOSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
ANGIOEDEMA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATOMYOSITIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS EXFOLIATIVE GENERALISED			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS CONTACT			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INGROWING NAIL			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSORIASIS			

subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
PUSTULAR PSORIASIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
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			
CALCULUS URINARY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 KIDNEY INJURY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (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
RENAL FAILURE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCONTINENCE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS URINARY INCONTINENCE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL STENOSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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			
GOITRE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACET JOINT SYNDROME			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CERVICAL SPINAL STENOSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BURSITIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOT DEFORMITY			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE NONUNION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 DEGENERATION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERVERTEBRAL DISC DISORDER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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	2 / 423 (0.47%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAW DISORDER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECK PAIN			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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	2 / 423 (0.47%)	0 / 430 (0.00%)	3 / 429 (0.70%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ROTATOR CUFF SYNDROME			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSORIATIC ARTHROPATHY			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEONECROSIS			
subjects affected / exposed	2 / 423 (0.47%)	0 / 430 (0.00%)	0 / 429 (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
SNAPPING HIP SYNDROME			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 RETROLISTHESIS			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPONDYLOLISTHESIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ABSCESS LIMB			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
ANAL ABSCESS			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS			
subjects affected / exposed	1 / 423 (0.24%)	1 / 430 (0.23%)	0 / 429 (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
ATYPICAL PNEUMONIA			
subjects affected / exposed	2 / 423 (0.47%)	0 / 430 (0.00%)	0 / 429 (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
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST ABSCESS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE ABSCESS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
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	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
CHRONIC TONSILLITIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYSTITIS			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 INTESTINAL PERFORATED			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ERYSIPELAS			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED DERMAL CYST			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			

subjects affected / exposed	1 / 423 (0.24%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS A			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 INFLUENZA			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (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
INFLUENZA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGITIS			
subjects affected / exposed	0 / 423 (0.00%)	1 / 430 (0.23%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT ABSCESS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC SEPSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			

subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
PERITONITIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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	4 / 423 (0.95%)	2 / 430 (0.47%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	3 / 4	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA ACINETOBACTER			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 ASPIRATION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 BACTERIAL			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 KLEBSIELLA			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 STREPTOCOCCAL			

subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY TUBERCULOSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
PYELONEPHRITIS ACUTE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SALPINGITIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 ABSCESS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 / 423 (0.00%)	2 / 430 (0.47%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPUTUM PURULENT			

subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
SKIN INFECTION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	1 / 429 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL SEPSIS			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUBERCULOSIS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUBERCULOUS PLEURISY			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
UROSEPSIS			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
VIRAL INFECTION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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			
DECREASED APPETITE			
subjects affected / exposed	1 / 423 (0.24%)	0 / 430 (0.00%)	0 / 429 (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
DIABETES MELLITUS			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRUCTOSE INTOLERANCE			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETIC KETOACIDOSIS			

subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
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	Upadacitinib 15 mg Period 2 (Weeks 56 to 260)	Upadacitinib 30 mg Period 2 (Weeks 56 to 260)	Adalimumab 40 mg Period 2 (Weeks 56 to 260)
Total subjects affected by serious adverse events			
subjects affected / exposed	108 / 378 (28.57%)	65 / 366 (17.76%)	72 / 366 (19.67%)
number of deaths (all causes)	16	10	5
number of deaths resulting from adverse events	5	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA GASTRIC			
subjects affected / exposed	2 / 378 (0.53%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA OF COLON			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (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
BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
BASAL CELL CARCINOMA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER STAGE II			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLEAR CELL RENAL CELL CARCINOMA			

subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
HORMONE RECEPTOR POSITIVE HER2 NEGATIVE BREAST CANCER			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (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
HAEMANGIOMA OF LIVER			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLON CANCER METASTATIC			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ADENOCARCINOMA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL NEOPLASM			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INVASIVE DUCTAL BREAST CARCINOMA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	2 / 366 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INVASIVE BREAST CARCINOMA			

subjects affected / exposed	0 / 378 (0.00%)	2 / 366 (0.55%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ADENOCARCINOMA STAGE IV			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT MELANOMA IN SITU			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYELOFIBROSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
OVARIAN CANCER			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROMA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROENDOCRINE CARCINOMA OF THE SKIN			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 METASTATIC			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATIC NEOPLASM			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
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 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
PLASMA CELL MYELOMA			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (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
POORLY DIFFERENTIATED THYROID CARCINOMA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
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 CANCER			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SCHWANNOMA			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF THE CERVIX			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
SQUAMOUS CELL CARCINOMA OF SKIN			
subjects affected / exposed	1 / 378 (0.26%)	1 / 366 (0.27%)	0 / 366 (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
THYROID ADENOMA			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UTERINE LEIOMYOMA			
subjects affected / exposed	2 / 378 (0.53%)	0 / 366 (0.00%)	0 / 366 (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
UTERINE CANCER			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 STENOSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CIRCULATORY COLLAPSE			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (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
DEEP VEIN THROMBOSIS			

subjects affected / exposed	1 / 378 (0.26%)	1 / 366 (0.27%)	0 / 366 (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
SUPERFICIAL VEIN THROMBOSIS			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICOSE VEIN			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UNINTENDED PREGNANCY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
CHEST PAIN			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CYST RUPTURE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
DROWNING			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
DEATH			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
PAIN			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETENTION CYST			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN DEATH			
subjects affected / exposed	2 / 378 (0.53%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Immune system disorders			

HYPERSENSITIVITY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (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
Reproductive system and breast disorders			
BENIGN PROSTATIC HYPERPLASIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALLOPIAN TUBE CYST			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 HYPERTROPHY			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL HYPERPLASIA			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL POLYP			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FIBROCYSTIC BREAST DISEASE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

HAEMORRHAGIC OVARIAN CYST			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEAVY MENSTRUAL BLEEDING			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 STROMAL HYPERPLASIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UTERINE HAEMORRHAGE			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UTERINE POLYP			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
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 PROLAPSE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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			

ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPHYXIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 RESPIRATORY FAILURE			
subjects affected / exposed	3 / 378 (0.79%)	2 / 366 (0.55%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
DYSPNOEA			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
COUGH			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPISTAXIS			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
HYPERVENTILATION			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
INTERSTITIAL LUNG DISEASE			

subjects affected / exposed	0 / 378 (0.00%)	2 / 366 (0.55%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE SLEEP APNOEA SYNDROME			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
PNEUMOTHORAX SPONTANEOUS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY FIBROSIS			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
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 EMBOLISM			
subjects affected / exposed	3 / 378 (0.79%)	4 / 366 (1.09%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	2 / 3	1 / 4	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
RESPIRATORY DISTRESS			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TONSILLAR HYPERTROPHY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TONSILLAR HAEMORRHAGE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
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			
BIPOLAR DISORDER			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BIPOLAR I DISORDER			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANXIETY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MAJOR DEPRESSION			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEPRESSION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 CREATININE INCREASED			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORTISOL ABNORMAL			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WEIGHT INCREASED			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ANKLE FRACTURE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST INJURY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLAVICLE FRACTURE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMMINUTED FRACTURE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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

CONCUSSION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	1 / 378 (0.26%)	1 / 366 (0.27%)	0 / 366 (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
FRACTURE DISPLACEMENT			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
FOOT FRACTURE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAND FRACTURE			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCISIONAL HERNIA			

subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT DISLOCATION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT INJURY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENISCUS INJURY			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULOSKELETAL FOREIGN BODY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OPTIC NERVE INJURY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATELLA FRACTURE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX TRAUMATIC			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RADIUS FRACTURE			

subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
SOFT TISSUE FOREIGN BODY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 FRACTURE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS FRACTURE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
UPPER LIMB FRACTURE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRAUMATIC LIVER INJURY			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
TIBIA FRACTURE			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENDON RUPTURE			
subjects affected / exposed	2 / 378 (0.53%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND DEHISCENCE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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			
HYDROCELE			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	2 / 366 (0.55%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
ANGINA PECTORIS			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
AORTIC VALVE STENOSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIOSCLEROSIS CORONARY ARTERY			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

ATRIAL FLUTTER			
subjects affected / exposed	1 / 378 (0.26%)	2 / 366 (0.55%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	4 / 378 (1.06%)	1 / 366 (0.27%)	3 / 366 (0.82%)
occurrences causally related to treatment / all	0 / 4	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK SECOND DEGREE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
CARDIAC DISORDER			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 ARREST			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (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
CARDIAC FAILURE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE ACUTE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
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 CORONARY SYNDROME			

subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
CARDIOGENIC SHOCK			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORONARY ARTERY DISEASE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	2 / 366 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	3 / 378 (0.79%)	1 / 366 (0.27%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	2 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
PAROXYSMAL ATRIOVENTRICULAR BLOCK			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDITIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	2 / 366 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
AMYOTROPHIC LATERAL SCLEROSIS			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL INFARCTION			
subjects affected / exposed	1 / 378 (0.26%)	1 / 366 (0.27%)	0 / 366 (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
DEMYELINATION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL RADICULOPATHY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETIC NEUROPATHY			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
HEPATIC ENCEPHALOPATHY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACUNAR STROKE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 RADICULOPATHY			
subjects affected / exposed	1 / 378 (0.26%)	2 / 366 (0.55%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVE COMPRESSION			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
RADICULOPATHY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SCIATICA			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
VITH NERVE PARALYSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VERTEBROBASILAR INSUFFICIENCY			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHADENOPATHY			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
ANAEMIA MACROCYTIC			

subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
NORMOCHROMIC NORMOCYTIC ANAEMIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOID TISSUE HYPERPLASIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
SUDDEN HEARING LOSS			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
VERTIGO POSITIONAL			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VERTIGO			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
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			
EYELID PTOSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIPLOPIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CATARACT			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VISUAL ACUITY REDUCED			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 STRANGULATED HERNIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
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 ADHESIONS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CROHN'S DISEASE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL ULCER			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
DUODENAL ULCER HAEMORRHAGE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
FOOD POISONING			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC ULCER PERFORATION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 EROSIVE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRODUODENAL HAEMORRHAGE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL PAIN			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
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 PERFORATION			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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	2 / 378 (0.53%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
INGUINAL HERNIA			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	2 / 366 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIATUS HERNIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHOIDS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 POLYP			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	2 / 366 (0.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MESENTERIC VEIN THROMBOSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
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	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
OESOPHAGEAL SPASM			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETROPERITONEAL HAEMATOMA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETROPERITONEAL HAEMORRHAGE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (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
VOMITING			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY COLIC			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
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	2 / 378 (0.53%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 FAILURE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	3 / 378 (0.79%)	0 / 366 (0.00%)	2 / 366 (0.55%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS ACUTE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
HEPATIC STEATOSIS			
subjects affected / exposed	1 / 378 (0.26%)	1 / 366 (0.27%)	0 / 366 (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
JAUNDICE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL VEIN THROMBOSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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			
ANGIOEDEMA			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATOMYOSITIS			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS EXFOLIATIVE GENERALISED			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS CONTACT			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INGROWING NAIL			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSORIASIS			
subjects affected / exposed	1 / 378 (0.26%)	1 / 366 (0.27%)	0 / 366 (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
PUSTULAR PSORIASIS			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
CALCULUS URINARY			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 KIDNEY INJURY			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCONTINENCE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
NEPHROLITHIASIS			
subjects affected / exposed	1 / 378 (0.26%)	2 / 366 (0.55%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS URINARY INCONTINENCE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETEROLITHIASIS			

subjects affected / exposed	2 / 378 (0.53%)	0 / 366 (0.00%)	0 / 366 (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
URETHRAL STENOSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
GOITRE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	1 / 366 (0.27%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACET JOINT SYNDROME			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL SPINAL STENOSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BURSITIS			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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

FOOT DEFORMITY			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	3 / 366 (0.82%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE NONUNION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 DEGENERATION			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERVERTEBRAL DISC DISORDER			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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	2 / 378 (0.53%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAW DISORDER			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
NECK PAIN			
subjects affected / exposed	2 / 378 (0.53%)	0 / 366 (0.00%)	0 / 366 (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
LUMBAR SPINAL STENOSIS			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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	5 / 378 (1.32%)	3 / 366 (0.82%)	5 / 366 (1.37%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ROTATOR CUFF SYNDROME			
subjects affected / exposed	3 / 378 (0.79%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSORIATIC ARTHROPATHY			
subjects affected / exposed	1 / 378 (0.26%)	1 / 366 (0.27%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEONECROSIS			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SNAPPING HIP SYNDROME			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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 RETROLISTHESIS			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPINAL STENOSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPONDYLOLISTHESIS			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ABSCESS LIMB			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAL ABSCESS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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	3 / 378 (0.79%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATYPICAL PNEUMONIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST ABSCESS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE ABSCESS			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	1 / 378 (0.26%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC TONSILLITIS			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	2 / 366 (0.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	1 / 378 (0.26%)	1 / 366 (0.27%)	2 / 366 (0.55%)
occurrences causally related to treatment / all	0 / 1	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	20 / 378 (5.29%)	19 / 366 (5.19%)	4 / 366 (1.09%)
occurrences causally related to treatment / all	1 / 20	3 / 19	2 / 4
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 1
COVID-19			
subjects affected / exposed	12 / 378 (3.17%)	9 / 366 (2.46%)	4 / 366 (1.09%)
occurrences causally related to treatment / all	2 / 12	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 0
CYSTITIS			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
ENTEROCOCCAL BACTERAEMIA			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 INTESTINAL PERFORATED			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ERYSIPELAS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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	1 / 378 (0.26%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED DERMAL CYST			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			
subjects affected / exposed	1 / 378 (0.26%)	4 / 366 (1.09%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	1 / 1	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS A			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 INFLUENZA			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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	2 / 378 (0.53%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
LARYNGITIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT ABSCESS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC SEPSIS			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (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
OPHTHALMIC HERPES ZOSTER			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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	7 / 378 (1.85%)	2 / 366 (0.55%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	3 / 7	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA ACINETOBACTER			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA ASPIRATION			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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 BACTERIAL			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
PNEUMONIA KLEBSIELLA			
subjects affected / exposed	0 / 378 (0.00%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA STREPTOCOCCAL			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY TUBERCULOSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			

subjects affected / exposed	2 / 378 (0.53%)	0 / 366 (0.00%)	0 / 366 (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
PYELONEPHRITIS ACUTE			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
SALPINGITIS			
subjects affected / exposed	0 / 378 (0.00%)	2 / 366 (0.55%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL ABSCESS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	1 / 378 (0.26%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
SEPTIC SHOCK			
subjects affected / exposed	2 / 378 (0.53%)	1 / 366 (0.27%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
SPUTUM PURULENT			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL SEPSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUBERCULOSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUBERCULOUS PLEURISY			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	1 / 366 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			

subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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	1 / 378 (0.26%)	0 / 366 (0.00%)	0 / 366 (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
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETES MELLITUS			
subjects affected / exposed	2 / 378 (0.53%)	0 / 366 (0.00%)	0 / 366 (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
DEHYDRATION			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRUCTOSE INTOLERANCE			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETIC KETOACIDOSIS			
subjects affected / exposed	0 / 378 (0.00%)	0 / 366 (0.00%)	0 / 366 (0.00%)
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 / Upadacitinib 15 mg Period 2 (Weeks 56 to 260)	Placebo / Upadacitinib 30 mg Period 2 (Weeks 56 to 260)	Upadacitinib 30 mg / Upadacitinib 15 mg Period 2 (Wks 56 - 260)
Total subjects affected by serious adverse events			
subjects affected / exposed	34 / 177 (19.21%)	25 / 178 (14.04%)	55 / 443 (12.42%)
number of deaths (all causes)	3	3	5

number of deaths resulting from adverse events	0	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA GASTRIC			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA OF COLON			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL CELL CARCINOMA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER STAGE II			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
CLEAR CELL RENAL CELL CARCINOMA			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HORMONE RECEPTOR POSITIVE HER2 NEGATIVE BREAST CANCER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMANGIOMA OF LIVER			

subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL ADENOCARCINOMA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLON CANCER METASTATIC			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ADENOCARCINOMA			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
LARYNGEAL NEOPLASM			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INVASIVE DUCTAL BREAST CARCINOMA			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
INVASIVE BREAST CARCINOMA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ADENOCARCINOMA STAGE IV			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG CANCER METASTATIC			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT MELANOMA IN SITU			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYELOFIBROSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CANCER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROMA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROENDOCRINE CARCINOMA OF THE SKIN			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATIC CARCINOMA METASTATIC			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 NEOPLASM			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLASMA CELL MYELOMA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POORLY DIFFERENTIATED THYROID CARCINOMA			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
PROSTATE CANCER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
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 CANCER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SCHWANNOMA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF THE CERVIX			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF SKIN			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THYROID ADENOMA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
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 STENOSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CIRCULATORY COLLAPSE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPERFICIAL VEIN THROMBOSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICOSE VEIN			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
ABORTION SPONTANEOUS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UNINTENDED PREGNANCY			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
General disorders and administration site conditions			
CHEST PAIN			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYST RUPTURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DROWNING			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

DEATH			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
PAIN			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETENTION CYST			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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	2 / 177 (1.13%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Immune system disorders			
HYPERSENSITIVITY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
BENIGN PROSTATIC HYPERPLASIA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALLOPIAN TUBE CYST			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 HYPERTROPHY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 HYPERPLASIA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL POLYP			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FIBROCYSTIC BREAST DISEASE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHAGIC OVARIAN CYST			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEAVY MENSTRUAL BLEEDING			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

OVARIAN CYST			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 STROMAL HYPERPLASIA			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
UTERINE HAEMORRHAGE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UTERINE POLYP			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL PROLAPSE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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			
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPHYXIA			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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

ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	1 / 177 (0.56%)	1 / 178 (0.56%)	0 / 443 (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
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPISTAXIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERVENTILATION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE SLEEP APNOEA SYNDROME			

subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
PLEURAL EFFUSION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX SPONTANEOUS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY FIBROSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	2 / 178 (1.12%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
RESPIRATORY DISTRESS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TONSILLAR HYPERTROPHY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TONSILLAR HAEMORRHAGE			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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			
BIPOLAR DISORDER			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
BIPOLAR I DISORDER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANXIETY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MAJOR DEPRESSION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEPRESSION			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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 CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 CREATININE INCREASED			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CORTISOL ABNORMAL			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WEIGHT INCREASED			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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			
ANKLE FRACTURE			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
CHEST INJURY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLAVICLE FRACTURE			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMMINUTED FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

FEMUR FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE DISPLACEMENT			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOT FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAND FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCISIONAL HERNIA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT DISLOCATION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT INJURY			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULOSKELETAL FOREIGN BODY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OPTIC NERVE INJURY			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
PATELLA FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX TRAUMATIC			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RADIUS FRACTURE			
subjects affected / exposed	1 / 177 (0.56%)	1 / 178 (0.56%)	0 / 443 (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
RIB FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ROAD TRAFFIC ACCIDENT			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE FOREIGN BODY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER LIMB FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRAUMATIC LIVER INJURY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENDON RUPTURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 DEHISCENCE			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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			
HYDROCELE			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
Cardiac disorders			
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 STENOSIS			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIOSCLEROSIS CORONARY ARTERY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 FLUTTER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ATRIOVENTRICULAR BLOCK SECOND DEGREE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC ARREST			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	2 / 443 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE ACUTE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 CORONARY SYNDROME			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIOGENIC SHOCK			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEFT VENTRICULAR DYSFUNCTION			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORONARY ARTERY DISEASE			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROXYSMAL ATRIOVENTRICULAR BLOCK			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDITIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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			
AMYOTROPHIC LATERAL SCLEROSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL HAEMORRHAGE			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEMYELINATION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL RADICULOPATHY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETIC NEUROPATHY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 ENCEPHALOPATHY			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACUNAR STROKE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 RADICULOPATHY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVE COMPRESSION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBARACHNOID HAEMORRHAGE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SCIATICA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
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	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
TRANSIENT ISCHAEMIC ATTACK			

subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VITH NERVE PARALYSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VERTEBROBASILAR INSUFFICIENCY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAEMIA MACROCYTIC			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NORMOCHROMIC NORMOCYTIC ANAEMIA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOID TISSUE HYPERPLASIA			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
SUDDEN HEARING LOSS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VERTIGO POSITIONAL			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
VERTIGO			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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			
EYELID PTOSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIPLOPIA			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CATARACT			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VISUAL ACUITY REDUCED			

subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
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 STRANGULATED HERNIA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 ADHESIONS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
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 FISTULA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL ULCER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL ULCER HAEMORRHAGE			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOD POISONING			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 EROSIVE			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRODUODENAL HAEMORRHAGE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INGUINAL HERNIA			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
HIATUS HERNIA			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHOIDS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 POLYP			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
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	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MESENTERIC VEIN THROMBOSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 SPASM			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETROPERITONEAL HAEMATOMA			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETROPERITONEAL HAEMORRHAGE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY COLIC			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FAILURE			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	2 / 443 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS ACUTE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC STEATOSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL VEIN THROMBOSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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			
ANGIOEDEMA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATOMYOSITIS			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS EXFOLIATIVE GENERALISED			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS CONTACT			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INGROWING NAIL			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSORIASIS			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
PUSTULAR PSORIASIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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			
CALCULUS URINARY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL COLIC			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCONTINENCE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEPHROLITHIASIS			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
STRESS URINARY INCONTINENCE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL STENOSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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			
GOITRE			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACET JOINT SYNDROME			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL SPINAL STENOSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BURSITIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOT DEFORMITY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE NONUNION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
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 DEGENERATION			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERVERTEBRAL DISC DISORDER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAW DISORDER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECK PAIN			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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	1 / 177 (0.56%)	1 / 178 (0.56%)	5 / 443 (1.13%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ROTATOR CUFF SYNDROME			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSORIATIC ARTHROPATHY			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEONECROSIS			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SNAPPING HIP SYNDROME			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 RETROLISTHESIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPONDYLOLISTHESIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ABSCESS LIMB			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
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 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATYPICAL PNEUMONIA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST ABSCESS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE ABSCESS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC TONSILLITIS			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 PNEUMONIA			
subjects affected / exposed	9 / 177 (5.08%)	8 / 178 (4.49%)	7 / 443 (1.58%)
occurrences causally related to treatment / all	2 / 9	3 / 8	0 / 7
deaths causally related to treatment / all	0 / 1	1 / 2	0 / 2
COVID-19			
subjects affected / exposed	1 / 177 (0.56%)	1 / 178 (0.56%)	4 / 443 (0.90%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
CYSTITIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS INTESTINAL PERFORATED			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA URINARY TRACT INFECTION			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ERYSIPELAS			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	3 / 443 (0.68%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
INFECTED DERMAL CYST			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS A			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 INFLUENZA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGITIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT ABSCESS			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (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
NEUTROPENIC SEPSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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
PNEUMONIA			
subjects affected / exposed	1 / 177 (0.56%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA ACINETOBACTER			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 ASPIRATION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 BACTERIAL			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 KLEBSIELLA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 STREPTOCOCCAL			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY TUBERCULOSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 ACUTE			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SALPINGITIS			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL ABSCESS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPUTUM PURULENT			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL SEPSIS			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUBERCULOSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUBERCULOUS PLEURISY			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	2 / 443 (0.45%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
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			
DECREASED APPETITE			

subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETES MELLITUS			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	0 / 443 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	0 / 177 (0.00%)	0 / 178 (0.00%)	1 / 443 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRUCTOSE INTOLERANCE			
subjects affected / exposed	0 / 177 (0.00%)	1 / 178 (0.56%)	0 / 443 (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
DIABETIC KETOACIDOSIS			
subjects affected / exposed	1 / 177 (0.56%)	0 / 178 (0.00%)	0 / 443 (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

Serious adverse events	Placebo / Upadacitinib 15 mg Period 1 (Weeks 24 to 56)	Placebo Period 1 (Weeks 1 to 24)	Placebo / Upadacitinib 30 mg Period 1 (Weeks 24 to 56)
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 188 (5.32%)	13 / 423 (3.07%)	11 / 190 (5.79%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA GASTRIC			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA OF COLON			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL CELL CARCINOMA			
subjects affected / exposed	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER STAGE II			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLEAR CELL RENAL CELL CARCINOMA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HORMONE RECEPTOR POSITIVE HER2 NEGATIVE BREAST CANCER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMANGIOMA OF LIVER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLON CANCER METASTATIC			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ADENOCARCINOMA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL NEOPLASM			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INVASIVE DUCTAL BREAST CARCINOMA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INVASIVE BREAST CARCINOMA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ADENOCARCINOMA STAGE IV			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT MELANOMA IN SITU			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYELOFIBROSIS			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CANCER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROMA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROENDOCRINE CARCINOMA OF THE SKIN			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 METASTATIC			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 NEOPLASM			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLASMA CELL MYELOMA			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POORLY DIFFERENTIATED THYROID CARCINOMA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL CANCER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SCHWANNOMA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF THE CERVIX			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF SKIN			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THYROID ADENOMA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 STENOSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CIRCULATORY COLLAPSE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	1 / 423 (0.24%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPERFICIAL VEIN THROMBOSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICOSE VEIN			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UNINTENDED PREGNANCY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
CHEST PAIN			
subjects affected / exposed	0 / 188 (0.00%)	1 / 423 (0.24%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYST RUPTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DROWNING			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETENTION CYST			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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			
HYPERSENSITIVITY			
subjects affected / exposed	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (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
IMMUNE SYSTEM DISORDER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
BENIGN PROSTATIC HYPERPLASIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

FALLOPIAN TUBE CYST			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 HYPERTROPHY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 HYPERPLASIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL POLYP			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FIBROCYSTIC BREAST DISEASE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHAGIC OVARIAN CYST			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEAVY MENSTRUAL BLEEDING			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 STROMAL HYPERPLASIA			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UTERINE HAEMORRHAGE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UTERINE POLYP			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL PROLAPSE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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			
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPHYXIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 RESPIRATORY FAILURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPISTAXIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERVENTILATION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 188 (0.00%)	1 / 423 (0.24%)	0 / 190 (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
OBSTRUCTIVE SLEEP APNOEA SYNDROME			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX SPONTANEOUS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY FIBROSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 DISTRESS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TONSILLAR HYPERTROPHY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TONSILLAR HAEMORRHAGE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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			
BIPOLAR DISORDER			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BIPOLAR I DISORDER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANXIETY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MAJOR DEPRESSION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEPRESSION			
subjects affected / exposed	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (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 CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 CREATININE INCREASED			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORTISOL ABNORMAL			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WEIGHT INCREASED			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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			
ANKLE FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 INJURY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLAVICLE FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMMINUTED FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE DISPLACEMENT			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOT FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAND FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	1 / 423 (0.24%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCISIONAL HERNIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT DISLOCATION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT INJURY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 FOREIGN BODY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OPTIC NERVE INJURY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATELLA FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX TRAUMATIC			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RADIUS FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE FOREIGN BODY			

subjects affected / exposed	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (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 FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER LIMB FRACTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRAUMATIC LIVER INJURY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TIBIA FRACTURE			
subjects affected / exposed	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENDON RUPTURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 DEHISCENCE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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			
HYDROCELE			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 STENOSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIOSCLEROSIS CORONARY ARTERY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 FLUTTER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK SECOND DEGREE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 DISORDER			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 ARREST			
subjects affected / exposed	0 / 188 (0.00%)	1 / 423 (0.24%)	0 / 190 (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
CARDIAC FAILURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE ACUTE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 CORONARY SYNDROME			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIOGENIC SHOCK			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAROXYSMAL ATRIOVENTRICULAR BLOCK			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDITIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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			
AMYOTROPHIC LATERAL SCLEROSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEMYELINATION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL RADICULOPATHY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETIC NEUROPATHY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 ENCEPHALOPATHY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACUNAR STROKE			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 RADICULOPATHY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVE COMPRESSION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SCIATICA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (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
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VITH NERVE PARALYSIS			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VERTEBROBASILAR INSUFFICIENCY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHADENOPATHY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAEMIA MACROCYTIC			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NORMOCHROMIC NORMOCYTIC ANAEMIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOID TISSUE HYPERPLASIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			

SUDDEN HEARING LOSS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VERTIGO POSITIONAL			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VERTIGO			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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			
EYELID PTOSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIPLOPIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CATARACT			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VISUAL ACUITY REDUCED			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 STRANGULATED HERNIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 ADHESIONS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL ULCER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL ULCER HAEMORRHAGE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTERITIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROVESICAL FISTULA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOLITIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOD POISONING			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 EROSIVE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRODUODENAL HAEMORRHAGE			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INGUINAL HERNIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIATUS HERNIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHOIDS			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	1 / 190 (0.53%)
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 POLYP			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 POLYP			
subjects affected / exposed	0 / 188 (0.00%)	1 / 423 (0.24%)	0 / 190 (0.00%)
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	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MESENTERIC VEIN THROMBOSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 SPASM			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETROPERITONEAL HAEMATOMA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETROPERITONEAL HAEMORRHAGE			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY COLIC			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 FAILURE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			

subjects affected / exposed	0 / 188 (0.00%)	1 / 423 (0.24%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS ACUTE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC STEATOSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PORTAL VEIN THROMBOSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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			
ANGIOEDEMA			
subjects affected / exposed	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (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
DERMATITIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATOMYOSITIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS EXFOLIATIVE GENERALISED			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERMATITIS CONTACT			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INGROWING NAIL			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSORIASIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PUSTULAR PSORIASIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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			
CALCULUS URINARY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 KIDNEY INJURY			
subjects affected / exposed	0 / 188 (0.00%)	1 / 423 (0.24%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCONTINENCE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRESS URINARY INCONTINENCE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETHRAL STENOSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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			
GOITRE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACET JOINT SYNDROME			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL SPINAL STENOSIS			
subjects affected / exposed	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (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
BURSITIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOT DEFORMITY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE NONUNION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 DEGENERATION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERVERTEBRAL DISC DISORDER			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAW DISORDER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECK PAIN			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ROTATOR CUFF SYNDROME			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PSORIATIC ARTHROPATHY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEONECROSIS			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SNAPPING HIP SYNDROME			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 RETROLISTHESIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	1 / 423 (0.24%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPONDYLOLISTHESIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ABSCESS LIMB			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	1 / 423 (0.24%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATYPICAL PNEUMONIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS BACTERIAL			
subjects affected / exposed	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (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
BACTERAEMIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST ABSCESS			
subjects affected / exposed	0 / 188 (0.00%)	1 / 423 (0.24%)	0 / 190 (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
BONE ABSCESS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC TONSILLITIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (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
COVID-19 PNEUMONIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYSTITIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 INTESTINAL PERFORATED			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ERYSIPELAS			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED DERMAL CYST			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS A			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 INFLUENZA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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	1 / 188 (0.53%)	0 / 423 (0.00%)	0 / 190 (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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGITIS			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT ABSCESS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIC SEPSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	2 / 423 (0.47%)	1 / 190 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA ACINETOBACTER			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 ASPIRATION			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 BACTERIAL			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 KLEBSIELLA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 STREPTOCOCCAL			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY TUBERCULOSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 ACUTE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SALPINGITIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 ABSCESS			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPUTUM PURULENT			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STAPHYLOCOCCAL SEPSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBCUTANEOUS ABSCESS			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	1 / 190 (0.53%)
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 INFECTION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUBERCULOSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUBERCULOUS PLEURISY			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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 / 188 (0.00%)	0 / 423 (0.00%)	1 / 190 (0.53%)
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			
DECREASED APPETITE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETES MELLITUS			

subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRUCTOSE INTOLERANCE			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETIC KETOACIDOSIS			
subjects affected / exposed	0 / 188 (0.00%)	0 / 423 (0.00%)	0 / 190 (0.00%)
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	Upadacitinib 30 mg Period 1 (Weeks 1 to 56)	Upadacitinib 15 mg Period 1 (Weeks 1 to 56)	Adalimumab 40 mg Period 1 (Weeks 1 to 56)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	262 / 423 (61.94%)	248 / 430 (57.67%)	220 / 429 (51.28%)
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	67 / 423 (15.84%)	52 / 430 (12.09%)	31 / 429 (7.23%)
occurrences (all)	95	69	38
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	29 / 423 (6.86%)	25 / 430 (5.81%)	28 / 429 (6.53%)
occurrences (all)	38	29	32
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	39 / 423 (9.22%)	32 / 430 (7.44%)	44 / 429 (10.26%)
occurrences (all)	52	45	53
Vascular disorders			

HYPERTENSION			
subjects affected / exposed	21 / 423 (4.96%)	33 / 430 (7.67%)	15 / 429 (3.50%)
occurrences (all)	22	37	15
Nervous system disorders			
HEADACHE			
subjects affected / exposed	21 / 423 (4.96%)	23 / 430 (5.35%)	23 / 429 (5.36%)
occurrences (all)	28	32	24
Blood and lymphatic system disorders			
LEUKOPENIA			
subjects affected / exposed	15 / 423 (3.55%)	16 / 430 (3.72%)	8 / 429 (1.86%)
occurrences (all)	20	19	10
LYMPHOPENIA			
subjects affected / exposed	15 / 423 (3.55%)	10 / 430 (2.33%)	1 / 429 (0.23%)
occurrences (all)	17	15	1
NEUTROPENIA			
subjects affected / exposed	21 / 423 (4.96%)	11 / 430 (2.56%)	16 / 429 (3.73%)
occurrences (all)	28	11	20
General disorders and administration site conditions			
PYREXIA			
subjects affected / exposed	16 / 423 (3.78%)	2 / 430 (0.47%)	5 / 429 (1.17%)
occurrences (all)	19	4	5
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	23 / 423 (5.44%)	23 / 430 (5.35%)	19 / 429 (4.43%)
occurrences (all)	26	25	20
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	23 / 423 (5.44%)	12 / 430 (2.79%)	9 / 429 (2.10%)
occurrences (all)	28	13	9
Skin and subcutaneous tissue disorders			
PSORIASIS			
subjects affected / exposed	8 / 423 (1.89%)	9 / 430 (2.09%)	18 / 429 (4.20%)
occurrences (all)	11	10	20
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			

subjects affected / exposed	5 / 423 (1.18%)	7 / 430 (1.63%)	4 / 429 (0.93%)
occurrences (all)	6	7	4
BACK PAIN			
subjects affected / exposed	13 / 423 (3.07%)	8 / 430 (1.86%)	11 / 429 (2.56%)
occurrences (all)	13	8	13
OSTEOARTHRITIS			
subjects affected / exposed	3 / 423 (0.71%)	6 / 430 (1.40%)	4 / 429 (0.93%)
occurrences (all)	3	6	4
PSORIATIC ARTHROPATHY			
subjects affected / exposed	21 / 423 (4.96%)	14 / 430 (3.26%)	20 / 429 (4.66%)
occurrences (all)	21	16	22
Infections and infestations			
LATENT TUBERCULOSIS			
subjects affected / exposed	1 / 423 (0.24%)	1 / 430 (0.23%)	1 / 429 (0.23%)
occurrences (all)	1	1	1
BRONCHITIS			
subjects affected / exposed	33 / 423 (7.80%)	28 / 430 (6.51%)	13 / 429 (3.03%)
occurrences (all)	39	30	14
COVID-19			
subjects affected / exposed	0 / 423 (0.00%)	0 / 430 (0.00%)	0 / 429 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	16 / 423 (3.78%)	10 / 430 (2.33%)	2 / 429 (0.47%)
occurrences (all)	17	10	2
ORAL HERPES			
subjects affected / exposed	28 / 423 (6.62%)	11 / 430 (2.56%)	10 / 429 (2.33%)
occurrences (all)	43	13	14
NASOPHARYNGITIS			
subjects affected / exposed	45 / 423 (10.64%)	36 / 430 (8.37%)	43 / 429 (10.02%)
occurrences (all)	52	49	56
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	72 / 423 (17.02%)	67 / 430 (15.58%)	53 / 429 (12.35%)
occurrences (all)	100	92	63
URINARY TRACT INFECTION			

subjects affected / exposed	30 / 423 (7.09%)	26 / 430 (6.05%)	18 / 429 (4.20%)
occurrences (all)	42	37	21

Non-serious adverse events	Upadacitinib 15 mg Period 2 (Weeks 56 to 260)	Upadacitinib 30 mg Period 2 (Weeks 56 to 260)	Adalimumab 40 mg Period 2 (Weeks 56 to 260)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	274 / 378 (72.49%)	218 / 366 (59.56%)	245 / 366 (66.94%)
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	43 / 378 (11.38%)	33 / 366 (9.02%)	21 / 366 (5.74%)
occurrences (all)	76	43	34
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	27 / 378 (7.14%)	23 / 366 (6.28%)	22 / 366 (6.01%)
occurrences (all)	38	26	28
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	33 / 378 (8.73%)	23 / 366 (6.28%)	30 / 366 (8.20%)
occurrences (all)	48	28	35
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	39 / 378 (10.32%)	11 / 366 (3.01%)	26 / 366 (7.10%)
occurrences (all)	44	12	27
Nervous system disorders			
HEADACHE			
subjects affected / exposed	15 / 378 (3.97%)	13 / 366 (3.55%)	17 / 366 (4.64%)
occurrences (all)	42	16	20
Blood and lymphatic system disorders			
LEUKOPENIA			
subjects affected / exposed	21 / 378 (5.56%)	10 / 366 (2.73%)	9 / 366 (2.46%)
occurrences (all)	30	14	15
LYMPHOPENIA			
subjects affected / exposed	13 / 378 (3.44%)	6 / 366 (1.64%)	1 / 366 (0.27%)
occurrences (all)	26	9	2
NEUTROPENIA			
subjects affected / exposed	14 / 378 (3.70%)	14 / 366 (3.83%)	17 / 366 (4.64%)
occurrences (all)	26	16	26
General disorders and administration site conditions			

PYREXIA			
subjects affected / exposed	8 / 378 (2.12%)	5 / 366 (1.37%)	3 / 366 (0.82%)
occurrences (all)	9	5	3
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	14 / 378 (3.70%)	9 / 366 (2.46%)	10 / 366 (2.73%)
occurrences (all)	14	9	10
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	16 / 378 (4.23%)	7 / 366 (1.91%)	9 / 366 (2.46%)
occurrences (all)	17	9	12
Skin and subcutaneous tissue disorders			
PSORIASIS			
subjects affected / exposed	22 / 378 (5.82%)	20 / 366 (5.46%)	23 / 366 (6.28%)
occurrences (all)	24	28	29
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	24 / 378 (6.35%)	8 / 366 (2.19%)	22 / 366 (6.01%)
occurrences (all)	34	8	27
BACK PAIN			
subjects affected / exposed	29 / 378 (7.67%)	8 / 366 (2.19%)	18 / 366 (4.92%)
occurrences (all)	29	8	20
OSTEOARTHRITIS			
subjects affected / exposed	12 / 378 (3.17%)	7 / 366 (1.91%)	14 / 366 (3.83%)
occurrences (all)	14	8	17
PSORIATIC ARTHROPATHY			
subjects affected / exposed	42 / 378 (11.11%)	20 / 366 (5.46%)	33 / 366 (9.02%)
occurrences (all)	61	24	46
Infections and infestations			
LATENT TUBERCULOSIS			
subjects affected / exposed	22 / 378 (5.82%)	4 / 366 (1.09%)	19 / 366 (5.19%)
occurrences (all)	22	4	19
BRONCHITIS			
subjects affected / exposed	27 / 378 (7.14%)	12 / 366 (3.28%)	16 / 366 (4.37%)
occurrences (all)	33	15	18
COVID-19			

subjects affected / exposed	132 / 378 (34.92%)	51 / 366 (13.93%)	106 / 366 (28.96%)
occurrences (all)	150	52	119
HERPES ZOSTER			
subjects affected / exposed	29 / 378 (7.67%)	21 / 366 (5.74%)	8 / 366 (2.19%)
occurrences (all)	30	21	8
ORAL HERPES			
subjects affected / exposed	9 / 378 (2.38%)	8 / 366 (2.19%)	9 / 366 (2.46%)
occurrences (all)	10	19	15
NASOPHARYNGITIS			
subjects affected / exposed	38 / 378 (10.05%)	24 / 366 (6.56%)	31 / 366 (8.47%)
occurrences (all)	54	27	46
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	56 / 378 (14.81%)	40 / 366 (10.93%)	42 / 366 (11.48%)
occurrences (all)	82	52	60
URINARY TRACT INFECTION			
subjects affected / exposed	41 / 378 (10.85%)	21 / 366 (5.74%)	26 / 366 (7.10%)
occurrences (all)	64	38	32

Non-serious adverse events	Placebo / Upadacitinib 15 mg Period 2 (Weeks 56 to 260)	Placebo / Upadacitinib 30 mg Period 2 (Weeks 56 to 260)	Upadacitinib 30 mg / Upadacitinib 15 mg Period 2 (Wks 56 - 260)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	130 / 177 (73.45%)	112 / 178 (62.92%)	272 / 443 (61.40%)
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	22 / 177 (12.43%)	25 / 178 (14.04%)	39 / 443 (8.80%)
occurrences (all)	33	32	46
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	14 / 177 (7.91%)	9 / 178 (5.06%)	18 / 443 (4.06%)
occurrences (all)	20	12	20
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	18 / 177 (10.17%)	9 / 178 (5.06%)	19 / 443 (4.29%)
occurrences (all)	25	15	21
Vascular disorders			

HYPERTENSION			
subjects affected / exposed	15 / 177 (8.47%)	10 / 178 (5.62%)	20 / 443 (4.51%)
occurrences (all)	18	10	21
Nervous system disorders			
HEADACHE			
subjects affected / exposed	6 / 177 (3.39%)	3 / 178 (1.69%)	12 / 443 (2.71%)
occurrences (all)	24	3	12
Blood and lymphatic system disorders			
LEUKOPENIA			
subjects affected / exposed	10 / 177 (5.65%)	4 / 178 (2.25%)	20 / 443 (4.51%)
occurrences (all)	16	5	23
LYMPHOPENIA			
subjects affected / exposed	10 / 177 (5.65%)	6 / 178 (3.37%)	17 / 443 (3.84%)
occurrences (all)	12	6	24
NEUTROPENIA			
subjects affected / exposed	8 / 177 (4.52%)	7 / 178 (3.93%)	12 / 443 (2.71%)
occurrences (all)	11	10	18
General disorders and administration site conditions			
PYREXIA			
subjects affected / exposed	9 / 177 (5.08%)	6 / 178 (3.37%)	8 / 443 (1.81%)
occurrences (all)	10	7	10
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	7 / 177 (3.95%)	8 / 178 (4.49%)	7 / 443 (1.58%)
occurrences (all)	7	8	9
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	9 / 177 (5.08%)	4 / 178 (2.25%)	13 / 443 (2.93%)
occurrences (all)	10	4	13
Skin and subcutaneous tissue disorders			
PSORIASIS			
subjects affected / exposed	12 / 177 (6.78%)	4 / 178 (2.25%)	26 / 443 (5.87%)
occurrences (all)	14	4	31
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			

subjects affected / exposed	13 / 177 (7.34%)	5 / 178 (2.81%)	15 / 443 (3.39%)
occurrences (all)	18	5	18
BACK PAIN			
subjects affected / exposed	3 / 177 (1.69%)	8 / 178 (4.49%)	11 / 443 (2.48%)
occurrences (all)	3	8	11
OSTEOARTHRITIS			
subjects affected / exposed	10 / 177 (5.65%)	3 / 178 (1.69%)	7 / 443 (1.58%)
occurrences (all)	12	3	7
PSORIATIC ARTHROPATHY			
subjects affected / exposed	15 / 177 (8.47%)	10 / 178 (5.62%)	33 / 443 (7.45%)
occurrences (all)	19	12	42
Infections and infestations			
LATENT TUBERCULOSIS			
subjects affected / exposed	17 / 177 (9.60%)	8 / 178 (4.49%)	5 / 443 (1.13%)
occurrences (all)	17	8	5
BRONCHITIS			
subjects affected / exposed	16 / 177 (9.04%)	6 / 178 (3.37%)	25 / 443 (5.64%)
occurrences (all)	19	6	32
COVID-19			
subjects affected / exposed	57 / 177 (32.20%)	29 / 178 (16.29%)	117 / 443 (26.41%)
occurrences (all)	67	30	132
HERPES ZOSTER			
subjects affected / exposed	12 / 177 (6.78%)	10 / 178 (5.62%)	9 / 443 (2.03%)
occurrences (all)	13	10	9
ORAL HERPES			
subjects affected / exposed	4 / 177 (2.26%)	5 / 178 (2.81%)	7 / 443 (1.58%)
occurrences (all)	5	5	10
NASOPHARYNGITIS			
subjects affected / exposed	15 / 177 (8.47%)	9 / 178 (5.06%)	36 / 443 (8.13%)
occurrences (all)	22	11	46
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	25 / 177 (14.12%)	15 / 178 (8.43%)	49 / 443 (11.06%)
occurrences (all)	48	18	62
URINARY TRACT INFECTION			

subjects affected / exposed	15 / 177 (8.47%)	12 / 178 (6.74%)	25 / 443 (5.64%)
occurrences (all)	18	18	37

Non-serious adverse events	Placebo / Upadacitinib 15 mg Period 1 (Weeks 24 to 56)	Placebo Period 1 (Weeks 1 to 24)	Placebo / Upadacitinib 30 mg Period 1 (Weeks 24 to 56)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	62 / 188 (32.98%)	151 / 423 (35.70%)	76 / 190 (40.00%)
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	11 / 188 (5.85%)	6 / 423 (1.42%)	15 / 190 (7.89%)
occurrences (all)	13	7	17
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	4 / 188 (2.13%)	8 / 423 (1.89%)	9 / 190 (4.74%)
occurrences (all)	4	9	9
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	6 / 188 (3.19%)	12 / 423 (2.84%)	8 / 190 (4.21%)
occurrences (all)	6	14	8
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	2 / 188 (1.06%)	10 / 423 (2.36%)	2 / 190 (1.05%)
occurrences (all)	2	10	2
Nervous system disorders			
HEADACHE			
subjects affected / exposed	3 / 188 (1.60%)	10 / 423 (2.36%)	2 / 190 (1.05%)
occurrences (all)	6	10	2
Blood and lymphatic system disorders			
LEUKOPENIA			
subjects affected / exposed	1 / 188 (0.53%)	4 / 423 (0.95%)	3 / 190 (1.58%)
occurrences (all)	1	4	8
LYMPHOPENIA			
subjects affected / exposed	1 / 188 (0.53%)	5 / 423 (1.18%)	1 / 190 (0.53%)
occurrences (all)	1	5	1
NEUTROPENIA			
subjects affected / exposed	3 / 188 (1.60%)	1 / 423 (0.24%)	3 / 190 (1.58%)
occurrences (all)	3	1	3
General disorders and administration			

site conditions			
PYREXIA			
subjects affected / exposed	1 / 188 (0.53%)	4 / 423 (0.95%)	1 / 190 (0.53%)
occurrences (all)	1	4	1
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	5 / 188 (2.66%)	10 / 423 (2.36%)	4 / 190 (2.11%)
occurrences (all)	5	10	4
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	3 / 188 (1.60%)	5 / 423 (1.18%)	3 / 190 (1.58%)
occurrences (all)	3	5	3
Skin and subcutaneous tissue disorders			
PSORIASIS			
subjects affected / exposed	0 / 188 (0.00%)	8 / 423 (1.89%)	0 / 190 (0.00%)
occurrences (all)	0	8	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	2 / 188 (1.06%)	2 / 423 (0.47%)	4 / 190 (2.11%)
occurrences (all)	2	2	4
BACK PAIN			
subjects affected / exposed	0 / 188 (0.00%)	7 / 423 (1.65%)	3 / 190 (1.58%)
occurrences (all)	0	8	6
OSTEOARTHRITIS			
subjects affected / exposed	2 / 188 (1.06%)	2 / 423 (0.47%)	0 / 190 (0.00%)
occurrences (all)	2	2	0
PSORIATIC ARTHROPATHY			
subjects affected / exposed	2 / 188 (1.06%)	13 / 423 (3.07%)	5 / 190 (2.63%)
occurrences (all)	2	14	5
Infections and infestations			
LATENT TUBERCULOSIS			
subjects affected / exposed	0 / 188 (0.00%)	2 / 423 (0.47%)	0 / 190 (0.00%)
occurrences (all)	0	2	0
BRONCHITIS			
subjects affected / exposed	6 / 188 (3.19%)	10 / 423 (2.36%)	3 / 190 (1.58%)
occurrences (all)	6	10	3
COVID-19			

subjects affected / exposed	1 / 188 (0.53%)	0 / 423 (0.00%)	1 / 190 (0.53%)
occurrences (all)	1	0	1
HERPES ZOSTER			
subjects affected / exposed	4 / 188 (2.13%)	3 / 423 (0.71%)	10 / 190 (5.26%)
occurrences (all)	4	3	11
ORAL HERPES			
subjects affected / exposed	2 / 188 (1.06%)	4 / 423 (0.95%)	2 / 190 (1.05%)
occurrences (all)	2	4	2
NASOPHARYNGITIS			
subjects affected / exposed	7 / 188 (3.72%)	21 / 423 (4.96%)	16 / 190 (8.42%)
occurrences (all)	10	24	18
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	13 / 188 (6.91%)	34 / 423 (8.04%)	11 / 190 (5.79%)
occurrences (all)	16	37	13
URINARY TRACT INFECTION			
subjects affected / exposed	4 / 188 (2.13%)	10 / 423 (2.36%)	9 / 190 (4.74%)
occurrences (all)	6	10	14

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 March 2017	Amendment 1 Key updates included: Title Page (Section 1.0) updated to provide current sponsor/emergency contact details with the country code; Section 1.2, Synopsis, to ensure consistent timing for hand and feet x-ray assessments and define inadequate MTX response for Japan; Section 5.2.1 and 5.2.2 addressed inclusion and exclusion criteria, removing duplicates and specifying MTX response; Table 2 updated clinical laboratory tests to require necessary tests for Japanese subjects with positive hepatitis markers, with clarifications on protocol deviation reporting; Updates to Section 5.3.1.1 ensured hepatitis screening for Japanese subjects; Section 6.1.5 added the country code to contacts for serious adverse event reporting; Section 9.3 clarified procedures on subject withdrawal concerning optional exploratory samples; and Appendix C updated the study activities table regarding hand/foot x-ray timing, footnotes on frequency, and protocol deviation reporting, ensuring required testing for Japanese subjects with hepatitis markers.
30 June 2017	Amendment 2 Key updates included: Section 1.0, added ABT-494's generic name and clarified Sponsor distinctions; Section 1.2, revised objectives, methodology, and evaluation criteria for efficacy and safety; Inclusion and exclusion criteria updates addressed specific dosages and testing requirements for China and Taiwan; Clarifications in the study design included criteria for subject non-responders, stratification, treatment modifications, and re-screening procedures; Changes in Section 5.2 entailed electrolyte criteria, prohibiting certain therapies, and refining HBV testing for specific regions; Contraceptive and pregnancy test clarifications were made alongside informed consent amendments; Section 5.3 procedures addressed ECG, CXR, and TB testing, and Table 2 and Figure 2 refined laboratory test requirements and HBV testing protocols; and Stratification clarifications continued across subject treatment assignments and analyses, along with updates on adverse event monitoring guidelines; Section 8 revisions involved laboratory and pharmacokinetic analysis adjustments, sample size determination, and randomization processes; and Appendices C, D, and E reflected updated follow-up requirements, exploratory sample guidelines, and the removal of outdated criteria.
22 March 2018	Amendment 3 Key updates included: Administrative changes and updated Sponsor information for non-EU countries; Cyclosporine is included as a qualifying DMARD for inadequate response in PsA treatment; The study design clarified non-replacement of withdrawn subjects and cessation of annual TB testing post-drug discontinuation; Inclusion criteria incorporated new guidelines for pregnancy testing, contraception, and PsA treatments; Exclusion criteria specified conditions for enrollment in non-interventional studies, prohibited certain therapies before Baseline, and clarified rules on pregnancy and other conditions; Background therapy stability is preferred but flexible for ensuring safety; Inhaled marijuana is excluded prior to Baseline due to infection risks; Contraception requirements for males were removed based on safety data; Study procedures clarified TB and hepatitis testing, pregnancy testing, and investigator assessments; Recommended to align AESI updates with recent studies on adverse events; Protocol deviations, efficacy variables, and analyses were updated to clarify methods and ensure accurate data interpretation.

11 October 2019	Amendment 4 Key updates included: Administrative changes; Inclusion of Cyclosporine in the methodology and study design sections as a therapy for inadequate response; Updatesd to ensure that Hong Kong is identified as part of China; Efficacy measures, such as FACIT-F and PsARC, were revised to match revised power calculations and endpoint descriptions; Abbreviations, safety information regarding thromboembolic events, and exclusion criteria were clarified; Permitted therapies and drug accountability guidelines were revised, aligning with new advisory information, including the discontinuation of male contraception recommendations due to updated safety findings; Requirements for skin biopsies were removed due to low enrollment likelihoods; ECG procedures and TB testing clarifications were streamlined, ensuring accurate safety evaluations; Toxicity management now included guidelines for herpes zoster and muscle-related symptoms, adjusted to match Rinvoq® labeling; Amendments to laboratory data assessment methodologies categorized results according to the National Cancer Institute's CTCAE grades; and Adjustments were made to appendices to align with these protocol updates, amending signatory lists and aligning optional sample instructions.
11 December 2019	Amendment 5 Key updates included: Changes to personnel contact information in Sections 1.0 and 6.1.5 to ensure the correct points of contact for the Sponsor and reporting of serious adverse events or malignancy; In Section 1.2, the evaluation criteria for efficacy was adjusted, emphasizing the resolution of enthesitis and dactylitis as more clinically significant outcomes than changes from Baseline, modifications were intended to enhance the clinical relevance and power calculations for the trial's multiplicity adjusted endpoints; Section 5.2.3.2 was updated to maintain participant safety by limiting the corticosteroid dosage to a maximum of prednisone ≤10 mg/day, as outlined in the inclusion criteria; Additionally, Section 5.3.3.2 was updated to align with the enhancements in evaluating enthesitis and dactylitis; To address concerns related to thrombosis risks associated with the JAK inhibitor class, Sections 5.4.1 and 6.1.7 incorporated additional safety precautions.
15 May 2020	Amendment 6 Key updates included: Extending the clinical trial duration by two years, adding extra timepoints for hands and feet x-rays to gather long-term safety and efficacy data for upadacitinib in treating PsA; Updates included personnel contact information and administrative changes; Protocol flexibility during emergencies or pandemics was improved by allowing the use of local laboratories and direct-to-patient drug shipments; Dispensing dosing diaries beyond Week 140 were deemed unnecessary, as compliance is tracked through the IRT system; Telephone interviews for patient-reported outcomes were added, ensuring data collection continuity during emergencies; TB testing guidelines were refined for consistency and clarity, minimizing unnecessary chest x-rays; Appendices were updated to reflect the extended study, detailing additional evaluation points for physical exams, pregnancy tests, and patient questionnaires; HBV DNA PCR testing was allowed during unscheduled visits; and Footnotes now stipulate that questionnaires EQ-5D-5L and WPAI will be every six months post-Week 152 instead of quarterly, maintaining scientific integrity while reducing participant burden.
30 January 2021	Amendment 7 Key updates included: Administrative changes; replacing "ABT-494" with the generic name "upadacitinib."; Subjects in Period 2 on a 30 mg QD dosage will switch to 15 mg QD to align with optimal dosing recommendations; Extension of study duration, and safety information about embryofetal risks was updated; Clarifications were added to prevent confounding data during discontinuation visits; South Korea was added in HBV-DNA PCR testing requirements; Flexibility was introduced for study procedures, allowing remote or delayed assessments during emergencies or pandemics; New guidelines were added for handling gastrointestinal perforations, COVID-19-related interruptions, and hematological toxicity; Amendments allowed remote monitoring, virtual consent processes, and specific data collection for COVID-19 impacts; Names of protocol signatories and vendors were updated, and footnotes re-sequenced to ensure protocol integrity.

20 December 2023	Amendment 8 Key updates included: Administrative updates and reinstating paper diary cards in China; Title page revised to include an EU-focused sponsor statement; Information from the ORAL Surveillance study, concerning another JAK inhibitor, informed current study benefits and risks, including upadacitinib's effects on COVID-19; Provisions were made for follow-up flexibility with phone calls and exemptions for subjects transitioning to commercial upadacitinib or adalimumab; A new section outlined treatment post-study per CTTP directives; Prohibited therapy list was expanded, distinguishing live vaccines' replicative capabilities, and updates to lab testing guidelines include changes for South Korea and revised menopause criteria; Adverse event management added new criteria such as serious hypersensitivity, cardiovascular events, and ECG changes for discontinuation; Protocol deviations updated contact information and consent protocols; Toxicity management guidelines were clarified, incorporating COVID-19 measures, discontinuation requirements, and elective surgery protocols, alongside updates for AST/ALT and creatinine metrics; A new adjudication committee for gastrointestinal perforations was established; The study completion definition was refined to align with CTTP—a directive ensuring protocol integrity; and Appendices were reorganized, updating protocol signatories, footnotes for clarity on interventions, and follow-up call flexibility.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported