Clinical trial results:
A 64-Week, Phase 3, Randomized, Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous Tildrakizumab (SCH 900222/MK-3222), Followed by an Optional Long-Term Safety Extension Study, in Subjects With Moderate-to-Severe Chronic Plaque Psoriasis (Protocol No. MK-3222-010)

Summary

EudraCT number	2012-002255-42
Trial protocol	GB
Global end of trial date	10 November 2021

Results information

Result version number	v2 (current)
This version publication date	21 June 2026
First version publication date	15 October 2023
Version creation reason	• New data added to full data set Addition of extension study data

Trial information

Trial identification

Sponsor protocol code	MK-3222-010

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01722331
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sun Pharmaceutical Industries Limited
Sponsor organisation address	Sun House, 201 B/1, Western Express Highway, Goregaon (E), Mumbai, India, 400063
Public contact	Head-Clinical Development, Sun Pharmaceutical Industries Limited, +91 2266455645 ext. 5689, Clinical.Trial@sunpharma.com
Scientific contact	Head-Clinical Development, Sun Pharmaceutical Industries Limited, +91 2266455645 ext. 5689, Clinical.Trial@sunpharma.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	28 October 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 October 2015
Global end of trial reached?	Yes
Global end of trial date	10 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary Efficacy Objective: To assess the efficacy of tildrakizumab (SCH-900222/MK-3222) (hereafter referred to as MK-3222) compared to placebo in the treatment of moderate-to-severe chronic plaque psoriasis as measured by the proportion of subjects with at least 75% improvement in the Psoriasis Area and Severity Index from baseline (PASI 75 response), and the proportion of subjects with a Physician's Global Assessment (PGA) score of "clear" or "minimal", with at least a 2 grade reduction from baseline, at Week 12.

Primary Safety/Tolerability Objective: To assess the safety/tolerability of tildrakizumab (MK-3222) in subjects with moderate-to-severe chronic plaque psoriasis at Week 12.

Extension Study:
To assess long-term safety and tolerability of tildrakizumab (MK-3222) in subjects with moderate-to-severe chronic plaque psoriasis for a minimum of 4 years.

Protection of trial subjects:

The following provisions are within the study protocol to ensure adequate protection of subjects:
1. Each subject will be monitored for the occurence of SAEs immediately after signing informed consent and will be followed up for adverse events (AEs, SAEs, ECIs) for upto 20 weeks after the last visit in the treatment period (base or extension)
2. Subject's right to withdraw his/her consent at any time during the trial with or without a stated reason
3. It is the right and the duty of the investigator or subinvestigator to stop treatment in any case in which emerging effects are of unacceptable risk to the individual subject
4. All subjects were screened for presence of latent or untreated TB infections, HIV, hepatitis B surface antigen, hepatitis C virus, chronic disease, organ dysfunction, use of prohibited medications and presence of any other such conditions to ensure to minimize the potential risk to study subjects prior to enrollment
-Every subject will be monitored for the occurrence of SAEs immediately after the subject has signed informed consent form
5. The study has constituted a DSMB for monitoring the safety of the trial subjects during the study

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 December 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	4 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 88
Country: Number of subjects enrolled	Canada: 192
Country: Number of subjects enrolled	United Kingdom: 8
Country: Number of subjects enrolled	Japan: 158
Country: Number of subjects enrolled	United States: 326
Worldwide total number of subjects	772
EEA total number of subjects	0

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)	697
From 65 to 84 years	75
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 977 subjects were screened for the study, of which 205 were not randomized.

Period 1

Period 1 title	Base study
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	No
Arm title	Placebo

Arm description:

Placebo administered SC once a week at Weeks 0 and 4

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

Dosage and administration details:

Matching placebo to tildrakizumab administered SC

Arm title	Tildrakizumab 100

Arm description:

Tildrakizumab 100 mg administered SC once a week at Weeks 0 and 4 and then every 12 weeks

Arm type	Experimental
Investigational medicinal product name	Tildrakizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Tildrakizumab 100 mg administered SC

Arm title	Tildrakizumab 200

Arm description:

Tildrakizumab 200 mg administered subcutaneously (SC) once a week at Weeks 0 and 4 and then every 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Tildrakizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:
Tildrakizumab 200 mg administered SC

Number of subjects in period 1	Placebo	Tildrakizumab 100	Tildrakizumab 200
Started	155	309	308
Completed	124	250	264
Not completed	31	59	44
Adverse event, serious fatal	-	-	1
Physician decision	2	6	1
Consent withdrawn by subject	10	14	11
Non-Compliance with Study Drug	-	2	1
Adverse event, non-fatal	1	3	10
Progressive Disease	1	1	-
Pregnancy	1	-	1
Protocol Violation	1	1	4
Other Protocol Specified Criteria	3	11	7
Lost to follow-up	4	9	4
Lack of efficacy	8	12	4

Period 2

Period 2 title	Extension Study
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Tildrakizumab 100 mg

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Tildrakizumab 100 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:
Each PFS contained 1 mL of solution.

Arm title	Tildrakizumab 200 mg
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Tildrakizumab 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:
Each PFS contained 1 mL of solution.

Number of subjects in period 2	Tildrakizumab 100 mg	Tildrakizumab 200 mg
Started	239	267
Completed	171	208
Not completed	68	59
Adverse event, serious fatal	1	1
Physician decision	5	5
Consent withdrawn by subject	22	25
Non-Compliance with Study Drug	-	1
Adverse event, non-fatal	19	8
Pregnancy	-	5
Lost to follow-up	15	9
Lack of efficacy	6	5

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo administered SC once a week at Weeks 0 and 4	
Reporting group title	Tildrakizumab 100
Reporting group description:	
Tildrakizumab 100 mg administered SC once a week at Weeks 0 and 4 and then every 12 weeks	
Reporting group title	Tildrakizumab 200
Reporting group description:	
Tildrakizumab 200 mg administered subcutaneously (SC) once a week at Weeks 0 and 4 and then every 12 weeks.	

Reporting group values	Placebo	Tildrakizumab 100	Tildrakizumab 200
Number of subjects	155	309	308
Age categorical Units: Subjects			
Age continuous Units: years median full range (min-max)	 47.5 19 to 76	 46.0 18 to 82	 48.0 18 to 76
Gender categorical Units: Subjects			
Female Male	55 100	102 207	82 226

Reporting group values	Total		
Number of subjects	772		
Age categorical Units: Subjects			
Age continuous Units: years median full range (min-max)	 -	 	
Gender categorical Units: Subjects			
Female Male	239 533		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Placebo administered SC once a week at Weeks 0 and 4	
Reporting group title	Tildrakizumab 100
Reporting group description: Tildrakizumab 100 mg administered SC once a week at Weeks 0 and 4 and then every 12 weeks	
Reporting group title	Tildrakizumab 200
Reporting group description: Tildrakizumab 200 mg administered subcutaneously (SC) once a week at Weeks 0 and 4 and then every 12 weeks.	
Reporting group title	Tildrakizumab 100 mg
Reporting group description: -	
Reporting group title	Tildrakizumab 200 mg
Reporting group description: -	

Primary: Percentage of Participants With Psoriasis Area Sensitivity Index 75 (PASI-75) Response at Week 12

End point title	Percentage of Participants With Psoriasis Area Sensitivity Index 75 (PASI-75) Response at Week 12
End point description:	
End point type	Primary
End point timeframe: Week 12	

End point values	Placebo	Tildrakizumab 100	Tildrakizumab 200	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	154	309	308	
Units: Percentage of Participant				
number (not applicable)	5.8	63.8	62.3	

Statistical analyses

Statistical analysis title	CMH analysis of PASI75 Response at Week 12
Comparison groups	Tildrakizumab 100 v Placebo

Number of subjects included in analysis	463
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Statistical analysis title	CMH analysis of PASI75 Response at Week 12
Comparison groups	Tildrakizumab 200 v Placebo
Number of subjects included in analysis	462
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Participants With a Physician's Global Assessment (PGA) Score of Clear or Minimal With at Least a 2 Grade Reduction From Baseline at Week 12

End point title	Percentage of Participants With a Physician's Global Assessment (PGA) Score of Clear or Minimal With at Least a 2 Grade Reduction From Baseline at Week 12

End point description:

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	Tildrakizumab 100	Tildrakizumab 200	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	154	309	308	
Units: Percentage of Participant				
number (not applicable)	7.1	57.9	59.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With PASI-90 Response At Week 12

End point title	Percentage of Participants With PASI-90 Response At Week 12

End point description:

End point type	Secondary

End point timeframe:
Week 12

End point values	Placebo	Tildrakizumab 100	Tildrakizumab 200	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	154	309	308	
Units: Percentage of Participants				
number (not applicable)	2.6	34.6	35.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with PASI-100 Response at Week 12

End point title	Percentage of Participants with PASI-100 Response at Week 12

End point description:

End point type	Secondary

End point timeframe:
Week 12

End point values	Placebo	Tildrakizumab 100	Tildrakizumab 200	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	154	309	308	
Units: Percentage of Participants With PASI-100				
number (not applicable)	1.3	13.9	14.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Participant DLQI Score at Week 12

End point title	Change From Baseline in the Participant DLQI Score at Week 12

End point description:

End point type	Secondary

End point timeframe:
Week 12

End point values	Placebo	Tildrakizumab 100	Tildrakizumab 200	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	154	309	308	
Units: Score on a scale				
least squares mean (confidence interval 95%)	-2.3 (-3.1 to -1.5)	-9.8 (-10.4 to -9.1)	-10.0 (-10.7 to -9.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with DLQI Score of 0 or 1 at Week 12

End point title	Percentage of Participants with DLQI Score of 0 or 1 at Week 12

End point description:

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	Tildrakizumab 100	Tildrakizumab 200	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	150	304	299	
Units: Percentage of Participants				
number (not applicable)	5.3	41.5	44.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Extension week 0

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	232	263		
Units: Percentage of Subjects				
number (not applicable)	97.8	98.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 60

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	210	252		
Units: Percentage of subject				
number (not applicable)	98.1	97.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 120

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	235		
Units: Percentage of Subjects				
number (not applicable)	96.8	95.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 216

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	105		
Units: Percentage of Subjects				
number (not applicable)	95.2	96.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 264

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	93		
Units: Percentage of Subjects				
number (not applicable)	97.3	96.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 312

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	23		
Units: Percentage of Subjects				
number (not applicable)	100.0	95.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 50 Response Over Time - PASI 50 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 368

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[1]		
Units: Percentage of Subjects				
number (not applicable)	100.0			

Notes:

[1] - Zero subjects were analysed as no subjects had evaluable data for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 0

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	215		
Units: Percentage of Subjects				
number (not applicable)	94.1	92.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 60

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	206		
Units: Percentage of Subjects				
number (not applicable)	92.0	91.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 120

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	169	192		
Units: Percentage of Subjects				
number (not applicable)	85.8	90.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:
Ext week 216

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	84		
Units: Percentage of Subjects				
number (not applicable)	86.1	90.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:
Ext week 264

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	71	75		
Units: Percentage of Subjects				
number (not applicable)	87.3	96.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 312

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	22		
Units: Percentage of Subjects				
number (not applicable)	89.5	95.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 75 Response Over Time – PASI 75 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 368

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[2]		
Units: Percentage of Subjects				
number (not applicable)	100.0			

Notes:

[2] - Zero subjects were analysed as no subjects had evaluable data for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 0

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	125	137		
Units: Percentage of Subjects				
number (not applicable)	88.8	87.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 60

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	120	133		
Units: Percentage of Subjects				
number (not applicable)	75.8	78.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 90 Response Over Time –

	PASI 90 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 120

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	55		
Units: Percentage of Subjects				
number (not applicable)	79.2	90.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 216

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	55		
Units: Percentage of Subjects				
number (not applicable)	79.2	90.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 264

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	49		
Units: Percentage of Subjects				
number (not applicable)	85.7	85.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 312

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	17		
Units: Percentage of Subjects				
number (not applicable)	80.0	94.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 90 Response Over Time – PASI 90

Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 90 Response Over Time – PASI 90 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 368

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	0[3]		
Units: Percentage of Subjects				
number (not applicable)	100.0			

Notes:

[3] - Zero subjects were analysed as no subjects had evaluable data for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 0

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	70	70		
Units: Percentage of Subjects				
number (not applicable)	68.6	78.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 60

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	68		
Units: Percentage of Subjects				
number (not applicable)	59.4	61.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 120

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	63		
Units: Percentage of Subjects				
number (not applicable)	58.1	65.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 216

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	28		
Units: Percentage of Subjects				
number (not applicable)	51.7	64.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 312

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	12		
Units: Percentage of Subjects				
number (not applicable)	33.3	75.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point title	Percentage of Subjects With PASI 100 Response Over Time – PASI 100 Responders at Week 64 (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 264

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	27		
Units: Percentage of Subjects				
number (not applicable)	65.5	70.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point title	Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 0

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	232	261		
Units: Percentage of Subjects				
number (not applicable)	64.7	59.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point title	Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 60

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	210	249		
Units: Percentage of Subjects				
number (not applicable)	59.5	55.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point title	Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 120

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	235		
Units: Percentage of Subjects				
number (not applicable)	55.6	60.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point title	Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 216

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	103		
Units: Percentage of Subjects				
number (not applicable)	65.5	58.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point title	Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 264

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	93		
Units: Percentage of Subjects				
number (not applicable)	66.7	57.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point title	Percentage of Subjects With PGA Score of Clear or Minimal, With at Least 2 Grade Reduction From Baseline Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 312

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	23		
Units: Percentage of Subjects				
number (not applicable)	42.1	60.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 0

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	233	263		
Units: score on a scale				
arithmetic mean (standard deviation)	-17.6 (± 7.54)	-18.3 (± 8.39)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 120

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	235		
Units: score on a scale				
arithmetic mean (standard deviation)	-17.1 (± 7.23)	-18.4 (± 8.49)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 60

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	210	252		
Units: Score on a scale				
arithmetic mean (standard deviation)	-17.5 (± 7.13)	-18.3 (± 8.61)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 216

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	105		
Units: score on a scale				
arithmetic mean (standard deviation)	-17.8 (± 7.84)	-19.5 (± 9.57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 264

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	93		
Units: score on a scale				
arithmetic mean (standard deviation)	-18.4 (± 7.97)	-20.0 (± 10.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 312

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	23		
Units: score on a scale				
arithmetic mean (standard deviation)	-14.1 (± 2.59)	-16.0 (± 6.34)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 0

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	233	263		
Units: score on scale				
arithmetic mean (standard deviation)	-88.0 (± 13.62)	-86.3 (± 14.86)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 60

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	210	252		
Units: score on scale				
arithmetic mean (standard deviation)	-88.1 (± 13.20)	-86.2 (± 15.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 120

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	235		
Units: score on scale				
arithmetic mean (standard deviation)	-86.2 (± 16.79)	-86.6 (± 15.57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 216

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	105		
Units: score on scale				
arithmetic mean (standard deviation)	-86.6 (± 18.64)	-86.8 (± 14.65)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 264

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	93		
Units: score on scale				
arithmetic mean (standard deviation)	-88.8 (± 15.40)	-87.4 (± 18.32)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point title	Percent Change From Baseline in Psoriasis Area and Severity Index Score Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 312

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	23		
Units: score on scale				
arithmetic mean (standard deviation)	-90.0 (± 11.93)	-92.1 (± 16.05)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 0

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	233	263		
Units: Percentage of Subjects				
number (not applicable)	85.4	79.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 60

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	210	252		
Units: Percentage of Subjects				
number (not applicable)	86.7	81.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 120

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	235		
Units: Percentage of Subjects				
number (not applicable)	81.5	80.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 216

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	105		
Units: Percentage of Subjects				
number (not applicable)	83.3	81.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 264

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	93		
Units: Percentage of Subjects				
number (not applicable)	84.0	84.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI75 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 312

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	23		
Units: Percentage of Subjects				
number (not applicable)	89.5	91.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 0

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	233	263		
Units: Percentage of Subjects				
number (not applicable)	57.1	52.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 60

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	210	252		
Units: Percentage of Subject				
number (not applicable)	55.2	52.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 120

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	235		
Units: Percentage of Subjects				
number (not applicable)	51.3	55.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 216

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	105		
Units: Percentage of Subjects				
number (not applicable)	58.3	55.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 264

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	93		
Units: Percentage of Subjects				
number (not applicable)	64.0	58.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI 90 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 312

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	23		
Units: Percentage of Subjects				
number (not applicable)	57.9	78.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 100 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI 100 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 0

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	233	263		
Units: Percentage of Subjects				
number (not applicable)	25.8	26.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 100 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI 100 Response Over Time

	(Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 60

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	210	252		
Units: Percentage of Subjects				
number (not applicable)	28.1	26.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 100 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI 100 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 120

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	235		
Units: Percentage of Subjects				
number (not applicable)	27.0	26.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 100 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI 100 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 216

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	105		
Units: Percentage of Subjects				
number (not applicable)	29.8	24.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 100 Response Over Time (Extension Study)

End point title	Percentage of Subjects With a PASI 100 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 264

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	93		
Units: Percentage of Subjects				
number (not applicable)	38.7	30.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a PASI 100 Response Over Time (Extension

Study)

End point title	Percentage of Subjects With a PASI 100 Response Over Time (Extension Study)

End point description:

End point type	Secondary

End point timeframe:

Ext week 312

End point values	Tildrakizumab 100 mg	Tildrakizumab 200 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	23		
Units: Percentage of Subjects				
number (not applicable)	31.6	56.5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

fvUp to 84 weeks including a 20-week follow-up period.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups

Reporting group title	Tildrakizumab 200 mg (Part 2)

Reporting group description:

Tildrakizumab 200 mg administered once a week at Week 16 (includes placebo participants re-randomized at Week 12 to receive tildrakizumab 200 mg)

Reporting group title	Tildrakizumab 200 mg (Part 1)

Reporting group description:

Tildrakizumab 200 mg administered once a week at Weeks 0 and 4.

Reporting group title	Tildrakizumab 200 mg (Part 3)

Reporting group description: -

Reporting group title	Tildrakizumab 100 mg (Part 2)

Reporting group description:

Tildrakizumab 100 mg administered once a week at Week 16 (includes placebo participants re-randomized at Week 12 to receive Tildrakizumab 100 mg). Includes 1 participant who did not enter Part 2, but received an unscheduled dose at Week 12.

Reporting group title	Tildrakizumab 100 mg (Part 3)

Reporting group description: -

Reporting group title	Placebo (Part 1)

Reporting group description:

Placebo administered once a week at Weeks 0 and 4.

Reporting group title	Tildrakizumab 100 mg (Part 1)

Reporting group description:

Tildrakizumab 100 mg administered once a week at Weeks 0 and 4.

Reporting group title	Tildrakizumab 100 mg - Extension Study

Reporting group description: -

Reporting group title	Tildrakizumab 200 mg - Extension Study

Reporting group description: -

Serious adverse events	Tildrakizumab 200 mg (Part 2)	Tildrakizumab 200 mg (Part 1)	Tildrakizumab 200 mg (Part 3)
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 370 (2.16%)	8 / 308 (2.60%)	21 / 360 (5.83%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign biliary neoplasm			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.27%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoma in situ of skin			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	1 / 370 (0.27%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	2 / 360 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign pancreatic neoplasm			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 cancer			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 cancer			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 lobular breast carcinoma			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobular breast carcinoma in situ			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 neoplasm malignant			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 carcinoma of the bladder			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 metastatic			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testis cancer			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Aneurysm			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	1 / 370 (0.27%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 dissection			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Anal fissure			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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	1 / 370 (0.27%)	1 / 308 (0.32%)	0 / 360 (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
Hyperemesis gravidarum			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Non-cardiac chest pain			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	2 / 360 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Uterine haemorrhage			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast enlargement			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 370 (0.00%)	1 / 308 (0.32%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 370 (0.27%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 distress syndrome			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 mass			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Suicide attempt			
subjects affected / exposed	0 / 370 (0.00%)	1 / 308 (0.32%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression suicidal			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 glucose fluctuation			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Lower limb fracture			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fascial rupture			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	1 / 370 (0.27%)	1 / 308 (0.32%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 370 (0.00%)	1 / 308 (0.32%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 chronic			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 stenosis			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Cerebellar infarction			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 infarction			
subjects affected / exposed	1 / 370 (0.27%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar haemorrhage			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinson's disease			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic cerebral infarction			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wernicke's encephalopathy			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 neonatal			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Cataract			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular fibrosis			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 370 (0.00%)	1 / 308 (0.32%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland enlargement			
subjects affected / exposed	0 / 370 (0.00%)	1 / 308 (0.32%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 polyps			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 ischaemia			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 hypertensive gastropathy			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth impacted			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Cholecystitis			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 function abnormal			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Psoriasis			
subjects affected / exposed	1 / 370 (0.27%)	0 / 308 (0.00%)	0 / 360 (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
Angioedema			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Nephrolithiasis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Rotator cuff syndrome			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 ankylosis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Epiglottitis			
subjects affected / exposed	0 / 370 (0.00%)	1 / 308 (0.32%)	0 / 360 (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
Cellulitis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	2 / 360 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone tuberculosis			
subjects affected / exposed	1 / 370 (0.27%)	0 / 308 (0.00%)	0 / 360 (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
Diverticulitis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	1 / 360 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 perforated			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 infective			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 of male external genital organ			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 E			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 gangrene			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 arthritis staphylococcal			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			

subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
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	Tildrakizumab 100 mg (Part 2)	Tildrakizumab 100 mg (Part 3)	Placebo (Part 1)
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 374 (1.87%)	14 / 316 (4.43%)	1 / 154 (0.65%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign biliary neoplasm			
subjects affected / exposed	0 / 374 (0.00%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	1 / 374 (0.27%)	2 / 316 (0.63%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 374 (0.00%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoma in situ of skin			
subjects affected / exposed	0 / 374 (0.00%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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	1 / 374 (0.27%)	2 / 316 (0.63%)	0 / 154 (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

Benign pancreatic neoplasm			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 cancer			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 cancer			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 lobular breast carcinoma			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobular breast carcinoma in situ			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 neoplasm malignant			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 carcinoma of the bladder			

subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 metastatic			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testis cancer			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Aneurysm			

subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Anal fissure			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperemesis gravidarum			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Non-cardiac chest pain			
subjects affected / exposed	0 / 374 (0.00%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Uterine haemorrhage			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 enlargement			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			

subjects affected / exposed	0 / 374 (0.00%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 mass			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Suicide attempt			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression suicidal			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 glucose fluctuation			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Lower limb fracture			
subjects affected / exposed	0 / 374 (0.00%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fascial rupture			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Skull fracture			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 chronic			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			

subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Cerebellar infarction			
subjects affected / exposed	0 / 374 (0.00%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			

subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar haemorrhage			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinson's disease			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic cerebral infarction			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wernicke's encephalopathy			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 neonatal			
subjects affected / exposed	0 / 374 (0.00%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			

Cataract			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular fibrosis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Constipation			
subjects affected / exposed	1 / 374 (0.27%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	1 / 374 (0.27%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 374 (0.00%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 374 (0.27%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland enlargement			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 ischaemic			

subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 polyps			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 ischaemia			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 hypertensive gastropathy			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth impacted			

subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Cholecystitis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 function abnormal			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Psoriasis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			

Nephrolithiasis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Rotator cuff syndrome			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 ankylosis			

subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Epiglottitis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 tuberculosis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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	1 / 374 (0.27%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 374 (0.27%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 374 (0.00%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 perforated			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 infective			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 of male external genital organ			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 E			

subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 gangrene			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 arthritis staphylococcal			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 374 (0.00%)	0 / 316 (0.00%)	0 / 154 (0.00%)
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	Tildrakizumab 100 mg (Part 1)	Tildrakizumab 100 mg - Extension Study	Tildrakizumab 200 mg - Extension Study
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 309 (1.62%)	60 / 239 (25.10%)	58 / 267 (21.72%)
number of deaths (all causes)	0	1	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign biliary neoplasm			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 / 309 (0.00%)	1 / 239 (0.42%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoma in situ of skin			

subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign pancreatic neoplasm			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 309 (0.00%)	2 / 239 (0.84%)	0 / 267 (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
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (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
Endometrial adenocarcinoma			

subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
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 cancer			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive breast carcinoma			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive lobular breast carcinoma			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobular breast carcinoma in situ			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
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	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			

subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (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
Malignant melanoma			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma in situ			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic carcinoma of the bladder			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (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
Neoplasm malignant			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 309 (0.00%)	2 / 239 (0.84%)	0 / 267 (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
Papillary thyroid cancer			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer metastatic			

subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testis cancer			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aneurysm			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 / 309 (0.00%)	1 / 239 (0.42%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (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
Surgical and medical procedures			

Anal fissure			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperemesis gravidarum			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
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			
Non-cardiac chest pain			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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			
Uterine haemorrhage			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 enlargement			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 / 309 (0.32%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	3 / 267 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 309 (0.00%)	2 / 239 (0.84%)	0 / 267 (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
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
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 respiratory failure			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Completed suicide			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression suicidal			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood glucose fluctuation			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
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			
Lower limb fracture			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (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

Fascial rupture			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
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	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
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 fracture			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
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	1 / 309 (0.32%)	0 / 239 (0.00%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			

subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 / 309 (0.00%)	2 / 239 (0.84%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure chronic			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (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
Congestive cardiomyopathy			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			

subjects affected / exposed	0 / 309 (0.00%)	2 / 239 (0.84%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebellar infarction			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 infarction			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	3 / 267 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (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
Carpal tunnel syndrome			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar haemorrhage			

subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
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 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 309 (0.00%)	2 / 239 (0.84%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (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
Intracranial aneurysm			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			

subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (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
Metabolic encephalopathy			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinson's disease			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic cerebral infarction			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wernicke's encephalopathy			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
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 neonatal			

subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
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			
Cataract			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular fibrosis			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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			
Constipation			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland enlargement			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 ischaemic			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric polyps			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal ischaemia			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Inguinal hernia			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			

subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	3 / 267 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertensive gastropathy			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth impacted			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 309 (0.00%)	2 / 239 (0.84%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			

subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	1 / 309 (0.32%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 309 (0.32%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 kidney injury			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
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			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Rotator cuff syndrome			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
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 ankylosis			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 309 (0.00%)	3 / 239 (1.26%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic arthropathy			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Epiglottitis			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 / 309 (0.32%)	1 / 239 (0.42%)	3 / 267 (1.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone tuberculosis			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 / 309 (0.00%)	2 / 239 (0.84%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 309 (0.00%)	2 / 239 (0.84%)	0 / 267 (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
Gastroenteritis salmonella			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	0 / 267 (0.00%)
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 / 309 (0.00%)	2 / 239 (0.84%)	0 / 267 (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
Appendicitis perforated			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			

subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis of male external genital organ			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
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 gangrene			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
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 acute			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic arthritis staphylococcal			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (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
Septic shock			

subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	2 / 267 (0.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 309 (0.00%)	0 / 239 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 309 (0.00%)	1 / 239 (0.42%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	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	Tildrakizumab 200 mg (Part 2)	Tildrakizumab 200 mg (Part 1)	Tildrakizumab 200 mg (Part 3)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 370 (10.27%)	35 / 308 (11.36%)	86 / 360 (23.89%)
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	0 / 360 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 370 (0.27%)	3 / 308 (0.97%)	11 / 360 (3.06%)
occurrences (all)	1	3	11

Nervous system disorders			
Headache			
subjects affected / exposed	5 / 370 (1.35%)	8 / 308 (2.60%)	9 / 360 (2.50%)
occurrences (all)	5	9	11
Type 2 diabetes mellitus			
subjects affected / exposed	2 / 370 (0.54%)	1 / 308 (0.32%)	1 / 360 (0.28%)
occurrences (all)	2	1	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 370 (1.08%)	2 / 308 (0.65%)	5 / 360 (1.39%)
occurrences (all)	4	2	5
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 370 (0.27%)	1 / 308 (0.32%)	1 / 360 (0.28%)
occurrences (all)	1	1	1
Nausea			
subjects affected / exposed	4 / 370 (1.08%)	4 / 308 (1.30%)	4 / 360 (1.11%)
occurrences (all)	4	4	5
Constipation			
subjects affected / exposed	1 / 370 (0.27%)	2 / 308 (0.65%)	3 / 360 (0.83%)
occurrences (all)	1	3	3
Dental caries			
subjects affected / exposed	0 / 370 (0.00%)	0 / 308 (0.00%)	2 / 360 (0.56%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 370 (1.35%)	9 / 308 (2.92%)	12 / 360 (3.33%)
occurrences (all)	5	9	13
Oropharyngeal pain			
subjects affected / exposed	3 / 370 (0.81%)	3 / 308 (0.97%)	7 / 360 (1.94%)
occurrences (all)	3	3	7
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	3 / 370 (0.81%)	0 / 308 (0.00%)	9 / 360 (2.50%)
occurrences (all)	4	0	9
Pruritus			

subjects affected / exposed	3 / 370 (0.81%)	1 / 308 (0.32%)	8 / 360 (2.22%)
occurrences (all)	3	1	10
Eczema			
subjects affected / exposed	1 / 370 (0.27%)	1 / 308 (0.32%)	4 / 360 (1.11%)
occurrences (all)	1	1	4
Dermatitis contact			
subjects affected / exposed	1 / 370 (0.27%)	0 / 308 (0.00%)	4 / 360 (1.11%)
occurrences (all)	1	0	5
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 370 (1.08%)	5 / 308 (1.62%)	8 / 360 (2.22%)
occurrences (all)	5	6	10
Back pain			
subjects affected / exposed	5 / 370 (1.35%)	5 / 308 (1.62%)	8 / 360 (2.22%)
occurrences (all)	5	5	12
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	17 / 370 (4.59%)	20 / 308 (6.49%)	44 / 360 (12.22%)
occurrences (all)	18	20	55
Upper respiratory tract infection			
subjects affected / exposed	20 / 370 (5.41%)	15 / 308 (4.87%)	37 / 360 (10.28%)
occurrences (all)	21	15	43
Influenza			
subjects affected / exposed	11 / 370 (2.97%)	4 / 308 (1.30%)	15 / 360 (4.17%)
occurrences (all)	11	4	16
Urinary tract infection			
subjects affected / exposed	4 / 370 (1.08%)	1 / 308 (0.32%)	8 / 360 (2.22%)
occurrences (all)	4	1	8
Gastroenteritis			
subjects affected / exposed	1 / 370 (0.27%)	8 / 308 (2.60%)	4 / 360 (1.11%)
occurrences (all)	1	8	4
Sinusitis			
subjects affected / exposed	1 / 370 (0.27%)	3 / 308 (0.97%)	11 / 360 (3.06%)
occurrences (all)	1	3	13
Bronchitis			

subjects affected / exposed	4 / 370 (1.08%)	1 / 308 (0.32%)	7 / 360 (1.94%)
occurrences (all)	4	1	7
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 370 (0.27%)	1 / 308 (0.32%)	3 / 360 (0.83%)
occurrences (all)	1	1	4

Non-serious adverse events	Tildrakizumab 100 mg (Part 2)	Tildrakizumab 100 mg (Part 3)	Placebo (Part 1)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	42 / 374 (11.23%)	78 / 316 (24.68%)	23 / 154 (14.94%)
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	1 / 374 (0.27%)	6 / 316 (1.90%)	0 / 154 (0.00%)
occurrences (all)	1	6	0
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 374 (1.07%)	8 / 316 (2.53%)	0 / 154 (0.00%)
occurrences (all)	4	8	0
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 374 (0.80%)	6 / 316 (1.90%)	3 / 154 (1.95%)
occurrences (all)	4	6	3
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 374 (0.00%)	5 / 316 (1.58%)	0 / 154 (0.00%)
occurrences (all)	0	5	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 374 (1.07%)	5 / 316 (1.58%)	0 / 154 (0.00%)
occurrences (all)	4	8	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 374 (0.53%)	3 / 316 (0.95%)	0 / 154 (0.00%)
occurrences (all)	2	3	0
Nausea			
subjects affected / exposed	2 / 374 (0.53%)	2 / 316 (0.63%)	2 / 154 (1.30%)
occurrences (all)	2	2	2
Constipation			

subjects affected / exposed	1 / 374 (0.27%)	3 / 316 (0.95%)	0 / 154 (0.00%)
occurrences (all)	2	3	0
Dental caries			
subjects affected / exposed	3 / 374 (0.80%)	1 / 316 (0.32%)	0 / 154 (0.00%)
occurrences (all)	3	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 374 (1.60%)	13 / 316 (4.11%)	3 / 154 (1.95%)
occurrences (all)	6	13	3
Oropharyngeal pain			
subjects affected / exposed	3 / 374 (0.80%)	7 / 316 (2.22%)	0 / 154 (0.00%)
occurrences (all)	4	8	0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	2 / 374 (0.53%)	9 / 316 (2.85%)	8 / 154 (5.19%)
occurrences (all)	2	9	8
Pruritus			
subjects affected / exposed	1 / 374 (0.27%)	3 / 316 (0.95%)	6 / 154 (3.90%)
occurrences (all)	1	3	6
Eczema			
subjects affected / exposed	0 / 374 (0.00%)	5 / 316 (1.58%)	1 / 154 (0.65%)
occurrences (all)	0	5	1
Dermatitis contact			
subjects affected / exposed	2 / 374 (0.53%)	6 / 316 (1.90%)	1 / 154 (0.65%)
occurrences (all)	2	7	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 374 (1.60%)	8 / 316 (2.53%)	4 / 154 (2.60%)
occurrences (all)	7	8	4
Back pain			
subjects affected / exposed	5 / 374 (1.34%)	8 / 316 (2.53%)	1 / 154 (0.65%)
occurrences (all)	5	8	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	24 / 374 (6.42%)	48 / 316 (15.19%)	8 / 154 (5.19%)
occurrences (all)	24	66	8

Upper respiratory tract infection			
subjects affected / exposed	16 / 374 (4.28%)	26 / 316 (8.23%)	9 / 154 (5.84%)
occurrences (all)	17	32	10
Influenza			
subjects affected / exposed	4 / 374 (1.07%)	14 / 316 (4.43%)	3 / 154 (1.95%)
occurrences (all)	5	14	3
Urinary tract infection			
subjects affected / exposed	3 / 374 (0.80%)	7 / 316 (2.22%)	0 / 154 (0.00%)
occurrences (all)	3	7	0
Gastroenteritis			
subjects affected / exposed	3 / 374 (0.80%)	3 / 316 (0.95%)	2 / 154 (1.30%)
occurrences (all)	3	3	2
Sinusitis			
subjects affected / exposed	3 / 374 (0.80%)	6 / 316 (1.90%)	4 / 154 (2.60%)
occurrences (all)	3	7	4
Bronchitis			
subjects affected / exposed	2 / 374 (0.53%)	8 / 316 (2.53%)	2 / 154 (1.30%)
occurrences (all)	2	8	2
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 374 (0.53%)	4 / 316 (1.27%)	1 / 154 (0.65%)
occurrences (all)	2	5	1

Non-serious adverse events	Tildrakizumab 100 mg (Part 1)	Tildrakizumab 100 mg - Extension Study	Tildrakizumab 200 mg - Extension Study
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 309 (11.65%)	231 / 239 (96.65%)	255 / 267 (95.51%)
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	0 / 309 (0.00%)	12 / 239 (5.02%)	6 / 267 (2.25%)
occurrences (all)	0	12	6
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 309 (0.32%)	39 / 239 (16.32%)	43 / 267 (16.10%)
occurrences (all)	1	45	46
Nervous system disorders			
Headache			

subjects affected / exposed	5 / 309 (1.62%)	22 / 239 (9.21%)	30 / 267 (11.24%)
occurrences (all)	5	26	43
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 309 (0.00%)	12 / 239 (5.02%)	11 / 267 (4.12%)
occurrences (all)	0	13	11
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 309 (0.65%)	17 / 239 (7.11%)	18 / 267 (6.74%)
occurrences (all)	2	20	23
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 309 (0.00%)	13 / 239 (5.44%)	21 / 267 (7.87%)
occurrences (all)	0	14	21
Nausea			
subjects affected / exposed	2 / 309 (0.65%)	8 / 239 (3.35%)	18 / 267 (6.74%)
occurrences (all)	2	8	28
Constipation			
subjects affected / exposed	1 / 309 (0.32%)	13 / 239 (5.44%)	10 / 267 (3.75%)
occurrences (all)	1	15	11
Dental caries			
subjects affected / exposed	1 / 309 (0.32%)	12 / 239 (5.02%)	7 / 267 (2.62%)
occurrences (all)	1	13	8
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	9 / 309 (2.91%)	20 / 239 (8.37%)	34 / 267 (12.73%)
occurrences (all)	9	25	40
Oropharyngeal pain			
subjects affected / exposed	1 / 309 (0.32%)	10 / 239 (4.18%)	19 / 267 (7.12%)
occurrences (all)	1	12	21
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	2 / 309 (0.65%)	13 / 239 (5.44%)	17 / 267 (6.37%)
occurrences (all)	2	15	21
Pruritus			
subjects affected / exposed	8 / 309 (2.59%)	13 / 239 (5.44%)	14 / 267 (5.24%)
occurrences (all)	8	18	18
Eczema			

subjects affected / exposed	1 / 309 (0.32%)	13 / 239 (5.44%)	11 / 267 (4.12%)
occurrences (all)	1	17	21
Dermatitis contact			
subjects affected / exposed	0 / 309 (0.00%)	12 / 239 (5.02%)	10 / 267 (3.75%)
occurrences (all)	0	18	12
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	9 / 309 (2.91%)	41 / 239 (17.15%)	41 / 267 (15.36%)
occurrences (all)	9	52	52
Back pain			
subjects affected / exposed	2 / 309 (0.65%)	17 / 239 (7.11%)	31 / 267 (11.61%)
occurrences (all)	2	18	39
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	24 / 309 (7.77%)	81 / 239 (33.89%)	101 / 267 (37.83%)
occurrences (all)	26	224	206
Upper respiratory tract infection			
subjects affected / exposed	10 / 309 (3.24%)	61 / 239 (25.52%)	68 / 267 (25.47%)
occurrences (all)	10	120	139
Influenza			
subjects affected / exposed	3 / 309 (0.97%)	30 / 239 (12.55%)	43 / 267 (16.10%)
occurrences (all)	3	33	56
Urinary tract infection			
subjects affected / exposed	5 / 309 (1.62%)	24 / 239 (10.04%)	24 / 267 (8.99%)
occurrences (all)	5	31	33
Gastroenteritis			
subjects affected / exposed	4 / 309 (1.29%)	16 / 239 (6.69%)	24 / 267 (8.99%)
occurrences (all)	4	16	32
Sinusitis			
subjects affected / exposed	4 / 309 (1.29%)	20 / 239 (8.37%)	18 / 267 (6.74%)
occurrences (all)	4	23	30
Bronchitis			
subjects affected / exposed	2 / 309 (0.65%)	18 / 239 (7.53%)	18 / 267 (6.74%)
occurrences (all)	2	19	24
Viral upper respiratory tract infection			

subjects affected / exposed occurrences (all)	2 / 309 (0.65%) 2	14 / 239 (5.86%) 22	9 / 267 (3.37%) 9

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 September 2012	Tier 2 endpoints revised, PK, ADA timepoints revised
14 January 2014	New objectives were added
08 January 2016	Other secondary objectives and endpoints were added
09 March 2018	Change in Sponsor, along with clarification of assessment procedures and document updates.
24 July 2018	The protocol was amended to support longterm safety and efficacy evaluation, and provide clarity on visit schedules, assessments, and patient management during the extended treatment period.
11 December 2020	Improve procedural clarity, and maintain study continuity and subject safety.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported