Clinical trial results:
A PHASE 2B, MULTI-SITE, RANDOMIZED, DOUBLE-BLIND, VEHICLE-CONTROLLED, PARALLEL-GROUP STUDY OF THE EFFICACY, SAFETY, LOCAL TOLERABILITY AND PHARMACOKINETICS OF 2 DOSE STRENGTHS AND 2 REGIMENS OF TOFACITINIB OINTMENT IN SUBJECTS WITH CHRONIC PLAQUE PSORIASIS

Summary

EudraCT number	2012-005645-20
Trial protocol	DK
Global end of trial date	16 September 2014

Results information

Result version number	v1 (current)
This version publication date	16 September 2016
First version publication date	16 September 2016

Trial information

Trial identification

Sponsor protocol code	A3921082

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York,, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	16 September 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 September 2014
Global end of trial reached?	Yes
Global end of trial date	16 September 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The Primary Objectives were: To characterize the efficacy of tofacitinib ointment (10 mg/g and 20 mg/g) applied once daily (QD) or twice daily (BID) over 12 weeks in subjects with mild or moderate chronic plaque psoriasis compared to the corresponding placebo ointment (vehicle) (QD or BID). To characterize safety of tofacitinib ointment (10 mg/g and 20 mg/g) applied QD or BID over 12 weeks in subjects with mild or moderate chronic plaque psoriasis. To characterize local tolerability of tofacitinib ointment (10 mg/g and 20 mg/g) applied QD or BID over 12 weeks in subjects with mild or moderate chronic plaque psoriasis. The Secondary Objectives were: To characterize effects on patient reported outcome (PRO) measures of tofacitinib ointment (10 mg/g and 20 mg/g) applied QD or BID over 12 weeks of treatment in subjects with mild or moderate chronic plaque psoriasis.

Protection of trial subjects:

The study was conducted in accordance with legal and regulatory requirements, as well as the general principles set forth in the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences 2002), Guidelines for Good Clinical Practice (ICH 1996), and the Declaration of Helsinki (World Medical Association 1996 and 2008). The informed consent document was in compliance with International Conference on Harmonisation (ICH) GCP, local regulatory requirements, and legal requirements. The informed consent document used during the informed consent process was reviewed by the sponsor, approved by the IRB/IEC, and available for inspection. The investigator was to inform Pfizer immediately of any urgent safety measures taken by the investigator to protect the study subjects against any immediate hazard, and of any serious breaches of this protocol or of ICH GCP that the investigator became aware of.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 May 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 127
Country: Number of subjects enrolled	Denmark: 5
Country: Number of subjects enrolled	Poland: 109
Country: Number of subjects enrolled	United States: 230
Worldwide total number of subjects	471
EEA total number of subjects	114

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)	393
From 65 to 84 years	77
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Advertisements approved by ethics committees and investigator databases could be used as recruitment procedures.

Pre-assignment

Screening details:

Subjects were screened within 28 days (+4 days) prior to Visit 1 (Baseline/Day 1) to confirm that they were suitable and potentially eligible for the study. Screening procedures could be performed over more than one visit in the 28 days (+4 days) prior to Visit 1 (Baseline/Day 1).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer

Blinding implementation details:

Carer equals the physician treating the subject Investigator equals the sponsor of the trial.

Arms

Are arms mutually exclusive?	Yes
Arm title	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID

Arm description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 20 mg/g, BID for 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

20 mg/g BID

Arm title	Mild/Moderate: Tofacitinib 10 mg/g BID

Arm description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 10 mg/g, BID for 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

10 mg/g BID

Arm title	Mild/Moderate: Placebo (vehicle) BID

Arm description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied placebo ointment (vehicle), BID for 12 weeks.

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

placebo BID

Arm title	Mild/Moderate: Tofacitinib 20 mg/g QD

Arm description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 20 mg/g, QD for 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

20 mg/g QD

Arm title	Mild/Moderate: Tofacitinib 10 mg/g QD

Arm description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment 10 mg/g, QD for 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

10 mg/g QD

Arm title	Mild/Moderate: Placebo (vehicle) QD

Arm description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied placebo ointment (vehicle), QD for 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

placebo QD

Arm title	Severe: Tofacitinib 20 mg/g BID

Arm description:

Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 20 mg/g, BID for 12 weeks.

Arm type	Active comparator

Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

20 mg/g BID

Arm title	Severe: Tofacitinib 10 mg/g BID

Arm description:

Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 10 mg/g, BID for 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

10 mg/g BID

Arm title	Severe: Placebo (vehicle) BID

Arm description:

Participants with a baseline PGA-C score of severe (4) applied placebo ointment (vehicle), BID for 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

placebo BID

Arm title	Severe: Tofacitinib 20 mg/g QD

Arm description:

Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 20 mg/g, QD for 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

20 mg/g QD

Arm title	Severe: Tofacitinib 10 mg/g QD

Arm description:

Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment 10 mg/g, QD for 12 weeks.

Arm type	Active comparator

Investigational medicinal product name	Tofacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

10 mg/g QD

Arm title	Severe: Placebo (vehicle) QD

Arm description:

Participants with a baseline PGA-C score of severe (4) applied placebo ointment (vehicle), QD for 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Ointment
Routes of administration	Topical use

Dosage and administration details:

placebo QD

Number of subjects in period 1	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID
Started	71	70	71
Completed	55	52	48
Not completed	16	18	23
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	6	3	3
Adverse event, non-fatal	-	-	4
Not specified	2	3	2
Non-compliance with study treatment	2	1	1
Lost to follow-up	-	1	4
Protocol deviation	1	1	2
Lack of efficacy	5	8	7

Number of subjects in period 1	Mild/Moderate: Tofacitinib 20 mg/g QD	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD
Started	70	74	74
Completed	51	57	48
Not completed	19	17	26
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	3	3	5
Adverse event, non-fatal	6	3	7
Not specified	2	2	1

Non-compliance with study treatment	-	-	1
Lost to follow-up	2	-	3
Protocol deviation	-	-	1
Lack of efficacy	6	9	8

Number of subjects in period 1	Severe: Tofacitinib 20 mg/g BID	Severe: Tofacitinib 10 mg/g BID	Severe: Placebo (vehicle) BID
Started	7	7	7
Completed	6	5	4
Not completed	1	2	3
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	1	1
Not specified	-	-	-
Non-compliance with study treatment	-	-	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-
Lack of efficacy	1	1	2

Number of subjects in period 1	Severe: Tofacitinib 20 mg/g QD	Severe: Tofacitinib 10 mg/g QD	Severe: Placebo (vehicle) QD
Started	7	6	7
Completed	2	4	3
Not completed	5	2	4
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	-	1
Adverse event, non-fatal	1	-	2
Not specified	-	-	-
Non-compliance with study treatment	-	-	-
Lost to follow-up	1	-	1
Protocol deviation	-	-	-
Lack of efficacy	2	2	-

Baseline characteristics

Reporting groups

Reporting group title	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 20 mg/g, BID for 12 weeks.	
Reporting group title	Mild/Moderate: Tofacitinib 10 mg/g BID
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 10 mg/g, BID for 12 weeks.	
Reporting group title	Mild/Moderate: Placebo (vehicle) BID
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied placebo ointment (vehicle), BID for 12 weeks.	
Reporting group title	Mild/Moderate: Tofacitinib 20 mg/g QD
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 20 mg/g, QD for 12 weeks.	
Reporting group title	Mild/Moderate: Tofacitinib 10 mg/g QD
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment 10 mg/g, QD for 12 weeks.	
Reporting group title	Mild/Moderate: Placebo (vehicle) QD
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied placebo ointment (vehicle), QD for 12 weeks.	
Reporting group title	Severe: Tofacitinib 20 mg/g BID
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 20 mg/g, BID for 12 weeks.	
Reporting group title	Severe: Tofacitinib 10 mg/g BID
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 10 mg/g, BID for 12 weeks.	
Reporting group title	Severe: Placebo (vehicle) BID
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied placebo ointment (vehicle), BID for 12 weeks.	
Reporting group title	Severe: Tofacitinib 20 mg/g QD
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 20 mg/g, QD for 12 weeks.	
Reporting group title	Severe: Tofacitinib 10 mg/g QD
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment 10 mg/g, QD for 12 weeks.	
Reporting group title	Severe: Placebo (vehicle) QD
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied placebo ointment (vehicle), QD for 12 weeks.	

Reporting group values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID
Number of subjects	71	70	71
Age categorical Units: Subjects			
Adults (18-64 years)	58	57	59
From 65-84 years	13	13	12
85 years and over	0	0	0
Gender, Male/Female Units: Participants			
Female	28	23	30
Male	43	47	41

Reporting group values	Mild/Moderate: Tofacitinib 20 mg/g QD	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD
Number of subjects	70	74	74
Age categorical Units: Subjects			
Adults (18-64 years)	59	65	64
From 65-84 years	11	8	10
85 years and over	0	1	0
Gender, Male/Female Units: Participants			
Female	33	24	32
Male	37	50	42

Reporting group values	Severe: Tofacitinib 20 mg/g BID	Severe: Tofacitinib 10 mg/g BID	Severe: Placebo (vehicle) BID
Number of subjects	7	7	7
Age categorical Units: Subjects			
Adults (18-64 years)	6	6	5
From 65-84 years	1	1	2
85 years and over	0	0	0
Gender, Male/Female Units: Participants			
Female	1	3	1
Male	6	4	6

Reporting group values	Severe: Tofacitinib 20 mg/g QD	Severe: Tofacitinib 10 mg/g QD	Severe: Placebo (vehicle) QD
Number of subjects	7	6	7
Age categorical Units: Subjects			
Adults (18-64 years)	5	5	4
From 65-84 years	2	1	3
85 years and over	0	0	0
Gender, Male/Female Units: Participants			
Female	1	0	0
Male	6	6	7

Reporting group values	Total		
Number of subjects	471		
Age categorical Units: Subjects			
Adults (18-64 years)	393		
From 65-84 years	77		
85 years and over	1		
Gender, Male/Female Units: Participants			
Female	176		
Male	295		

End points

End points reporting groups

Reporting group title	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 20 mg/g, BID for 12 weeks.	
Reporting group title	Mild/Moderate: Tofacitinib 10 mg/g BID
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 10 mg/g, BID for 12 weeks.	
Reporting group title	Mild/Moderate: Placebo (vehicle) BID
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied placebo ointment (vehicle), BID for 12 weeks.	
Reporting group title	Mild/Moderate: Tofacitinib 20 mg/g QD
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 20 mg/g, QD for 12 weeks.	
Reporting group title	Mild/Moderate: Tofacitinib 10 mg/g QD
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment 10 mg/g, QD for 12 weeks.	
Reporting group title	Mild/Moderate: Placebo (vehicle) QD
Reporting group description:	
Participants with a baseline PGA-C score of mild (2) or moderate (3) applied placebo ointment (vehicle), QD for 12 weeks.	
Reporting group title	Severe: Tofacitinib 20 mg/g BID
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 20 mg/g, BID for 12 weeks.	
Reporting group title	Severe: Tofacitinib 10 mg/g BID
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 10 mg/g, BID for 12 weeks.	
Reporting group title	Severe: Placebo (vehicle) BID
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied placebo ointment (vehicle), BID for 12 weeks.	
Reporting group title	Severe: Tofacitinib 20 mg/g QD
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 20 mg/g, QD for 12 weeks.	
Reporting group title	Severe: Tofacitinib 10 mg/g QD
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment 10 mg/g, QD for 12 weeks.	
Reporting group title	Severe: Placebo (vehicle) QD
Reporting group description:	
Participants with a baseline PGA-C score of severe (4) applied placebo ointment (vehicle), QD for 12 weeks.	

Primary: Percentage of Participants Achieving a PGA-C Response of Clear (0) or Almost Clear (1) and Greater Than or Equal to (≥) 2 Grade/point Improvement from Baseline at Week 12

End point title	Percentage of Participants Achieving a PGA-C Response of Clear (0) or Almost Clear (1) and Greater Than or Equal to (≥) 2 Grade/point Improvement from Baseline at Week 12[1]

End point description:

Clinical signs of plaque psoriasis (erythema [E], induration [I], and scaling [S]) were scored separately according to a 5-point severity scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. The PGA-C was a static assessment; i.e., without regard to a previous assessment. The PGA subscores are then summed and averaged after which the total average was rounded to the nearest whole number to determine the PGA-C score and category. A higher score indicated a higher level of severity. 0 is equal to (=) cleared except for any residual discoloration and 1=almost clear, majority of lesions had individual scores for E+I+S that when summed, averaged, and rounded equaled 1.

End point type	Primary

End point timeframe:

Baseline, Week 12

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	70	71	70
Units: Percentage of Participants				
number (not applicable)	21.1	12.9	16.9	20

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	74		
Units: Percentage of Participants				
number (not applicable)	21.6	17.6		

Statistical analyses

Statistical analysis title	Mild/Moderate BID: Tofacitinib 20 mg/g vs Placebo

Statistical analysis description:

The mild/moderate full analysis set (FASm) included all participants in the FAS with a baseline PGA-C disease severity of mild (2) or moderate (3). A participant with a missing value was considered a non-responder.

Comparison groups	Mild/Moderate: Placebo (vehicle) BID v Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID

Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	other[2]
P-value	= 0.5425
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rates
Point estimate	3.9
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-4.3
upper limit	12
Variability estimate	Standard error of the mean
Dispersion value	6.36

Notes:

[2] - Large sample approximation to the difference in binomial proportions adjusted for the baseline PGA-C disease severity using the CochranMantel-Haenszel approach.

Statistical analysis title	Mild/Moderate BID: Tofacitinib 10 mg/g vs Placebo

Statistical analysis description:

FASm included all participants in the FAS with a baseline PGA-C disease severity of mild (2) or moderate (3). A participant with a missing value was considered a non-responder.

Comparison groups	Mild/Moderate: Tofacitinib 10 mg/g BID v Mild/Moderate: Placebo (vehicle) BID
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	other[3]
P-value	= 0.4976
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rates
Point estimate	-4
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-11.5
upper limit	3.5
Variability estimate	Standard error of the mean
Dispersion value	5.87

Notes:

[3] - Large sample approximation to the difference in binomial proportions adjusted for the baseline PGA-C disease severity using the CochranMantel-Haenszel approach

Statistical analysis title	Mild/Moderate QD: Tofacitinib 20 mg/g vs Placebo

Statistical analysis description:

FASm included all participants in the FAS with a baseline PGA-C disease severity of mild (2) or moderate (3). A participant with a missing value was considered a non-responder.

Comparison groups	Mild/Moderate: Tofacitinib 20 mg/g QD v Mild/Moderate: Placebo (vehicle) QD

Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[4]
P-value	= 0.6039
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rates
Point estimate	3.3
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-4.9
upper limit	11.5
Variability estimate	Standard error of the mean
Dispersion value	6.36

Notes:

[4] - Large sample approximation to the difference in binomial proportions adjusted for the baseline PGA-C disease severity using the CochranMantel-Haenszel approach

Statistical analysis title	Mild/Moderate QD: Tofacitinib 10 mg/g vs Placebo

Statistical analysis description:

FASm included all participants in the FAS with a baseline PGA-C disease severity of mild (2) or moderate (3). A participant with a missing value was considered a non-responder.

Comparison groups	Mild/Moderate: Tofacitinib 10 mg/g QD v Mild/Moderate: Placebo (vehicle) QD
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other[5]
P-value	= 0.5279
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rate
Point estimate	4
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-4.1
upper limit	12.1
Variability estimate	Standard error of the mean
Dispersion value	6.34

Notes:

[5] - Large sample approximation to the difference in binomial proportions adjusted for the baseline PGA-C disease severity using the CochranMantel-Haenszel approach

Primary: Percentage of Participants Achieving a PGA-C Response of Clear (0) or Almost Clear (1) and ≥2 Grade/point Improvement from Baseline at Week 8

End point title	Percentage of Participants Achieving a PGA-C Response of Clear (0) or Almost Clear (1) and ≥2 Grade/point Improvement from Baseline at Week 8[6]

End point description:

Clinical signs of plaque psoriasis (E, I, and S) were scored separately according to a 5-point severity scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. The PGA-C was a static assessment; i.e., without regard to a previous assessment. The PGA subscores are then summed and averaged after which the total average was rounded to the nearest whole number to determine the PGA-C score and category. A higher score indicated a higher level of severity. 0 is equal to (=) cleared except for any residual discoloration and 1=almost clear, majority of lesions had individual scores for E+I+S that when summed, averaged, and rounded equaled 1.

End point type	Primary

End point timeframe:

Baseline, Week 8

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	70	71	70
Units: Percentage of Participants				
number (not applicable)	22.5	10	11.3	18.6

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	74		
Units: Percentage of Participants				
number (not applicable)	14.9	8.1		

Statistical analyses

Statistical analysis title	Mild/Moderate BID: Tofacitinib 20 mg/g vs Placebo

Statistical analysis description:

FASm. A participant with a missing value was considered a non-responder.

Comparison groups	Mild/Moderate: Placebo (vehicle) BID v Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	other[7]
P-value	= 0.071
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rates
Point estimate	10.8
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	3.1
upper limit	18.5
Variability estimate	Standard error of the mean
Dispersion value	5.99

Notes:

[7] - Large sample approximation to the difference in binomial proportions adjusted for the baseline PGA-C disease severity using the CochranMantel-Haenszel approach

Statistical analysis title	Mild/Moderate BID: Tofacitinib 10 mg/g vs Placebo

Statistical analysis description:

FASm. A participant with a missing value was considered a non-responder.

Comparison groups	Mild/Moderate: Tofacitinib 10 mg/g BID v Mild/Moderate: Placebo (vehicle) BID
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	other[8]
P-value	= 0.8175
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rates
Point estimate	-1.2
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-7.9
upper limit	5.5
Variability estimate	Standard error of the mean
Dispersion value	5.2

Notes:

[8] - Large sample approximation to the difference in binomial proportions adjusted for the baseline PGA-C disease severity using the CochranMantel-Haenszel approach

Statistical analysis title	Mild/Moderate QD: Tofacitinib 20 mg/g vs Placebo

Statistical analysis description:

FASm. A participant with a missing value was considered a non-responder.

Comparison groups	Mild/Moderate: Tofacitinib 20 mg/g QD v Mild/Moderate: Placebo (vehicle) QD
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	other[9]
P-value	= 0.0513
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rates
Point estimate	11
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	3.8
upper limit	18.2
Variability estimate	Standard error of the mean
Dispersion value	5.63

Notes:

[9] - Large sample approximation to the difference in binomial proportions adjusted for the baseline PGA-C disease severity using the CochranMantel-Haenszel approach

Statistical analysis title	Mild/Moderate QD: Tofacitinib 10 mg/g vs Placebo

Statistical analysis description:

FASm. A participant with a missing value was considered a non-responder.

Comparison groups	Mild/Moderate: Tofacitinib 10 mg/g QD v Mild/Moderate: Placebo (vehicle) QD
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other[10]
P-value	= 0.2021
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in response rates
Point estimate	6.7
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0
upper limit	13.4
Variability estimate	Standard error of the mean
Dispersion value	5.23

Notes:

[10] - Large sample approximation to the difference in binomial proportions adjusted for the baseline PGA-C disease severity using the CochranMantel-Haenszel approach

Secondary: Percentage of Participants Achieving a PGA-C Response of Clear (0) or Almost Clear (1) at Week 12

End point title	Percentage of Participants Achieving a PGA-C Response of Clear (0) or Almost Clear (1) at Week 12[11]

End point description:

Clinical signs of plaque psoriasis (E, I, and S) were scored separately according to a 5-point severity scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. The PGA-C was a static assessment; i.e., without regard to a previous assessment. The PGA subscores are then summed and averaged after which the total average was rounded to the nearest whole number to determine the PGA-C score and category. A higher score indicated a higher level of severity. 0 is equal to (=) cleared except for any residual discoloration and 1=almost clear, majority of lesions had individual scores for E+I+S that when summed, averaged, and rounded equaled 1.

End point type	Secondary

End point timeframe:

Week 12

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	70	71	70
Units: Percentage of Participants				
number (not applicable)	33.8	25.7	23.9	27.1

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	74		
Units: Percentage of Participants				
number (not applicable)	29.7	23		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a PGA-C Response of Clear (0) or Almost Clear (1) at Week 8

End point title	Percentage of Participants Achieving a PGA-C Response of Clear (0) or Almost Clear (1) at Week 8[12]

End point description:

Clinical signs of plaque psoriasis (E, I, and S) were scored separately according to a 5-point severity scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. The PGA-C was a static assessment; i.e., without regard to a previous assessment. The PGA subscores are then summed and averaged after which the total average was rounded to the nearest whole number to determine the PGA-C score and category. A higher score indicated a higher level of severity. 0 is equal to (=) cleared except for any residual discoloration and 1=almost clear, majority of lesions had individual scores for E+I+S that when summed, averaged, and rounded equaled 1.

End point type	Secondary

End point timeframe:

Week 8

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	70	71	70
Units: Percentage of Participants				
number (not applicable)	36.6	20	22.5	32.9

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	74		
Units: Percentage of Participants				
number (not applicable)	21.6	12.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a Gestalt Physician's Global Assessment (PGA-G) Response of Clear (0) or Almost Clear (1) and ≥2 Grade/point Improvement from Baseline at Week 12

End point title	Percentage of Participants Achieving a Gestalt Physician's Global Assessment (PGA-G) Response of Clear (0) or Almost Clear (1) and ≥2 Grade/point Improvement from Baseline at Week 12[13]

End point description:

Clinical signs of plaque psoriasis (E, I and S) were scored separately according to a 5-point severity scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. After scoring each of the PGA subscores, a clinical evaluator of psoriasis performed an assessment of the overall severity of psoriasis and assigned a PGA-G score and category. 0=Clear, except for any residual discoloration (post-inflammatory hyperpigmentation and/or hypopigmentation) and 1=almost clear, the psoriasis is not entirely cleared and remaining plaques are light pink (not including post inflammatory hyperpigmentation), and/or have barely palpable elevation and/or have occasional fine scale. The PGA-G was a static assessment; i.e., without regard to a previous assessment.

End point type	Secondary

End point timeframe:

Baseline, Week 12

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	70	71	70
Units: Percentage of Participants				
number (not applicable)	18.3	11.4	14.1	15.7

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	74		
Units: Percentage of Participants				
number (not applicable)	18.9	12.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a PGA-G Response of Clear (0) or Almost Clear (1) and ≥2 Grade/point Improvement from Baseline at Week 8

End point title	Percentage of Participants Achieving a PGA-G Response of Clear (0) or Almost Clear (1) and ≥2 Grade/point Improvement from Baseline at Week 8[14]

End point description:

Clinical signs of plaque psoriasis (E, I and S) were scored separately according to a 5-point severity scale (0 to 4) to provide PGA subscores, which described the overall severity of each clinical sign. After scoring each of the PGA subscores, a clinical evaluator of psoriasis performed an assessment of the overall severity of psoriasis and assigned a PGA-G score and category. 0=Clear, except for any residual discoloration (post-inflammatory hyperpigmentation and/or hypopigmentation) and 1=almost clear, the psoriasis is not entirely cleared and remaining plaques are light pink (not including post inflammatory hyperpigmentation), and/or have barely palpable elevation and/or have occasional fine scale. The PGA-G was a static assessment; i.e., without regard to a previous assessment.

End point type	Secondary

End point timeframe:

Baseline, Week 8

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	70	71	70
Units: Percentage of Participants				
number (not applicable)	21.1	7.1	11.3	15.7

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	74		
Units: Percentage of Participants				
number (not applicable)	9.5	4.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline to Week 12 in Psoriasis Area and Severity Index (PASI)

End point title	Percent Change from Baseline to Week 12 in Psoriasis Area and Severity Index (PASI)[15]

End point description:

Combined assessment of lesion severity and area affected into single score. Body was divided into 4 regions: head, arms, trunk, legs. For each region, percent (%) area of skin involved was estimated: 0=0% to 6=90–100%. Severity was estimated by clinical signs: erythema, induration, scaling; scale: 0=none to 4=maximum. Final PASI = sum of severity parameters for each region*area score*weight of region (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0=no disease to

72=maximal disease. The maximum PASI score was <72 since the PASI assessment excluded scalp, palms, finger nails, soles, and toe nails.

End point type	Secondary

End point timeframe:

Baseline, Week 12

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	55	53
Units: Percent Change from Baseline				
arithmetic mean (standard deviation)	-36.6 (± 40.88)	-35.7 (± 43.78)	-32 (± 49.47)	-38.6 (± 36.37)

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	52		
Units: Percent Change from Baseline				
arithmetic mean (standard deviation)	-31.4 (± 42.36)	-30 (± 38.68)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline to Week 8 in PASI

End point title	Percent Change from Baseline to Week 8 in PASI[16]

End point description:

Combined assessment of lesion severity and area affected into single score. Body was divided into 4 regions: head, arms, trunk, legs. For each region, percent area of skin involved was estimated: 0=0% to 6=90-100%. Severity was estimated by clinical signs: erythema, induration, scaling; scale: 0=none to 4=maximum. Final PASI = sum of severity parameters for each region*area score*weight of region (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0=no disease to 72=maximal disease. The maximum PASI score was <72 since the PASI assessment excluded scalp, palms, finger nails, soles, and toe nails.

End point type	Secondary

End point timeframe:

Baseline, Week 8

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	64	55	60
Units: Percent Change from Baseline				
arithmetic mean (standard deviation)	-36.7 (± 36.01)	-29.1 (± 40.86)	-28.8 (± 37.06)	-36.5 (± 33.87)

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	58		
Units: Percent Change from Baseline				
arithmetic mean (standard deviation)	-29 (± 29.47)	-27.1 (± 32.93)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving at Least a 75% Reduction in PASI Response (PASI75), Relative to Baseline at Week 12

End point title	Percentage of Participants Achieving at Least a 75% Reduction in PASI Response (PASI75), Relative to Baseline at Week 12[17]

End point description:

Combined assessment of lesion severity and area affected into single score. Body was divided into 4 regions: head, arms, trunk, legs. For each region, percent area of skin involved was estimated: 0=0% to 6=90-100%. Severity was estimated by clinical signs: erythema, induration, scaling; scale: 0=none to 4=maximum. Final PASI = sum of severity parameters for each region*area score*weight of region (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0=no disease to 72=maximal disease. The maximum PASI score was <72 since the PASI assessment excluded scalp, palms, finger nails, soles, and toe nails.

End point type	Secondary

End point timeframe:

Baseline, Week 12

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	70	71	70
Units: Percentage of Participants				
number (not applicable)	16.9	12.9	12.7	15.7

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	74		
Units: Percentage of Participants				
number (not applicable)	10.8	6.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving PASI75, Relative to Baseline at Week 8

End point title	Percentage of Participants Achieving PASI75, Relative to Baseline at Week 8[18]

End point description:

Combined assessment of lesion severity and area affected into single score. Body was divided into 4 regions: head, arms, trunk, legs. For each region, percent area of skin involved was estimated: 0=0% to 6=90-100%. Severity was estimated by clinical signs: erythema, induration, scaling; scale: 0=none to 4=maximum. Final PASI = sum of severity parameters for each region*area score*weight of region (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0=no disease to 72=maximal disease. The maximum PASI score was <72 since the PASI assessment excluded scalp, palms, finger nails, soles, and toe nails.

End point type	Secondary

End point timeframe:

Baseline, Week 8

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	70	71	70
Units: Percentage of Participants				
number (not applicable)	14.1	8.6	7	15.7

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	74		
Units: Percentage of Participants				
number (not applicable)	6.8	6.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline to Week 12 in Body Surface Area (BSA) Affected with Psoriasis

End point title	Percent Change from Baseline to Week 12 in Body Surface Area (BSA) Affected with Psoriasis[19]

End point description:

Assessment of BSA with psoriasis was performed separately for 4 body regions: head and neck, upper limbs, trunk (including axillae and groin), and lower limbs (including buttocks). The percent surface area with psoriasis was estimated by means of the handprint method, where the full palmar hand of the participant represents approximately 1% of the total BSA. The number of handprints of psoriatic skin in a body region can be used to determine the extent (%) to which a body regions is involved with psoriasis. BSA (%)=the sum of the BSAs of the 4 body regions. BSA assessment excluded head and neck, palms, finger nails, soles and toe nails.

End point type	Secondary

End point timeframe:

Baseline, Week 12

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	55	53
Units: Percent Change from Baseline				
arithmetic mean (standard deviation)	-32.8 (± 40.92)	-27.5 (± 36.4)	-27.7 (± 43.43)	-24.6 (± 36.29)

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	52		

Units: Percent Change from Baseline				
arithmetic mean (standard deviation)	-15.6 (± 36.63)	-11.2 (± 56.38)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change from Baseline to Week 8 in BSA Affected with Psoriasis

End point title	Percent Change from Baseline to Week 8 in BSA Affected with Psoriasis[20]

End point description:

Assessment of BSA with psoriasis was performed separately for 4 body regions: head and neck, upper limbs, trunk (including axillae and groin), and lower limbs (including buttocks). The percent surface area with psoriasis was estimated by means of the handprint method, where the full palmar hand of the participant represents approximately 1% of the total BSA. The number of handprints of psoriatic skin in a body region can be used to determine the extent (%) to which a body regions is involved with psoriasis. BSA (%)=the sum of the BSAs of the 4 body regions. BSA assessment excluded head and neck, palms, finger nails, soles and toe nails.

End point type	Secondary

End point timeframe:

Baseline, Week 8

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	64	55	60
Units: Percent Change from Baseline				
arithmetic mean (standard deviation)	-25.4 (± 44.75)	-22.5 (± 35.87)	-20.5 (± 34.9)	-17.8 (± 28.59)

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	58		
Units: Percent Change from Baseline				
arithmetic mean (standard deviation)	-9 (± 30.08)	-11.7 (± 38.29)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 12 in Clinic-Based Itch Severity Item (ISI) Scores

End point title	Change from Baseline to Week 12 in Clinic-Based Itch Severity Item (ISI) Scores[21]

End point description:

The severity of itch (pruritus) due to psoriasis was assessed using the ISI. Participants were asked to assess their "worst itching due to psoriasis over the past 24 hours" on a numeric rating scale anchored by the terms "no itching" (0) and "worst possible itching" (10) at the ends. Participants completed the ISI assessments at the clinic (i.e., clinic-based).

End point type	Secondary

End point timeframe:

Baseline, Week 12

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	57	55	52
Units: Score on a Scale				
arithmetic mean (standard deviation)	-2.88 (± 3.14)	-2.89 (± 3.32)	-1.73 (± 2.46)	-2.38 (± 3.182)

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	52		
Units: Score on a Scale				
arithmetic mean (standard deviation)	-1.94 (± 3.151)	-1.5 (± 2.961)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 8 in Clinic-Based ISI Scores

End point title	Change from Baseline to Week 8 in Clinic-Based ISI Scores[22]

End point description:

The severity of itch (pruritus) due to psoriasis was assessed using the ISI. Participants were asked to assess their "worst itching due to psoriasis over the past 24 hours" on a numeric rating scale anchored by the terms "no itching" (0) and "worst possible itching" (10) at the ends. Participants completed the ISI assessments at the clinic (i.e., clinic-based).

End point type	Secondary

End point timeframe:

Baseline, Week 8

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	64	55	59
Units: Score on a Scale				
arithmetic mean (standard deviation)	-3.07 (± 2.971)	-2.38 (± 2.984)	-1.45 (± 2.847)	-2.49 (± 2.769)

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	58		
Units: Score on a Scale				
arithmetic mean (standard deviation)	-1.91 (± 3.166)	-1.34 (± 3.285)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 12 in the Dermatology Life Quality Index (DLQI) Total Score

End point title	Change from Baseline to Week 12 in the Dermatology Life Quality Index (DLQI) Total Score[23]

End point description:

DLQI is the dermatology-specific quality of life measure used for psoriatic population. The 10-item questionnaire assesses participant health-related quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). The DLQI questions are rated by the participant as 0 (not at all/not relevant) to 3 (very much) with a total score range of 0 (best) to 30 (worst); higher scores indicate poor quality of life.

End point type	Secondary

End point timeframe:

Baseline, Week 12

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	55	53
Units: Score on a Scale				
arithmetic mean (standard deviation)	-4.6 (± 5.55)	-3.2 (± 5.32)	-2.6 (± 5.45)	-5.6 (± 7.04)

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	52		
Units: Score on a Scale				
arithmetic mean (standard deviation)	-3.3 (± 5.97)	-2.3 (± 6.34)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline to Week 8 in the DLQI Total Score

End point title	Change from Baseline to Week 8 in the DLQI Total Score[24]

End point description:

DLQI is the dermatology-specific quality of life measure used for psoriatic population. The 10-item questionnaire assesses participant health-related quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). The DLQI questions are rated by the participant as 0 (not at all/not relevant) to 3 (very much) with a total score range of 0 (best) to 30 (worst); higher scores indicate poor quality of life.

End point type	Secondary

End point timeframe:

Baseline, Week 8

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	64	55	60
Units: Score on a Scale				
arithmetic mean (standard deviation)	-4.6 (± 5.16)	-2.6 (± 4.98)	-2.8 (± 4.01)	-5 (± 5.85)

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	58		
Units: Score on a Scale				
arithmetic mean (standard deviation)	-2.7 (± 4.79)	-2.2 (± 5.63)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a Patient's Global Assessment (PtGA) Response of Clear (0) or Almost Clear (1) and ≥2 Grade/point Improvement from Baseline at Week 12 for Participants with a PtGA Score ≥2 at Baseline

End point title	Percentage of Participants Achieving a Patient's Global Assessment (PtGA) Response of Clear (0) or Almost Clear (1) and ≥2 Grade/point Improvement from Baseline at Week 12 for Participants with a PtGA Score ≥2 at Baseline[25]

End point description:

The PtGA asks the participant to evaluate the overall cutaneous disease at that point in time on a single item, 5-point scale (0=clear; 1=almost clear; 2=mild; 3=moderate; 4=severe).

End point type	Secondary

End point timeframe:

Baseline, Week 12

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	57	55	53
Units: Percentage of Participants				
number (not applicable)	8.8	17.5	7.3	13.2

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	52		
Units: Percentage of Participants				
number (not applicable)	14.5	7.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a PtGA Response of Clear (0) or Almost Clear (1) and ≥2 Grade/point Improvement from Baseline at Week 8 for Participants with a PtGA Score ≥2 at Baseline

End point title	Percentage of Participants Achieving a PtGA Response of Clear (0) or Almost Clear (1) and ≥2 Grade/point Improvement from Baseline at Week 8 for Participants with a PtGA Score ≥2 at Baseline[26]

End point description:

The PtGA asks the participant to evaluate the overall cutaneous disease at that point in time on a single item, 5-point scale (0=clear; 1=almost clear; 2=mild; 3=moderate; 4=severe).

End point type	Secondary

End point timeframe:

Baseline, Week 8

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A statistical analysis for this outcome measure was not included, because this study was an estimation trial, not a confirmatory trial.

End point values	Mild/Moderate: Tofacitinib 20 mg/gram (mg/g) BID	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Placebo (vehicle) BID	Mild/Moderate: Tofacitinib 20 mg/g QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	64	55	60
Units: Percentage of Participants				
number (not applicable)	5	6.3	10.9	10

End point values	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Placebo (vehicle) QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	58		
Units: Percentage of Participants				
number (not applicable)	6	1.7		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

SAEs were assessed from informed consent through and including 28 calendar days after last administration of study treatment. Non-SAEs were recorded from time of first dose of study treatment through last participant visit.

Adverse event reporting additional description:

The same event may appear as both an AE and an SAE. However, what is presented are distinct events. An event may be categorized as serious in 1 participant and as nonserious in another participant, or 1 participant may have experienced both a serious and nonserious event during the study. All AEs (including treatment area AEs) are presented.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Mild/Moderate: Tofacitinib 10 mg/g BID

Reporting group description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 10 mg/g, BID for 12 weeks.

Reporting group title	Mild/Moderate: Tofacitinib 20 mg/g BID

Reporting group description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 20 mg/g, BID for 12 weeks.

Reporting group title	Mild/Moderate: Placebo (vehicle) BID

Reporting group description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied placebo ointment (vehicle), BID for 12 weeks.

Reporting group title	Mild/Moderate: Tofacitinib 10 mg/g QD

Reporting group description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment 10 mg/g, QD for 12 weeks.

Reporting group title	Mild/Moderate: Tofacitinib 20 mg/g QD

Reporting group description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied tofacitinib ointment, 20 mg/g, QD for 12 weeks.

Reporting group title	Mild/Moderate: Placebo (vehicle) QD

Reporting group description:

Participants with a baseline PGA-C score of mild (2) or moderate (3) applied placebo ointment (vehicle), QD for 12 weeks.

Reporting group title	Severe: Tofacitinib 20 mg/g BID

Reporting group description:

Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 20 mg/g, BID for 12 weeks.

Reporting group title	Severe: Tofacitinib 10 mg/g BID

Reporting group description:

Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 10 mg/g, BID for 12 weeks.

Reporting group title	Severe: Placebo (vehicle) BID

Reporting group description:

Participants with a baseline PGA-C score of severe (4) applied placebo ointment (vehicle), BID for 12 weeks.

Reporting group title	Severe: Tofacitinib 20 mg/g QD

Reporting group description:

Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment, 20 mg/g, QD for 12 weeks.

Reporting group title	Severe: Tofacitinib 10 mg/g QD

Reporting group description:

Participants with a baseline PGA-C score of severe (4) applied tofacitinib ointment 10 mg/g, QD for 12 weeks.

Reporting group title	Severe: Placebo (vehicle) QD

Reporting group description:

Participants with a baseline PGA-C score of severe (4) applied placebo ointment (vehicle), QD for 12 weeks.

Serious adverse events	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Tofacitinib 20 mg/g BID	Mild/Moderate: Placebo (vehicle) BID
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 70 (7.14%)	0 / 71 (0.00%)	2 / 71 (2.82%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
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 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
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	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
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			
Osteoarthritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic arthropathy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
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			
Diabetes mellitus			

subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Tofacitinib 20 mg/g QD	Mild/Moderate: Placebo (vehicle) QD
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 74 (2.70%)	0 / 70 (0.00%)	1 / 74 (1.35%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
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			
Arrhythmia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (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
Atrial fibrillation			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
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 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
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			
Transient ischaemic attack			

subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
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 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
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 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
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			
Urinary tract infection			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (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
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
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	Severe: Tofacitinib 20 mg/g BID	Severe: Tofacitinib 10 mg/g BID	Severe: Placebo (vehicle) BID
Total subjects affected by serious			

adverse events			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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			
Arrhythmia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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			
Transient ischaemic attack			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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			
Osteoarthritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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			
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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			
Diabetes mellitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
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	Severe: Tofacitinib 20 mg/g QD	Severe: Tofacitinib 10 mg/g QD	Severe: Placebo (vehicle) QD
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Arrhythmia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Transient ischaemic attack			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Osteoarthritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
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			
Diabetes mellitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Mild/Moderate: Tofacitinib 10 mg/g BID	Mild/Moderate: Tofacitinib 20 mg/g BID	Mild/Moderate: Placebo (vehicle) BID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 70 (41.43%)	30 / 71 (42.25%)	27 / 71 (38.03%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Lipoma			

subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	1 / 70 (1.43%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	1	1	0
Hypotension			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Vasculitis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Application site pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Application site papules			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			

subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Application site pruritus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Vaginal haemorrhage			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Dry throat			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Respiratory tract congestion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Sneezing			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	1	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 70 (2.86%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	2	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	2 / 70 (2.86%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	2	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Blood triglycerides increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Eosinophil percentage increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accident at work			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			

subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Burns first degree			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Drug dispensing error			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Foot fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	1	0	1
Muscle strain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Post-traumatic neck syndrome			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	2	0	0
Scar			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1

Dysaesthesia			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	2 / 70 (2.86%)	0 / 71 (0.00%)	2 / 71 (2.82%)
occurrences (all)	2	0	2
Migraine			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	2 / 70 (2.86%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	2	0	0
Ear discomfort			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Vertigo			

subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Erythema of eyelid			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Chronic gastritis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Dental caries			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 70 (0.00%)	2 / 71 (2.82%)	1 / 71 (1.41%)
occurrences (all)	0	2	1
Dyspepsia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Food poisoning			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	1 / 70 (1.43%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	1	1	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Hiatus hernia			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Inguinal hernia			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	1 / 70 (1.43%)	2 / 71 (2.82%)	1 / 71 (1.41%)
occurrences (all)	2	2	2
Tongue ulceration			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	2
Abdominal tenderness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Dermal cyst			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Dermatitis contact			
subjects affected / exposed	1 / 70 (1.43%)	1 / 71 (1.41%)	2 / 71 (2.82%)
occurrences (all)	1	1	2
Dry skin			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0

Erythema			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	2
Hyperhidrosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Nail psoriasis			
subjects affected / exposed	1 / 70 (1.43%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	1	2	0
Onychoclasis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	1 / 71 (1.41%)
occurrences (all)	0	2	2
Psoriasis			
subjects affected / exposed	1 / 70 (1.43%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	1	1	0
Rash macular			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Skin burning sensation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Skin fissures			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			

subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Glycosuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Exostosis			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Joint range of motion decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Pain in extremity			

subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Intervertebral disc degeneration			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	1 / 70 (1.43%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	1	2	0
Chronic tonsillitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal viral infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Infected bites			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	2 / 70 (2.86%)	3 / 71 (4.23%)	1 / 71 (1.41%)
occurrences (all)	2	3	1
Oral candidiasis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Otitis externa			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	1 / 70 (1.43%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	1	1	0
Pharyngitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Pulpitis dental			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0

Rash pustular			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 70 (1.43%)	1 / 71 (1.41%)	2 / 71 (2.82%)
occurrences (all)	1	1	2
Tooth abscess			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 70 (0.00%)	2 / 71 (2.82%)	0 / 71 (0.00%)
occurrences (all)	0	3	0
Upper respiratory tract infection			
subjects affected / exposed	10 / 70 (14.29%)	2 / 71 (2.82%)	6 / 71 (8.45%)
occurrences (all)	11	2	7
Urinary tract infection			
subjects affected / exposed	2 / 70 (2.86%)	0 / 71 (0.00%)	6 / 71 (8.45%)
occurrences (all)	2	0	6
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Cystitis escherichia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0

Impetigo			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 70 (0.00%)	1 / 71 (1.41%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Hyperlipidaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 70 (1.43%)	0 / 71 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Mild/Moderate: Tofacitinib 10 mg/g QD	Mild/Moderate: Tofacitinib 20 mg/g QD	Mild/Moderate: Placebo (vehicle) QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 74 (37.84%)	34 / 70 (48.57%)	40 / 74 (54.05%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Lipoma			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application site pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	2 / 74 (2.70%)
occurrences (all)	0	0	2
Application site papules			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Asthenia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0

Influenza like illness			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 74 (1.35%)	1 / 70 (1.43%)	1 / 74 (1.35%)
occurrences (all)	1	1	1
Application site pruritus			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	1	0	1
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Catarrh			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0

Nasal congestion			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	1 / 74 (1.35%)
occurrences (all)	0	1	1
Oropharyngeal pain			
subjects affected / exposed	0 / 74 (0.00%)	2 / 70 (2.86%)	3 / 74 (4.05%)
occurrences (all)	0	3	3
Paranasal sinus discomfort			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Sinus congestion			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	1 / 74 (1.35%)
occurrences (all)	0	1	1
Cough			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Stress			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Blood cholesterol increased			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Eosinophil percentage increased			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	1 / 74 (1.35%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	1	1	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Vitamin B12 decreased			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			

Accident at work			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Burns first degree			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Drug dispensing error			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	2	0
Foot fracture			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Laceration			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	1 / 74 (1.35%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	1	1	0
Post-traumatic neck syndrome			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Scar			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 74 (4.05%)	3 / 70 (4.29%)	2 / 74 (2.70%)
occurrences (all)	3	3	2
Migraine			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Tension headache			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Leukocytosis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Pancytopenia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			

subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Erythema of eyelid			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Eyelid oedema			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Lacrimation increased			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 74 (1.35%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	1	1	0
Chronic gastritis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	1 / 74 (1.35%)	3 / 70 (4.29%)	0 / 74 (0.00%)
occurrences (all)	1	3	0
Dyspepsia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Food poisoning			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Gastritis			

subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Hiatus hernia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 74 (4.05%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	4	1	0
Tongue ulceration			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 74 (1.35%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	1	1	0
Abdominal tenderness			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0

Dry skin			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	2 / 74 (2.70%)
occurrences (all)	0	0	2
Erythema			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Intertrigo			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Nail psoriasis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Onychoclasis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	2 / 74 (2.70%)	2 / 70 (2.86%)	4 / 74 (5.41%)
occurrences (all)	3	2	4
Psoriasis			
subjects affected / exposed	6 / 74 (8.11%)	7 / 70 (10.00%)	6 / 74 (8.11%)
occurrences (all)	8	12	6
Rash macular			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Skin burning sensation			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	1 / 74 (1.35%)
occurrences (all)	0	1	1
Skin fissures			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	1 / 74 (1.35%)
occurrences (all)	0	2	1
Skin lesion			
subjects affected / exposed	2 / 74 (2.70%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	2	1	0

Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Nephrolithiasis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 74 (1.35%)	1 / 70 (1.43%)	3 / 74 (4.05%)
occurrences (all)	1	1	2
Glycosuria			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	1 / 74 (1.35%)
occurrences (all)	0	1	1
Exostosis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Joint stiffness			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0

Pain in extremity			
subjects affected / exposed	1 / 74 (1.35%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	1	1	0
Psoriatic arthropathy			
subjects affected / exposed	1 / 74 (1.35%)	1 / 70 (1.43%)	2 / 74 (2.70%)
occurrences (all)	1	1	2
Spinal osteoarthritis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 74 (1.35%)	1 / 70 (1.43%)	1 / 74 (1.35%)
occurrences (all)	1	1	1
Chronic tonsillitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			

subjects affected / exposed	0 / 74 (0.00%)	2 / 70 (2.86%)	1 / 74 (1.35%)
occurrences (all)	0	2	1
Gastrointestinal viral infection			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Gingivitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Infected bites			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 74 (1.35%)	2 / 70 (2.86%)	0 / 74 (0.00%)
occurrences (all)	1	2	0
Nasopharyngitis			
subjects affected / exposed	7 / 74 (9.46%)	5 / 70 (7.14%)	11 / 74 (14.86%)
occurrences (all)	7	6	13
Oral candidiasis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Paronychia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Pulpitis dental			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Pyelonephritis			

subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Rash pustular			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Sepsis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	1	0	1
Tooth abscess			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 74 (0.00%)	2 / 70 (2.86%)	1 / 74 (1.35%)
occurrences (all)	0	2	1
Urinary tract infection			
subjects affected / exposed	2 / 74 (2.70%)	1 / 70 (1.43%)	1 / 74 (1.35%)
occurrences (all)	2	1	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Cystitis escherichia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Erysipelas			

subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	2 / 74 (2.70%)
occurrences (all)	1	0	2
Hyperglycaemia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	2 / 74 (2.70%)	1 / 70 (1.43%)	0 / 74 (0.00%)
occurrences (all)	2	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	1	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 74 (0.00%)	0 / 70 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Severe: Tofacitinib 20 mg/g BID	Severe: Tofacitinib 10 mg/g BID	Severe: Placebo (vehicle) BID
Total subjects affected by non-serious adverse events			

subjects affected / exposed	2 / 7 (28.57%)	4 / 7 (57.14%)	4 / 7 (57.14%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application site pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Application site papules			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Fatigue			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Application site pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Stress			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eosinophil percentage increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Accident at work			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Burns first degree			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Drug dispensing error			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Post-traumatic neck syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scar			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Dysaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Erythema of eyelid			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chronic gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tongue ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail psoriasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Psoriasis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rash macular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin burning sensation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glycosuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Exostosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Chronic tonsillitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infected bites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Cystitis escherichia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Erysipelas			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hyperlipidaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Severe: Tofacitinib 20 mg/g QD	Severe: Tofacitinib 10 mg/g QD	Severe: Placebo (vehicle) QD
Total subjects affected by non-serious adverse events			

subjects affected / exposed	3 / 7 (42.86%)	2 / 6 (33.33%)	2 / 7 (28.57%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application site pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Application site papules			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Application site pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eosinophil percentage increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Liver function test abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Accident at work			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Burns first degree			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Drug dispensing error			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post-traumatic neck syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scar			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Erythema of eyelid			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chronic gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail psoriasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	4	0	2
Rash macular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin burning sensation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glycosuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Exostosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chronic tonsillitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infected bites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cystitis escherichia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erysipelas			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperlipidaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 December 2013	Added Text for clarity in Sections: Protocol Summary, Schedule of Activities, Section 1.1.4, Section 3, Section 4, Section 5.2, Section 6, Section 7.1, Section 7.3.1, Section 7.4, Section 7.5, Section 7.7, Section 7.8, Section 8.2, Section 8.3, Section 8.5, Section 8.9, Section 8.10, Section 8.12.3, Section 9.5, Section 9.7, Section 9.9, Section 12.2, Section 12.3, Appendix 2.1, Appendix 4, Appendix 5.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Efficacy results for participants in the severe population were not reported since this was considered an exploratory population.

Notes: