Clinical trial results:
A Phase 3, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Safety and Efficacy of Baricitinib in Combination with Topical Corticosteroids in Adult Patients with Moderate-to-Severe Atopic Dermatitis Who Have Experienced Failure to Cyclosporine or Are Intolerant to, or Have Contraindication to, Cyclosporine

Summary

EudraCT number	2017-004574-34
Trial protocol	GB NL FR AT BE PL FI ES IT
Global end of trial date	20 April 2023
Results information	
Result version number	v2 (current)
This version publication date	05 May 2024
First version publication date	13 December 2020
Version creation reason	• New data added to full data set New data added to full data set

Trial information

Trial identification	
Sponsor protocol code	I4V-MC-JAIN
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01624259
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16841

Notes:

Sponsors	
Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559,

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	19 September 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 September 2019
Global end of trial reached?	Yes
Global end of trial date	20 April 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to determine the efficacy and safety of baricitinib in combination with topical corticosteroids in participants with moderate to severe atopic dermatitis who have experienced failure to cyclosporine or are intolerant to, or have contraindication to cyclosporine.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 May 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 10
Country: Number of subjects enrolled	Netherlands: 16
Country: Number of subjects enrolled	Belgium: 26
Country: Number of subjects enrolled	Finland: 7
Country: Number of subjects enrolled	Poland: 41
Country: Number of subjects enrolled	Brazil: 48
Country: Number of subjects enrolled	Italy: 37
Country: Number of subjects enrolled	France: 39
Country: Number of subjects enrolled	Germany: 88
Country: Number of subjects enrolled	Japan: 79
Country: Number of subjects enrolled	Russian Federation: 14
Country: Number of subjects enrolled	Spain: 35
Country: Number of subjects enrolled	United Kingdom: 19
Country: Number of subjects enrolled	Switzerland: 4
Worldwide total number of subjects	463
EEA total number of subjects	318

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)	448
From 65 to 84 years	14
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

At Week 52: responders (IGA 0 or 1) and partial responders (PR) (IGA 2) randomized to Baricitinib (Bari) 4mg or 2mg, without use of high potency TCS in the previous 14 days, were enrolled into the substudy.

Pre-assignment

Screening details:

Responders (IGA 0 or 1) and PR (IGA 2) who received Bari 4mg, 2mg, 1mg or PBO and not eligible for the substudy remained on their dose. If worsening of the symptoms occurred (IGA ≥3), those receiving PBO, Bari 2mg or 1mg were rerandomized to Bari 4mg or 2mg. Nonresponders (IGA ≥ 3) in the PBO, Bari 2mg or 1mg were rerandomized to Bari 4mg or 2mg.

Period 1

Period 1 title	Double-Blind Treatment Week 0 to Week 52
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo administered orally once daily in combination with topical corticosteroids.

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

Dosage and administration details:

Placebo administered orally once daily.

Arm title	1 mg Baricitinib

Arm description:

1 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg Baricitinib administered orally once daily.

Arm title	2 mg Baricitinib

Arm description:

2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 mg Baricitinib administered orally once daily.

Arm title	4 mg Baricitinib

Arm description:

4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Placebo
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 mg Baricitinib administered orally once daily.

Number of subjects in period 1	Placebo	1 mg Baricitinib	2 mg Baricitinib
Started	93	93	185
Received at Least One Dose of Study Drug	93	93	184
Completed	72	80	173
Not completed	21	13	12
Consent withdrawn by subject	4	-	-
Physician decision	-	1	-
Adverse event, non-fatal	1	-	3
Lack of efficacy	16	10	7
Protocol deviation	-	2	2

Number of subjects in period 1	4 mg Baricitinib
Started	92
Received at Least One Dose of Study Drug	92
Completed	85
Not completed	7
Consent withdrawn by subject	-
Physician decision	-
Adverse event, non-fatal	1
Lack of efficacy	6
Protocol deviation	-

Period 2

Period 2 title	Long-Term Extension Week 52 to Week 200
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	LTE Substudy 4 mg Baricitinib to 4 mg Baricitinib

Arm description:

LTE Substudy 4 mg Baricitinib to 4 mg Baricitinib (Responders/Partial Responders)
4 mg Baricitinib administered orally once daily (continued previous dose) in combination with topical corticosteroids (TCS). Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib

Arm description:

LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib (Responders/Partial Responders)
4 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	2 mg Baricitinb
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib

Arm description:

LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib (Responders/Partial Responders)
2 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	2 mg Baricitinb
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with

topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib

Arm description:

LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib (Responders/Partial Responders)
2 mg Baricitinib rerandomized to 1 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 mg Baricitinib rerandomized to 1 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE 4 mg Baricitinib (Responders/Partial Responders)

Arm description:

LTE 4 mg Baricitinib (Responders/Partial Responders) - Did Not Enter Substudy.
4 mg Baricitinib administered orally once daily (continued previous dose) in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE 2 mg Baricitinib (Responders/Partial Responders)

Arm description:

LTE 2 mg Baricitinib (Responders/Partial Responders) - Did Not Enter Substudy
2 mg Baricitinib administered orally once daily (continued previous dose) in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	2 mg Baricitinb
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE 1 mg Baricitinib (Responders/Partial Responders)

Arm description:

LTE 1 mg Baricitinib (Responders/Partial Responders) - Did Not Enter Substudy
Placebo administered orally once daily (continued previous dose) in combination with topical corticosteroids. Additional placebo administered orally to maintain the blind.

Arm type	Experimental

Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE Placebo (Responders/Partial Responders)

Arm description:

LTE Placebo (Responders/Partial Responders) - Did Not Enter Substudy
Placebo administered orally once daily in combination with topical corticosteroids. Additional placebo administered orally to maintain the blind.

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

Dosage and administration details:

Placebo administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE 4 mg Baricitinib (Non-Responders)

Arm description:

LTE 4 mg Baricitinib (Non-Responders) - Did not Enter Substudy
4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE 2 mg Baricitinib to 2 mg Baricitinib (Non-Responders)

Arm description:

LTE 2 mg Baricitinib to 2 mg Baricitinib (Non-Responders) - Did Not Enter Substudy
2 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	2 mg Baricitinb
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE 2 mg Baricitinib to 4 mg Baricitinib (Non-responders)

Arm description:

LTE 2 mg Baricitinib to 4 mg Baricitinib (Non-responders) - Did Not Enter Substudy
2 mg Baricitinib rerandomized to 4 mg Baricitinib administered orally once daily in combination with

topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	2 mg Baricitinb
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE 1 mg Baricitinib to 2 mg Baricitinib (Non-responders)

Arm description:

LTE 1 mg Baricitinib to 2 mg Baricitinib (Non-responders) - Did Not Enter Substudy
1 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE 1 mg Baricitinib to 4 mg Baricitinib (Non-responders)

Arm description:

LTE 1 mg Baricitinib to 4 mg Baricitinib (Non-responders) - Did Not Enter Study
1 mg Baricitinib rerandomized to 4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE Placebo to 2 mg Baricitinib (Non-responders)

Arm description:

LTE Placebo to 2 mg Baricitinib (Non-responders) - Did Not Enter Substudy
Placebo rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	LY3009104
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Arm title	LTE Placebo to 4 mg Baricitinib (Non-responders)

Arm description:

LTE Placebo to 4 mg Baricitinib (Non-responders) - Did Not Enter Substudy
Placebo rerandomized to 4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

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

Dosage and administration details:

Placebo administered orally once daily.

Number of subjects in period 2[1]	LTE Substudy 4 mg Baricitinib to 4 mg Baricitinib	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib
Started	16	16	25
Completed	2	6	5
Not completed	14	10	20
Not	-	-	2
Physician decision	-	-	1
Adverse event, non-fatal	-	4	1
Death	-	-	-
Not specified	-	-	-
Study terminated by sponsor	10	4	8
Lost to follow-up	-	-	-
Lack of efficacy	2	2	3
Withdrawal by subject	2	-	5

Number of subjects in period 2[1]	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib	LTE 4 mg Baricitinib (Responders/Partial Responders)	LTE 2 mg Baricitinib (Responders/Partial Responders)
Started	24	7	22
Completed	6	3	5
Not completed	18	4	17
Not	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	2	1	-
Death	1	-	-
Not specified	-	-	-
Study terminated by sponsor	8	3	7
Lost to follow-up	1	-	-
Lack of efficacy	4	-	4
Withdrawal by subject	2	-	6

Number of subjects in period 2[1]	LTE 1 mg Baricitinib (Responders/Partial Responders)	LTE Placebo (Responders/Partial Responders)	LTE 4 mg Baricitinib (Non-Responders)
Started	34	29	24
Completed	5	10	1
Not completed	29	19	23
Not	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	1	-	3
Death	-	-	-
Not specified	-	1	-
Study terminated by sponsor	11	11	8
Lost to follow-up	-	2	1
Lack of efficacy	4	-	9
Withdrawal by subject	13	5	2

Number of subjects in period 2[1]	LTE 2 mg Baricitinib to 2 mg Baricitinib (Non-Responders)	LTE 2 mg Baricitinib to 4 mg Baricitinib (Non-responders)	LTE 1 mg Baricitinib to 2 mg Baricitinib (Non-responders)
Started	27	26	13
Completed	6	4	4
Not completed	21	22	9
Not	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	1	1	1
Death	-	-	-
Not specified	-	-	-
Study terminated by sponsor	6	12	5
Lost to follow-up	-	2	-
Lack of efficacy	9	6	3
Withdrawal by subject	5	1	-

Number of subjects in period 2[1]	LTE 1 mg Baricitinib to 4 mg Baricitinib (Non-responders)	LTE Placebo to 2 mg Baricitinib (Non-responders)	LTE Placebo to 4 mg Baricitinib (Non-responders)
Started	14	11	12
Completed	1	1	2
Not completed	13	10	10
Not	-	-	-
Physician decision	-	-	1
Adverse event, non-fatal	2	-	-
Death	-	-	-
Not specified	-	2	1
Study terminated by sponsor	3	1	7
Lost to follow-up	-	1	-

Lack of efficacy	4	4	1
Withdrawal by subject	4	2	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Participants who completed the study through Week 52 progressed into the double-blind long-term extension phase.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo administered orally once daily in combination with topical corticosteroids.	
Reporting group title	1 mg Baricitinib
Reporting group description:	
1 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.	

Reporting group title	2 mg Baricitinib
Reporting group description:	
2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.	
Reporting group title	4 mg Baricitinib
Reporting group description:	
4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.	

Reporting group values	Placebo	1 mg Baricitinib	2 mg Baricitinib
Number of subjects	93	93	185
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	38.7	38.9	37.3
standard deviation	± 13.6	± 14.0	± 13.6
Gender categorical Units: Subjects			
Female	44	35	52
Male	49	58	133
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	11	13	26
Not Hispanic or Latino	54	62	101
Unknown or Not Reported	28	18	58
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	16	19	36
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	3	2
White	74	70	145
More than one race	0	1	2
Unknown or Not Reported	0	0	0
Region of Enrollment			

Units: Subjects			
Austria	1	3	2
Netherlands	3	0	9
Belgium	3	5	12
Finland	2	2	2
Poland	10	9	15
Brazil	8	10	20
Italy	11	9	13
France	9	6	16
Germany	15	18	37
Japan	15	16	32
Russia	5	2	5
Spain	7	7	15
United Kingdom	4	5	6
Switzerland	0	1	1

Reporting group values	4 mg Baricitinib	Total	
Number of subjects	92	463	
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	38.7		
standard deviation	± 13.3	-	
Gender categorical Units: Subjects			
Female	35	166	
Male	57	297	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	14	64	
Not Hispanic or Latino	55	272	
Unknown or Not Reported	23	127	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	18	89	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	3	11	
White	71	360	
More than one race	0	3	
Unknown or Not Reported	0	0	
Region of Enrollment Units: Subjects			
Austria	4	10	
Netherlands	4	16	
Belgium	6	26	
Finland	1	7	
Poland	7	41	

Brazil	10	48	
Italy	4	37	
France	8	39	
Germany	18	88	
Japan	16	79	
Russia	2	14	
Spain	6	35	
United Kingdom	4	19	
Switzerland	2	4	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Placebo administered orally once daily in combination with topical corticosteroids.	

Reporting group title	1 mg Baricitinib
Reporting group description:	
1 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.	

Reporting group title	2 mg Baricitinib
Reporting group description:	
2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.	

Reporting group title	4 mg Baricitinib
Reporting group description:	
4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.	

Reporting group title	LTE Substudy 4 mg Baricitinib to 4 mg Baricitinib
Reporting group description:	
LTE Substudy 4 mg Baricitinib to 4 mg Baricitinib (Responders/Partial Responders) 4 mg Baricitinib administered orally once daily (continued previous dose) in combination with topical corticosteroids (TCS). Placebo administered orally to maintain the blind.	

Reporting group title	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib
Reporting group description:	
LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib (Responders/Partial Responders) 4 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.	

Reporting group title	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib
Reporting group description:	
LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib (Responders/Partial Responders) 2 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.	

Reporting group title	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib
Reporting group description:	
LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib (Responders/Partial Responders) 2 mg Baricitinib rerandomized to 1 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.	

Reporting group title	LTE 4 mg Baricitinib (Responders/Partial Responders)
Reporting group description:	
LTE 4 mg Baricitinib (Responders/Partial Responders) - Did Not Enter Substudy. 4 mg Baricitinib administered orally once daily (continued previous dose) in combination with topical corticosteroids. Placebo administered orally to maintain the blind.	

Reporting group title	LTE 2 mg Baricitinib (Responders/Partial Responders)
Reporting group description:	
LTE 2 mg Baricitinib (Responders/Partial Responders) - Did Not Enter Substudy 2 mg Baricitinib administered orally once daily (continued previous dose) in combination with topical corticosteroids. Placebo administered orally to maintain the blind.	

Reporting group title	LTE 1 mg Baricitinib (Responders/Partial Responders)
Reporting group description:	
LTE 1 mg Baricitinib (Responders/Partial Responders) - Did Not Enter Substudy Placebo administered orally once daily (continued previous dose) in combination with topical corticosteroids. Additional placebo administered orally to maintain the blind.	

Reporting group title	LTE Placebo (Responders/Partial Responders)

Reporting group description:

LTE Placebo (Responders/Partial Responders) - Did Not Enter Substudy
Placebo administered orally once daily in combination with topical corticosteroids. Additional placebo administered orally to maintain the blind.

Reporting group title	LTE 4 mg Baricitinib (Non-Responders)

Reporting group description:

LTE 4 mg Baricitinib (Non-Responders) - Did not Enter Substudy
4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE 2 mg Baricitinib to 2 mg Baricitinib (Non-Responders)

Reporting group description:

LTE 2 mg Baricitinib to 2 mg Baricitinib (Non-Responders) - Did Not Enter Substudy
2 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE 2 mg Baricitinib to 4 mg Baricitinib (Non-responders)

Reporting group description:

LTE 2 mg Baricitinib to 4 mg Baricitinib (Non-responders) - Did Not Enter Substudy
2 mg Baricitinib rerandomized to 4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE 1 mg Baricitinib to 2 mg Baricitinib (Non-responders)

Reporting group description:

LTE 1 mg Baricitinib to 2 mg Baricitinib (Non-responders) - Did Not Enter Substudy
1 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE 1 mg Baricitinib to 4 mg Baricitinib (Non-responders)

Reporting group description:

LTE 1 mg Baricitinib to 4 mg Baricitinib (Non-responders) - Did Not Enter Study
1 mg Baricitinib rerandomized to 4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE Placebo to 2 mg Baricitinib (Non-responders)

Reporting group description:

LTE Placebo to 2 mg Baricitinib (Non-responders) - Did Not Enter Substudy
Placebo rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE Placebo to 4 mg Baricitinib (Non-responders)

Reporting group description:

LTE Placebo to 4 mg Baricitinib (Non-responders) - Did Not Enter Substudy
Placebo rerandomized to 4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Subject analysis set title	4 mg Bari to 4 mg Bari LTE Substudy with IGA 0, 1 at Week 52
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who received at least one study medication during Week 52 to Week 200 in Study JAIN and entered the downtitration substudy with IGA 0 or 1 at Week 52

Subject analysis set title	4 mg Bari to 2 mg Bari LTE Substudy with IGA 0, 1 at Week 52
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Substudy population with IGA 0, 1 at Week 52

Subject analysis set title	2 mg Bari to 2 mg Bari LTE Substudy with IGA 0, 1 at Week 52
Subject analysis set type	Sub-group analysis

Subject analysis set description:

LTE Substudy with IGA 0, 1 at Week 52

Subject analysis set title	2 mg Bari to 1 mg Bari LTE Substudy with IGA 0, 1 at Week 52
Subject analysis set type	Sub-group analysis

Subject analysis set description:

LTE Substudy with IGA 0, 1 at Week 52

Subject analysis set title	4-mg Bari to 4-mg Bari to 4-mg Bari

Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who entered the Substudy and relapsed with an IGA ≥3.
Participants randomized to 4 mg Baricitinib in the downtitration substudy who experienced worsening symptoms (IGA increased to ≥3), were retreated with their presubstudy Baricitinib dose.

Subject analysis set title	4 mg Bari to 2 mg Bari to 4 mg Bari
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who entered the Substudy and relapsed with an IGA ≥3.
Participants randomized to 4 mg Baricitinib in the downtitration substudy who experienced worsening symptoms (IGA increased to ≥3), were retreated with their presubstudy Baricitinib dose.

Subject analysis set title	2 mg Bari to 2 mg Bari to 2 mg Bari
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who entered the Substudy and relapsed with an IGA ≥3.
Participants randomized to 2 mg Baricitinib in the downtitration substudy who experienced worsening symptoms (IGA increased to ≥3), were retreated with their presubstudy Baricitinib dose.

Subject analysis set title	2 mg Bari to 1 mg Bari to 2 mg Bari
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who entered the Substudy and relapsed with an IGA ≥3.
Participants randomized to 2 mg Baricitinib in the downtitration substudy who experienced worsening symptoms (IGA increased to ≥3), were retreated with their presubstudy Baricitinib dose.

Primary: Percentage of Participants Achieving Eczema Area and Severity Index 75 (EASI75) (Placebo, 2 mg or 4 mg Baricitinib)

End point title	Percentage of Participants Achieving Eczema Area and Severity Index 75 (EASI75) (Placebo, 2 mg or 4 mg Baricitinib)[1]

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

Analysis Population Description (APD): All participants randomized to placebo, 2 mg or 4 mg of study drug.

End point type	Primary

End point timeframe:

Week 16

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: Per protocol, results reported on Placebo, 2 mg and 4 mg Baricitinib.

End point values	Placebo	2 mg Baricitinib	4 mg Baricitinib	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	93	185	92	
Units: percentage of participants				
number (confidence interval 95%)	17.2 (10.9 to 26.1)	27.6 (21.6 to 34.4)	31.5 (22.9 to 41.6)	

Statistical analyses

Statistical analysis title	EASI75 - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.071
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	3.32

Statistical analysis title	EASI75 - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.031
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	4.3

Secondary: Percentage of Participants Achieving EASI75 (Placebo, 1 mg Baricitinib)	
End point title	Percentage of Participants Achieving EASI75 (Placebo, 1 mg Baricitinib)[2]

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will

range from 0 (no disease) to 72 (severe disease). Missing values were imputed using Non-Responder Imputation (NRI), where non-responders were participants who permanently discontinue, are rescued, or are without at least 1 post-baseline observation.

APD: All participants randomized to placebo or 1 mg of study drug.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, results reported on Placebo and 1 mg Baricitinib.

End point values	Placebo	1 mg Baricitinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	93		
Units: percentage of participants				
number (confidence interval 95%)	17.2 (10.9 to 26.1)	22.6 (15.3 to 32.1)		

Statistical analyses

Statistical analysis title	EASI75 - 1 mg
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.427
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	2.77

Secondary: Percentage of Participants Achieving IGA of 0 or 1 with a ≥ 2 Point Improvement

End point title	Percentage of Participants Achieving IGA of 0 or 1 with a ≥ 2 Point Improvement

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.

APD: All randomized participants.

End point type	Secondary

End point timeframe:
Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	93	185	92
Units: percentage of participants				
number (confidence interval 95%)	9.7 (5.2 to 17.4)	12.9 (7.5 to 21.2)	15.1 (10.7 to 21.0)	21.7 (14.5 to 31.2)

Statistical analyses

Statistical analysis title	IGA of 0 or 1 - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.513
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	3.35

Statistical analysis title	IGA of 0 or 1 - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.242
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	3.53

Statistical analysis title	IGA of 0 or 1 - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.03
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.09
upper limit	5.9

Secondary: Percentage of Participants Achieving EASI90

End point title	Percentage of Participants Achieving EASI90

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI90 is defined as a ≥ 90% improvement from baseline in the EASI score.

APD: All randomized participants.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	93	185	92
Units: percentage of participants				
number (confidence interval 95%)	6.5 (3.0 to 13.4)	8.6 (4.4 to 16.1)	10.3 (6.7 to 15.5)	14.1 (8.4 to 22.7)

Statistical analyses

Statistical analysis title	EASI90 - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.611
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	3.83

Statistical analysis title	EASI90 - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.325
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	3.99

Statistical analysis title	EASI90 - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	6.14

Secondary: Percent Change from Baseline in EASI Score

End point title	Percent Change from Baseline in EASI Score

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease).
Least Squares Mean (LSM) were calculated using mixed model repeated measures (MMRM) model with treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interaction as fixed categorical effects and baseline score and baseline score-by-visit-interaction as fixed continuous effects.

End point type	Secondary

End point timeframe:

Baseline, Week 16

APD: All randomized participants with Week 16 EASI data.

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54	61	144	65
Units: percent change				
least squares mean (standard error)	-42.69 (± 4.135)	-60.34 (± 4.018)	-56.05 (± 2.755)	-63.31 (± 3.922)

Statistical analyses

Statistical analysis title	PCFB EASI - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-17.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.71
upper limit	-6.58
Variability estimate	Standard error of the mean
Dispersion value	5.627

Statistical analysis title	PCFB EASI - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-13.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.83
upper limit	-3.87
Variability estimate	Standard error of the mean
Dispersion value	4.82

Statistical analysis title	PCFB EASI - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-20.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.54
upper limit	-9.7
Variability estimate	Standard error of the mean
Dispersion value	5.554

Secondary: Percentage of Participants Achieving SCORing Atopic Dermatitis 75 (SCORAD75)

End point title	Percentage of Participants Achieving SCORing Atopic Dermatitis 75 (SCORAD75)

End point description:

The SCORAD index uses the rule of nines to assess disease extent and evaluates 6 clinical characteristics to determine disease severity: (1) erythema, (2) edema/papulation, (3)oozing/crusts, (4) excoriation, (5) lichenification, and (6) dryness on a scale of 0 to 3 (0=absence, 1=mild, 2=moderate, 3=severe). The SCORAD index also assesses subjective symptoms of pruritus and sleep loss with a visual analogue scales (VAS) where 0 is no itching or no trouble sleeping and 10 is unbearable itching or a lot of trouble sleeping. These 3 aspects: extent of disease (A: 0-1-2), disease severity (B: 0-18), &

subjective symptoms (C: 0-20) combine using A/5 + 7*B/2+ C to give a maximum possible score of 103, where 0 = no disease and 103 = severe disease.
The SCORAD75 responder is defined as a participant who achieves a ≥ 75% improvement from baseline in the SCORAD score.

APD: All randomized participants.

End point type	Secondary
End point timeframe:	
Week 16	

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	93	185	92
Units: percentage of participants				
number (confidence interval 95%)	1.1 (0.2 to 5.8)	6.5 (3.0 to 13.4)	8.1 (5.0 to 12.9)	6.5 (3.0 to 13.5)

Statistical analyses

Statistical analysis title	SCORAD75 - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.115
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	24.29

Statistical analysis title	SCORAD75 - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.037
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.85

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	30.88

Statistical analysis title	SCORAD75 - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.083
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	28.08

Secondary: Percentage of Participants Achieving a 4-Point Improvement in Itch Numeric Rating Scale (NRS)

End point title	Percentage of Participants Achieving a 4-Point Improvement in Itch Numeric Rating Scale (NRS)

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable." Overall severity of a participant's itching is indicated by selecting the number, using a daily diary, that best describes the worst level of itching in the past 24 hours.

All randomized participants with a baseline Itch NRS score >=4.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	85	78	166	76
Units: percentage of participants				
number (confidence interval 95%)	8.2 (4.0 to 16.0)	23.1 (15.1 to 33.6)	22.9 (17.2 to 29.9)	38.2 (28.1 to 49.4)

Statistical analyses

Statistical analysis title	NRS - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.29
upper limit	8.32

Statistical analysis title	NRS - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.59
upper limit	8.66

Statistical analysis title	NRS - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib

Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.00002
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	6.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.79
upper limit	16.82

Secondary: Change from Baseline in the Score of Item 2 of the Atopic Dermatitis Sleep Scale (ADSS)

End point title	Change from Baseline in the Score of Item 2 of the Atopic Dermatitis Sleep Scale (ADSS)

End point description:

The ADSS is a 3-item, participant-administered questionnaire developed to assess the impact of itch on sleep including difficulty falling asleep due to itch, frequency of waking due to itch, and difficulty getting back to sleep last night due to itch. Item 2 frequency of waking last night is reported by selecting the number of times they woke up each night, ranging from 0 to 29 times, where the higher a number indicates a worse outcome. The ADSS is designed to be completed daily, using a daily diary, with respondents thinking about sleep "last night." Each item is scored individually.
LS Mean were calculated using an MMRM model with treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interaction as fixed categorical and baseline and baseline-by-visit-interaction as fixed continuous effects.

All randomized participants with Week 16 ADSS Item 2 (frequency of waking) data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	62	135	66
Units: units on a scale				
least squares mean (standard error)	-0.63 (± 0.149)	-1.05 (± 0.142)	-0.85 (± 0.099)	-1.42 (± 0.140)

Statistical analyses

Statistical analysis title	Change from Baseline (CFB) ADSS - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib

Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.82
upper limit	-0.02
Variability estimate	Standard error of the mean
Dispersion value	0.203

Statistical analysis title	CFB ADSS - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	188
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.23
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.56
upper limit	0.13
Variability estimate	Standard error of the mean
Dispersion value	0.175

Statistical analysis title	CFB ADSS - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.18
upper limit	-0.39

Variability estimate	Standard error of the mean
Dispersion value	0.201

Secondary: Change from Baseline in Skin Pain NRS

End point title	Change from Baseline in Skin Pain NRS

End point description:

Skin Pain NRS is a participant-administered,11-point horizontal scale anchored at 0 and 10, with 0 representing "no pain" and 10 representing "worst pain imaginable." Overall severity of a participant's skin pain is indicated by selecting the number, using a daily diary, that best describes the worst level of skin pain in the past 24 hours.

LS Mean were calculated using MMRM model includes treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interaction as fixed categorical effects and baseline and baseline-by-visit-interaction as fixed continuous effects.

APD: All randomized participants with Week 16 Skin Pain NRS data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	62	135	66
Units: units on a scale				
least squares mean (standard error)	-1.56 (± 0.284)	-2.27 (± 0.274)	-2.40 (± 0.193)	-3.02 (± 0.271)

Statistical analyses

Statistical analysis title	CFB Skin Pain NRS - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0714
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.47
upper limit	0.06
Variability estimate	Standard error of the mean
Dispersion value	0.388

Statistical analysis title	CFB Skin Pain NRS - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	188
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0134
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	-0.17
Variability estimate	Standard error of the mean
Dispersion value	0.337

Statistical analysis title	CFB Skin Pain NRS - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.21
upper limit	-0.69
Variability estimate	Standard error of the mean
Dispersion value	0.386

Secondary: Percentage of Participants Achieving IGA of 0 or 1 with a >=2-point improvement

End point title	Percentage of Participants Achieving IGA of 0 or 1 with a >=2-point improvement

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.

APD: All randomized participants.

End point type	Secondary
End point timeframe: 24 Weeks	

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	93	185	92
Units: percentage of participants				
number (confidence interval 95%)	12.9 (7.5 to 21.2)	20.4 (13.5 to 29.7)	18.9 (13.9 to 25.2)	13.0 (7.6 to 21.4)

Statistical analyses

Statistical analysis title	IGA of 0 or 1 - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.183
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	3.75

Statistical analysis title	IGA of 0 or 1 - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.235
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	3.11

Statistical analysis title	IGA of 0 or 1 - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.991
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	2.36

Secondary: Percentage of Participants Achieving EASI50

End point title	Percentage of Participants Achieving EASI50

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI50 is defined as a ≥ 50% improvement from baseline in the EASI score.

APD: All randomized participants.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	93	185	92
Units: percentage of participants				
number (confidence interval 95%)	35.5 (26.5 to 45.6)	45.2 (35.4 to 55.3)	51.4 (44.2 to 58.5)	52.2 (42.1 to 62.1)

Statistical analyses

Statistical analysis title	EASI50 - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.263
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	2.57

Statistical analysis title	EASI50 - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.016
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	3.19

Statistical analysis title	EASI50 - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.031
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.06
upper limit	3.52

Secondary: Percentage of Participants Achieving EASI75

End point title	Percentage of Participants Achieving EASI75

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: All randomized participants.

End point type	Secondary

End point timeframe:

Week 24

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	93	185	92
Units: percentage of participants				
number (confidence interval 95%)	17.2 (10.9 to 26.1)	30.1 (21.7 to 40.1)	27.6 (21.6 to 34.4)	25.0 (17.3 to 34.7)

Statistical analyses

Statistical analysis title	EASI75 - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.058
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	3.96

Statistical analysis title	EASI75 - 2 mg Baricitinib

Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.072
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	3.32

Statistical analysis title	EASI75 - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.224
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	3.18

Secondary: Percentage of Participants Achieving IGA of 0

End point title	Percentage of Participants Achieving IGA of 0

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.

APD: All randomized participants.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	93	185	92
Units: percentage of participants				
number (confidence interval 95%)	0.00 (0.0 to 4.0)	2.2 (0.6 to 7.5)	1.1 (0.3 to 3.9)	3.3 (1.1 to 9.2)

Statistical analyses

Statistical analysis title	IGA of 0 - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.265
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	86.08

Statistical analysis title	IGA of 0 - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.52
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	43.09

Statistical analysis title	IGA of 0 - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib

Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.164
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	7.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	99.99

Secondary: Change from Baseline in SCORAD

End point title	Change from Baseline in SCORAD

End point description:

The SCORAD index uses the rule of nines to assess disease extent and evaluates 6 clinical characteristics to determine disease severity: (1) erythema, (2) edema/papulation, (3) oozing/crusts, (4) excoriation, (5) lichenification, and (6) dryness on a scale of 0 to 3 (0=absence, 1=mild, 2=moderate, 3=severe). The SCORAD index also assesses subjective symptoms of pruritus and sleep loss with VAS where 0 is no itching or no trouble sleeping and 10 is unbearable itching or a lot of trouble sleeping. These 3 aspects: extent of disease (A: 0-1-2), disease severity (B: 0-18), & subjective symptoms (C: 0-20) combine using A/5 + 7*B/2+ C to give a maximum possible score of 103, where 0 = no disease and 103 = severe disease.
LS Mean were calculated using MMRM model with treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interaction as fixed categorical effects and baseline and baseline-by-visit-interaction as fixed continuous effects.

End point type	Secondary

End point timeframe:

Baseline, Week 16

APD: All randomized participants with Week 16 SCORAD data.

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54	60	142	64
Units: units on a scale				
least squares mean (standard error)	-21.98 (± 2.171)	-28.06 (± 2.097)	-28.54 (± 1.438)	-31.74 (± 2.052)

Statistical analyses

Statistical analysis title	CFB SCORAD - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib

Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.04
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-6.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.88
upper limit	-0.29
Variability estimate	Standard error of the mean
Dispersion value	2.948

Statistical analysis title	CFB SCORAD - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-6.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.54
upper limit	-1.58
Variability estimate	Standard error of the mean
Dispersion value	2.533

Statistical analysis title	CFB SCORAD - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-9.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.51
upper limit	-4.03

Variability estimate	Standard error of the mean
Dispersion value	2.919

Secondary: Percentage of Participants Achieving SCORAD90

End point title	Percentage of Participants Achieving SCORAD90

End point description:

The SCORAD index uses the rule of nines to assess disease extent and evaluates 6 clinical characteristics to determine disease severity: (1) erythema, (2) edema/papulation, (3)oozing/crusts, (4) excoriation, (5) lichenification, and (6) dryness on a scale of 0 to 3 (0=absence, 1=mild, 2=moderate, 3=severe). The SCORAD index also assesses subjective symptoms of pruritus and sleep loss with a visual analogue scales (VAS) where 0 is no itching or no trouble sleeping and 10 is unbearable itching or a lot of trouble sleeping. These 3 aspects: extent of disease (A: 0-1-2), disease severity (B: 0-18), & subjective symptoms (C: 0-20) combine using A/5 + 7*B/2+ C to give a maximum possible score of 103, where 0 = no disease and 103 = severe disease. The SCORAD90 responder is defined as a participant who achieves a ≥ 90% improvement from baseline in the SCORAD score.

APD: All randomized participants.

End point type	Secondary

End point timeframe:

Week 16

APD: All randomized participants.

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	93	185	92
Units: percentage of participants				
number (confidence interval 95%)	0.00 (0.0 to 4.0)	2.2 (0.6 to 7.5)	1.1 (0.3 to 3.9)	2.2 (0.6 to 7.6)

Statistical analyses

Statistical analysis title	SCORAD90 - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.265
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	73.93

Statistical analysis title	SCORAD90 - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.511
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	38.4

Statistical analysis title	SCORAD90 - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.253
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	77.11

Secondary: Change from Baseline in Body Surface Area (BSA) Affected

End point title	Change from Baseline in Body Surface Area (BSA) Affected

End point description:

The BSA affected by AD will be assessed for 4 separate body regions and is collected as part of the EASI assessment: head and neck, trunk (including genital region), upper extremities, and lower extremities (including the buttocks). Each body region will be assessed for disease extent ranging from 0% to 100% involvement. The overall total percentage will be reported based off of all 4 body regions combined, after applying specific multipliers to the different body regions to account for the percent of the total BSA represented by each of the 4 regions. Use the percentage of skin affected for each region (0 to 100%) in EASI as follows: BSA Total = 0.1*BSAhead and neck + 0.3*BSAtrunk + 0.2* BSAupper limbs + 0.4*BSAlower limbs.
LS Mean were calculated using MMRM model with treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interaction as fixed categorical effects and baseline-by-visit-interaction as fixed continuous effects.

End point type	Secondary

End point timeframe:
Baseline, Week 16

APD: All randomized participants with Week 16 BSA data.

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54	61	144	65
Units: units on a scale				
least squares mean (standard error)	-19.76 (± 2.257)	-25.98 (± 2.178)	-25.26 (± 1.488)	-28.17 (± 2.125)

Statistical analyses

Statistical analysis title	CFB BSA - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.044
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-6.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.26
upper limit	-0.16
Variability estimate	Standard error of the mean
Dispersion value	3.078

Statistical analysis title	CFB BSA - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	198
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.037
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-5.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.67
upper limit	-0.32
Variability estimate	Standard error of the mean
Dispersion value	2.632

Statistical analysis title	CFB BSA - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-8.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.37
upper limit	-2.45
Variability estimate	Standard error of the mean
Dispersion value	3.03

Secondary: Percentage of Participants Developing Skin Infections Requiring Antibiotic Treatment

End point title	Percentage of Participants Developing Skin Infections Requiring Antibiotic Treatment

End point description:

Percentage of participants developing skin infections requiring antibiotic treatment.

APD: All randomized participants who received at least one dose of study drug and who did not discontinue from the study for the reason of "Lost to Follow-up" at the first post-baseline visit.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	93	184	92
Units: percentage of participants				
number (not applicable)	5.4	6.5	6.5	5.4

Statistical analyses

Statistical analysis title	Skin Infections - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999
Method	Fisher exact

Statistical analysis title	Skin Infections - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	277
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.797
Method	Fisher exact

Statistical analysis title	Skin Infections - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.999
Method	Fisher exact

Secondary: Mean Number of Days without Topical Corticosteroids (TCS) Use

End point title	Mean Number of Days without Topical Corticosteroids (TCS) Use

End point description:

The ANCOVA model includes treatment, region, and baseline disease severity (IGA) as factors.

APD: All randomized participants without use of TCS.

End point type	Secondary

End point timeframe:
Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	89	92	178	89
Units: days				
least squares mean (standard error)	12.18 (± 3.39)	20.80 (± 3.37)	17.65 (± 2.53)	19.43 (± 3.41)

Statistical analyses

Statistical analysis title	TCS - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	181
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.056
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	8.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	17.45
Variability estimate	Standard error of the mean
Dispersion value	4.49

Statistical analysis title	TCS - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	267
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.164
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	5.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.24
upper limit	13.19

Variability estimate	Standard error of the mean
Dispersion value	3.92

Statistical analysis title	TCS - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.11
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	7.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.66
upper limit	16.15
Variability estimate	Standard error of the mean
Dispersion value	4.53

Secondary: Mean Gram Quantity of Low and Moderate Potency Background Topical Corticosteroid (TCS) Used (Tube Weights)

End point title	Mean Gram Quantity of Low and Moderate Potency Background Topical Corticosteroid (TCS) Used (Tube Weights)

End point description:

Average weights of full tubes were used to determine the dispensed weights for each region. Returned tubes were weighed with cap without carton to determine the amount of TCS in grams (g) used at each visit. Analysis was done via analysis of variance (ANOVA), with geographic region, baseline disease severity, and treatment as factors in the model.

APD: All randomized participants.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	93	185	92
Units: grams				
least squares mean (standard error)	242.59 (± 27.60)	194.53 (± 27.42)	185.70 (± 20.67)	171.17 (± 27.16)

Statistical analyses

Statistical analysis title	Low and Moderate Potency TCS - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.178
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-48.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-118
upper limit	21.88
Variability estimate	Standard error of the mean
Dispersion value	35.63

Statistical analysis title	Low and Moderate Potency TCS - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.066
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-56.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-117.56
upper limit	3.77
Variability estimate	Standard error of the mean
Dispersion value	30.9

Statistical analysis title	Low and Moderate Potency TCS - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.045
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-71.42

Confidence interval	
level	95 %
sides	2-sided
lower limit	-141.24
upper limit	-1.6
Variability estimate	Standard error of the mean
Dispersion value	35.57

Secondary: Percent Change from Baseline in Itch NRS

End point title	Percent Change from Baseline in Itch NRS

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale, with 0 representing "no itch" and 10 representing "worst itch imaginable." Overall severity of a participant's itching is indicated by selecting the number, using a daily diary, that best describes the worst level of itching in the past 24 hours.
LS Means were calculated using MMRM model with treatment, region, baseline disease severity, visit, and treatment-by-visit-interaction as fixed categorical effects and baseline and baseline-by-interaction as fixed continuous effects.

APD: All randomized participants with Week 16 Itch NRS data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	62	135	66
Units: percent change				
least squares mean (standard error)	-17.48 (± 4.835)	-28.80 (± 4.663)	-32.89 (± 3.258)	-37.24 (± 4.609)

Statistical analyses

Statistical analysis title	PCFB Itch NRS - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.088
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-11.32

Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.33
upper limit	1.7
Variability estimate	Standard error of the mean
Dispersion value	6.62

Statistical analysis title	PCFB Itch NRS - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	188
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-15.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.67
upper limit	-4.16
Variability estimate	Standard error of the mean
Dispersion value	5.725

Statistical analysis title	PCFB Itch NRS - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-19.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.71
upper limit	-6.82
Variability estimate	Standard error of the mean
Dispersion value	6.583

Secondary: Percent Change From Baseline in Itch NRS at Week 24

End point title	Percent Change From Baseline in Itch NRS at Week 24

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale, with 0 representing "no itch" and 10 representing "worst itch imaginable." Overall severity of a participant's itching is indicated by selecting the number, using a daily diary, that best describes the worst level of itching in the past 24 hours.

LS Means were calculated using MMRM model with treatment, region, baseline disease severity, visit, and treatment-by-visit-interaction as fixed categorical effects and baseline and baseline-by-interaction as fixed continuous effects.

APD: All randomized participants with Week 24 Itch NRS data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	50	108	54
Units: units on a scale				
least squares mean (standard error)	-15.35 (± 5.349)	-29.35 (± 5.039)	-30.11 (± 3.495)	-33.16 (± 4.972)

Statistical analyses

Statistical analysis title	PCFB Itch NRS - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.055
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.28
upper limit	0.28
Variability estimate	Standard error of the mean
Dispersion value	7.263

Statistical analysis title	PCFB Itch NRS - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib

Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.02
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-14.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.15
upper limit	-2.38
Variability estimate	Standard error of the mean
Dispersion value	6.297

Statistical analysis title	PCFB Itch NRS - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.014
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-17.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.01
upper limit	-3.62
Variability estimate	Standard error of the mean
Dispersion value	7.216

Secondary: Change from Baseline in the Total Score of the Patient Oriented Eczema Measure (POEM)

End point title	Change from Baseline in the Total Score of the Patient Oriented Eczema Measure (POEM)

End point description:

The POEM is a 7-item self-assessment questionnaire that assesses disease symptoms (dryness, itching, flaking, cracking, sleep loss, bleeding and weeping) on a scale ranging from 0-4 (0 = no days, 1 = 1-2 days, 2 = 3-4 days, 3 = 5-6 days, 4 = everyday). The sum of the 7 items gives the total POEM score of 0 (absent disease) to 28 (severe disease). High scores are indicative of more severe disease and poor quality of life.

LS Mean were calculated using MMRM model with treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interaction as fixed categorical effects and baseline and baseline-by visit-interactions as fixed continuous effects.

APD: All randomized participants with Week 16 POEM data.

End point type	Secondary

End point timeframe:
Baseline, Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	62	145	67
Units: units on a scale				
least squares mean (standard error)	-4.18 (± 0.907)	-6.24 (± 0.872)	-7.27 (± 0.602)	-9.27 (± 0.855)

Statistical analyses

Statistical analysis title	CFB POEM - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.095
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.47
upper limit	-0.36
Variability estimate	Standard error of the mean
Dispersion value	1.229

Statistical analysis title	CFB POEM - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.16
upper limit	-1.01

Variability estimate	Standard error of the mean
Dispersion value	1.057

Statistical analysis title	CFB POEM - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-5.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.48
upper limit	-2.7
Variability estimate	Standard error of the mean
Dispersion value	1.216

Secondary: Change from Baseline in the Patient Global Impression of Severity - Atopic Dermatitis (PGI-S-AD) Score

End point title	Change from Baseline in the Patient Global Impression of Severity -Atopic Dermatitis (PGI-S-AD) Score

End point description:

The PGI-S-AD is a single-item question asking the participant how they would rate their overall AD symptoms over the past 24 hours, using a daily diary. The 5 categories of responses are "(0) no symptoms", "(1) very mild", "(2) mild" "(3) moderate", and "(4) severe."

LS Means were calculated using MMRM model with treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interaction as fixed categorical effects and baseline and baseline-by-visit-interaction as fixed continuous effects.

APD: All randomized participants with Week 16 PGI-S-AD data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	62	135	66
Units: units on a scale				
least squares mean (standard error)	-0.49 (± 0.107)	-0.74 (± 0.103)	-0.77 (± 0.072)	-1.07 (± 0.101)

Statistical analyses

Statistical analysis title	CFB PGI-S-AD - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.097
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.53
upper limit	0.04
Variability estimate	Standard error of the mean
Dispersion value	0.146

Statistical analysis title	CFB PGI-S-AD - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	188
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.033
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	-0.02
Variability estimate	Standard error of the mean
Dispersion value	0.126

Statistical analysis title	CFB PGI-S-AD - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib

Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.86
upper limit	-0.29
Variability estimate	Standard error of the mean
Dispersion value	0.145

Secondary: Change from Baseline on the Hospital Anxiety Depression Scale (HADS)

End point title	Change from Baseline on the Hospital Anxiety Depression Scale (HADS)

End point description:

The HADS is a participant-rated instrument used to assess both anxiety and depression. This instrument consists of 14 item questionnaire, each item is rated on a 4-point scale, giving maximum scores of 21 for anxiety and depression. Scores of 11 or more on either subscale are considered to be a significant 'case' of psychological morbidity, while scores of 8-10 represent 'borderline' and 0-7, 'normal.'

LS Mean were calculated using MMRM model with treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interaction as fixed categorical effects and baseline and baseline-by-visit-interaction as fixed continuous effects.

APD: All randomized participants with Week 16 HADS data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	62	145	67
Units: units on a scale				
least squares mean (standard error)				
Anxiety	-0.48 (± 0.382)	-1.04 (± 0.366)	-1.59 (± 0.256)	-1.32 (± 0.362)
Depression	-0.40 (± 0.383)	-0.69 (± 0.367)	-1.03 (± 0.256)	-1.57 (± 0.362)

Statistical analyses

Statistical analysis title	CFB HADS - 1 mg Baricitinib
Statistical analysis description: HADS Anxiety	
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.272
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.58
upper limit	0.45
Variability estimate	Standard error of the mean
Dispersion value	0.516

Notes:
[3] - Anxiety

Statistical analysis title	CFB HADS - 2 mg Baricitinib
Statistical analysis description: HADS Anxiety	
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	= 0.013
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.99
upper limit	-0.24
Variability estimate	Standard error of the mean
Dispersion value	0.446

Notes:
[4] - Anxiety

Statistical analysis title	CFB HADS - 4 mg Baricitinib
Statistical analysis description: HADS Anxiety	
Comparison groups	Placebo v 4 mg Baricitinib

Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	= 0.099
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.85
upper limit	0.16
Variability estimate	Standard error of the mean
Dispersion value	0.511

Notes:
[5] - Anxiety

Statistical analysis title	CFB HADS - 1 mg Baricitinib
Statistical analysis description:	
HADS Depression	
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	= 0.584
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	0.74
Variability estimate	Standard error of the mean
Dispersion value	0.519

Notes:
[6] - Depression

Statistical analysis title	CFB HADS - 2 mg Baricitinib
Statistical analysis description:	
HADS Depression	
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	= 0.162
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.63

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.51
upper limit	0.25
Variability estimate	Standard error of the mean
Dispersion value	0.448

Notes:

[7] - Depression

Statistical analysis title	CFB HADS - 4 mg Baricitinib

Statistical analysis description:

HADS Depression

Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	= 0.024
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.18
upper limit	-0.15
Variability estimate	Standard error of the mean
Dispersion value	0.515

Notes:

[8] - Depression

Secondary: Change from Baseline in the Dermatology Life Quality Index (DLQI)

End point title	Change from Baseline in the Dermatology Life Quality Index (DLQI)

End point description:

The DLQI is a simple, participant-administered,10 question, validated, quality-of-life questionnaire that covers 6 domains including symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. The recall period of this scale is over the last "week." Response categories include "not at all," "a little," "a lot," and "very much," with corresponding scores of 0, 1, 2, and 3, respectively, and unanswered or "not relevant" responses scored as "0." Scores range from 0 to 30 (“no impact on participant's life” to “extremely large effect on participant's life”), and a 4-point change from baseline is considered as the minimal clinically important difference threshold.

LS Means were calculated using MMRM model with treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interaction as fixed categorical effects and baseline and baseline-by-visit-interaction as fixed continuous effects.

End point type	Secondary

End point timeframe:

Baseline, Week 16

APD: All randomized participants with Week 16 DLQI data.

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	62	145	67
Units: units on a scale				
least squares mean (standard error)	-4.95 (± 0.752)	-6.18 (± 0.719)	-6.57 (± 0.494)	-7.95 (± 0.705)

Statistical analyses

Statistical analysis title	CFB DLQI - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.228
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.23
upper limit	0.77
Variability estimate	Standard error of the mean
Dispersion value	1.018

Statistical analysis title	CFB DLQI - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.065
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.35
upper limit	0.1
Variability estimate	Standard error of the mean
Dispersion value	0.876

Statistical analysis title	CFB DLQI - 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.99
upper limit	-1.02
Variability estimate	Standard error of the mean
Dispersion value	1.007

Secondary: Change from Baseline on the Work Productivity and Activity Impairment - Atopic Dermatitis (WPAI-AD) Questionnaire

End point title	Change from Baseline on the Work Productivity and Activity Impairment - Atopic Dermatitis (WPAI-AD) Questionnaire

End point description:

The WPAI-AD participant questionnaire was developed to measure the effect of general health and symptom severity on work productivity and regular activities in the 7 days prior to the visit. The WPAI-AD consists of 6 items grouped in 4 domains: absenteeism (work time missed), presenteeism (impairment at work/reduced on-the-job effectiveness), work productivity loss (overall work impairment/absenteeism plus presenteeism), and activity impairment, that range from 0% to 100%, with higher values indicating greater impairment.

LS Means were calculated using MMRM model with treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interaction as fixed categorical effects and baseline and baseline-by-visit-interaction as fixed continuous effects.

APD: All randomized participants with Week 16 WPAI-AD data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	62	145	67
Units: units on a scale				
least squares mean (standard error)				
Absenteeism (37, 36, 85, 42)	-4.77 (± 2.365)	-5.69 (± 2.433)	-2.98 (± 1.639)	-4.56 (± 2.258)

Presenteeism (34, 35, 83, 39)	-14.86 (± 3.182)	-11.80 (± 3.161)	-14.56 (± 2.133)	-14.81 (± 3.000)
Work Productivity Loss (34, 35, 83, 39)	-13.22 (± 3.560)	-12.07 (± 3.565)	-13.07 (± 2.440)	-14.12 (± 3.396)
Activity Impairment (55, 62, 145, 67)	-16.46 (± 2.853)	-18.46 (± 2.729)	-20.86 (± 1.847)	-23.92 (± 2.660)

Statistical analyses

Statistical analysis title	CFB Absenteeism - 1 mg Baricitinib
Statistical analysis description:	
Change from Baseline (CFB) Absenteeism	
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	= 0.784
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.5
upper limit	5.67
Variability estimate	Standard error of the mean
Dispersion value	3.339

Notes:

[9] - Change from Baseline (CFB) Absenteeism

Statistical analysis title	CFB Absenteeism - 2 mg Baricitinib
Statistical analysis description:	
CFB Absenteeism	
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority[10]
P-value	= 0.525
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.75
upper limit	7.34
Variability estimate	Standard error of the mean
Dispersion value	2.813

Notes:
[10] - CFB Absenteeism

Statistical analysis title	CFB Absenteeism - 4 mg Baricitinib
Statistical analysis description: CFB Absenteeism	
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	= 0.947
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.11
upper limit	6.53
Variability estimate	Standard error of the mean
Dispersion value	3.204

Notes:
[11] - CFB Absenteeism

Statistical analysis title	CFB Presenteeism - 1 mg Baricitinib
Statistical analysis description: CFB Presenteeism	
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority[12]
P-value	= 0.488
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.62
upper limit	11.74
Variability estimate	Standard error of the mean
Dispersion value	4.409

Notes:
[12] - CFB Presenteeism

Statistical analysis title	CFB Presenteeism - 2 mg Baricitinib
Statistical analysis description: CFB Presenteeism	
Comparison groups	Placebo v 2 mg Baricitinib

Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority[13]
P-value	= 0.936
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.02
upper limit	7.62
Variability estimate	Standard error of the mean
Dispersion value	3.72

Notes:
[13] - CFB Presenteeism

Statistical analysis title	CFB Presenteeism - 4 mg Baricitinib
Statistical analysis description:	
CFB Presenteeism	
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority[14]
P-value	= 0.991
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.35
upper limit	8.45
Variability estimate	Standard error of the mean
Dispersion value	4.267

Notes:
[14] - CFB Presenteeism

Statistical analysis title	CFB Work Productivity Loss - 1 mg Baricitinib
Statistical analysis description:	
CFB Work Productivity Loss	
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority[15]
P-value	= 0.816
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.15

Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.57
upper limit	10.88
Variability estimate	Standard error of the mean
Dispersion value	4.938

Notes:
[15] - CFB Work Productivity Loss

Statistical analysis title	CFB Work Productivity Loss - 2 mg Baricitinib
Statistical analysis description:	
CFB Work Productivity Loss	
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority[16]
P-value	= 0.971
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.08
upper limit	8.38
Variability estimate	Standard error of the mean
Dispersion value	4.178

Notes:
[16] - CFB Work Productivity Loss

Statistical analysis title	CFB Work Productivity Loss - 4 mg Baricitinib
Statistical analysis description:	
CFB Work Productivity Loss	
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority[17]
P-value	= 0.852
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.36
upper limit	8.56
Variability estimate	Standard error of the mean
Dispersion value	4.804

Notes:
[17] - CFB Work Productivity Loss

Statistical analysis title	CFB Activity Impairment - 1 mg Baricitinib
Statistical analysis description:	
CFB Activity Impairment	
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority[18]
P-value	= 0.607
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.61
upper limit	5.63
Variability estimate	Standard error of the mean
Dispersion value	3.877

Notes:
[18] - CFB Activity Impairment

Statistical analysis title	CFB Activity Impairment - 2 mg Baricitinib
Statistical analysis description:	
CFB Activity Impairment	
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority[19]
P-value	= 0.186
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-4.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.92
upper limit	2.12
Variability estimate	Standard error of the mean
Dispersion value	3.319

Notes:
[19] - CFB Activity Impairment

Statistical analysis title	CFB Activity Impairment - 4 mg Baricitinib
Statistical analysis description:	
CFB Activity Impairment	
Comparison groups	Placebo v 4 mg Baricitinib

Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority[20]
P-value	= 0.052
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-7.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.96
upper limit	0.06
Variability estimate	Standard error of the mean
Dispersion value	3.82

Notes:

[20] - CFB Activity Impairment

Secondary: Change from Baseline in the European Quality of Life–5 Dimensions–5 Levels (EQ-5D-5L) Index Score United States and United Kingdom Algorithm

End point title	Change from Baseline in the European Quality of Life–5 Dimensions–5 Levels (EQ-5D-5L) Index Score United States and United Kingdom Algorithm

End point description:

The EQ-5D-5L is a 2-part measurement. The first part is comprised of the following 5 participant-reported dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The responses are used to derive the health state index scores using the United Kingdom (UK) algorithm, with scores ranging from -0.594 to 1, and the United States (US) algorithm, with scores ranging from -0.109 to 1, with higher score indicating better health state.
LS Means were calculated using MMRM model with treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interaction as fixed categorical effects and baseline and baseline-by-visit-interaction as fixed continuous effects.

APD: All randomized participants with EQ-5D-5L US and UK Health scores.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	62	145	67
Units: units on a scale				
least squares mean (standard error)				
US Health State Index	0.04 (± 0.016)	0.08 (± 0.016)	0.09 (± 0.011)	0.11 (± 0.015)
UK Health State Index	0.06 (± 0.023)	0.11 (± 0.022)	0.13 (± 0.016)	0.15 (± 0.022)

Statistical analyses

Statistical analysis title	Health State Index US - 1 mg Baricitinib
Statistical analysis description: CFB US Health State Index	
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority[21]
P-value	= 0.131
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.01
upper limit	0.08
Variability estimate	Standard error of the mean
Dispersion value	0.022

Notes:
[21] - CFB US Health State Index

Statistical analysis title	Health State Index US - 2 mg Baricitinib
Statistical analysis description: CFB US Health State Index	
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority[22]
P-value	= 0.017
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.01
upper limit	0.08
Variability estimate	Standard error of the mean
Dispersion value	0.019

Notes:
[22] - CFB US Health State Index

Statistical analysis title	Health State Index US - 4 mg Baricitinib
Statistical analysis description: CFB US Health State Index	
Comparison groups	Placebo v 4 mg Baricitinib

Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority[23]
P-value	= 0.003
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.02
upper limit	0.11
Variability estimate	Standard error of the mean
Dispersion value	0.022

Notes:

[23] - CFB US Health State Index

Statistical analysis title	Health State Index UK - 1 mg Baricitinib
Statistical analysis description:	
CFB UK Health State Index	
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority[24]
P-value	= 0.102
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.01
upper limit	0.11
Variability estimate	Standard error of the mean
Dispersion value	0.031

Notes:

[24] - CFB UK Health State Index

Statistical analysis title	Health State Index UK - 2 mg Baricitinib
Statistical analysis description:	
CFB UK Health State Index	
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority[25]
P-value	= 0.014
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.07

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.01
upper limit	0.12
Variability estimate	Standard error of the mean
Dispersion value	0.027

Notes:

[25] - CFB UK Health State Index

Statistical analysis title	Health State Index UK - 4 mg Baricitinib

Statistical analysis description:

CFB UK Health State Index

Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority[26]
P-value	= 0.003
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.03
upper limit	0.15
Variability estimate	Standard error of the mean
Dispersion value	0.031

Notes:

[26] - CFB UK Health State Index

Secondary: Change From Baseline on the European Quality of Life-5 Dimensions 5 Levels (EQ-5D-5L) Visual Analog Score (VAS)

End point title	Change From Baseline on the European Quality of Life-5 Dimensions 5 Levels (EQ-5D-5L) Visual Analog Score (VAS)

End point description:

EQ-5D-5L is a 2-part measurement. The second part is assessed using a visual analog scale (VAS) that ranged from 0 to 100 millimeter (mm), where 0 is the worst health you can imagine and 100 is the best health you can imagine.

LS Means were calculated using MMRM model with treatment, region, baseline disease severity (IGA), visit, and treatment-by-visit-interactions as fixed categorical effects and baseline and baseline-by-visit-interaction as fixed continuous effects.

APD: All randomized participants with Week 16 EQ-5D-5L VAS data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	62	145	67
Units: units on a scale				
least squares mean (standard error)	7.64 (± 2.407)	11.63 (± 2.306)	8.76 (± 1.588)	11.03 (± 2.260)

Statistical analyses

Statistical analysis title	CFB EQ-5D-5L VAS - 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.221
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.41
upper limit	10.39
Variability estimate	Standard error of the mean
Dispersion value	3.256

Statistical analysis title	CFB EQ-5D-5L VAS - 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.689
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.4
upper limit	6.65
Variability estimate	Standard error of the mean
Dispersion value	2.807

Statistical analysis title	CFB EQ-5D-5L VAS - 4 mg Baricitinib

Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.294
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.95
upper limit	9.74
Variability estimate	Standard error of the mean
Dispersion value	3.226

Secondary: Percentage of Participants Achieving EASI75

End point title	Percentage of Participants Achieving EASI75

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: All randomized participants.

End point type	Secondary

End point timeframe:

Week 52

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	93	185	92
Units: Percentage of participants				
number (confidence interval 95%)	26.9 (18.9 to 36.7)	33.3 (24.6 to 43.4)	30.3 (24.1 to 37.2)	37.0 (27.8 to 47.2)

Statistical analyses

Statistical analysis title	Placebo, 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib

Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.382
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	2.54

Statistical analysis title	Placebo, 2 mg Baricitinib
Comparison groups	2 mg Baricitinib v Placebo
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.638
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.15
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.65
upper limit	2.02

Statistical analysis title	Placebo, 4 mg Baricitinib
Comparison groups	Placebo v 4 mg Baricitinib
Number of subjects included in analysis	185
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.169
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	2.96

Secondary: Percent Change From Baseline in Itch NRS at Week 52

End point title	Percent Change From Baseline in Itch NRS at Week 52

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale, with 0 representing "no itch" and 10 representing "worst itch imaginable." Overall severity of a participant's itching is indicated by selecting the number, using a daily diary, that best describes the worst level of itching in the past 24 hours.
LS Means were calculated using MMRM model with treatment, region, baseline disease severity, visit, and treatment-by-visit-interaction as fixed categorical effects and baseline and baseline-by-interaction as fixed continuous effects.
APD: All randomized participants with Week 52 Itch NRS data.

End point type	Secondary

End point timeframe:

Baseline, Week 52

End point values	Placebo	1 mg Baricitinib	2 mg Baricitinib	4 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	54	110	56
Units: Percent change				
least squares mean (standard error)	-12.13 (± 7.075)	-19.49 (± 6.679)	-16.01 (± 4.279)	-29.31 (± 6.619)

Statistical analyses

Statistical analysis title	Placebo, 1 mg Baricitinib
Comparison groups	Placebo v 1 mg Baricitinib
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.447
Method	Regression, Linear
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-7.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.38
upper limit	11.66
Variability estimate	Standard error of the mean
Dispersion value	9.674

Statistical analysis title	Placebo, 2 mg Baricitinib
Comparison groups	Placebo v 2 mg Baricitinib

Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.646
Method	Regression, Linear
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-3.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.5
upper limit	12.74
Variability estimate	Standard error of the mean
Dispersion value	8.454

Statistical analysis title	Placebo, 4 mg Baricitinib
Comparison groups	4 mg Baricitinib v Placebo
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.075
Method	Regression, Linear
Parameter estimate	LS Mean Difference (Final Values)
Point estimate	-17.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.14
upper limit	1.77
Variability estimate	Standard error of the mean
Dispersion value	9.64

Secondary: Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at 16 Weeks After Rerandomization (Week 68) Randomized Downtitration (All Participants Entering the Substudy)

End point title	Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at 16 Weeks After Rerandomization (Week 68) Randomized Downtitration (All Participants Entering the Substudy)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All missing values were imputed using modified last observation carried forward (mLOCF).

APD: Participants who received at least one study medication during Week 52 to Week 200 in Study JAIN and entered the downtitration substudy. Additionally, those participants who did not meet study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 68

End point values	LTE Substudy 4 mg Baricitinib to 4 mg Baricitinib	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	25	24
Units: Percentage of participants				
number (confidence interval 85%)	93.8 (71.7 to 98.9)	56.3 (33.2 to 76.9)	84.0 (65.3 to 93.6)	50.0 (31.4 to 68.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at 16 Weeks After Rerandomization (Week 104) Randomized Downtitration (All Participants Entering the Substudy)

End point title	Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at 16 Weeks After Rerandomization (Week 104) Randomized Downtitration (All Participants Entering the Substudy)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All missing values were imputed using modified last observation carried forward (mLOCF).

APD: Participants who received at least one study medication during Week 52 to Week 200 in Study JAIN and entered the downtitration substudy. Additionally, those participants who did not meet study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 104

End point values	LTE Substudy 4 mg Baricitinib to 4 mg Baricitinib	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	25	24
Units: Percentage of participants				
number (confidence interval 95%)	68.8 (44.4 to 85.8)	50.0 (28.0 to 72.0)	72.0 (52.4 to 85.7)	25.0 (12.0 to 44.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0, 1 Assessed at 16 Weeks After Rerandomization (Week 68) Randomized Downtitration (All Participants Entering tSubstudy)

End point title	Percentage of Participants With a Response of IGA 0, 1 Assessed at 16 Weeks After Rerandomization (Week 68) Randomized Downtitration (All Participants Entering tSubstudy)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.

APD: Participants who received at least one study medication during Week 52 to Week 200 in Study JAIN and entered the downtitration substudy. Additionally, those participants who did not meet study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 68

End point values	LTE Substudy 4 mg Baricitinib to 4 mg Baricitinib	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	25	24
Units: Percentage of participants				
number (confidence interval 95%)	50 (28.0 to 72.0)	25.0 (10.2 to 49.5)	44.0 (26.7 to 62.9)	20.8 (9.2 to 40.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0, 1 Assessed at 16 Weeks After Rerandomization (Week 104) Randomized Downtitration (All Participants Entering the Substudy)

End point title	Percentage of Participants With a Response of IGA 0, 1 Assessed at 16 Weeks After Rerandomization (Week 104) Randomized Downtitration (All Participants Entering the Substudy)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification.

APD: Participants who received at least one study medication during Week 52 to Week 200 in Study JAIN and entered the downtitration substudy. Additionally, those participants who did not meet study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 104

End point values	LTE Substudy 4 mg Baricitinib to 4 mg Baricitinib	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	25	24
Units: Percentage of participants				
number (confidence interval 95%)	43.8 (23.1 to 66.8)	25.0 (10.2 to 49.5)	44.0 (26.7 to 62.9)	8.3 (2.3 to 25.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of EASI75 From Baseline Assessed at 16 Weeks After Rerandomization (Week 68) Randomized Downtitration (All Participants Entering the Substudy)

End point title	Percentage of Participants With a Response of EASI75 From Baseline Assessed at 16 Weeks After Rerandomization (Week 68) Randomized Downtitration (All Participants Entering the Substudy)

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: Participants who received at least 1 dose of study medication during Week 52 to Week 200 in Study JAIN and entered the downtitration substudy. Those participants who did not meet study discontinuation criteria and continued were included in the analysis.

End point type	Secondary

End point timeframe:

Week 68

End point values	LTE Substudy 4 mg Baricitinib to 4 mg Baricitinib	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	25	24
Units: Percentage of participants				
number (confidence interval 95%)	75.0 (50.5 to 89.8)	56.3 (33.2 to 76.9)	72.0 (52.4 to 85.7)	41.7 (24.5 to 61.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of EASI75 From Baseline Assessed at 16 Weeks After Rerandomization (Week 104) Randomized Downtitration (All Participants Entering the Substudy)

End point title	Percentage of Participants With a Response of EASI75 From Baseline Assessed at 16 Weeks After Rerandomization (Week 104) Randomized Downtitration (All Participants Entering the Substudy)

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: Participants who received at least 1 dose of study medication during Week 52 to Week 200 in Study JAIN and entered the downtitration substudy. Those participants who did not meet study discontinuation criteria and continued were included in the analysis.

End point type	Secondary

End point timeframe:

Week 104

End point values	LTE Substudy 4 mg Baricitinib to 4 mg Baricitinib	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	25	24
Units: Percentage of participants				
number (confidence interval 95%)	68.8 (44.4 to 85.8)	56.3 (33.2 to 76.9)	56.0 (37.1 to 73.3)	33.3 (18.0 to 53.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at 16 Weeks After Rerandomization (Week 68) Randomized Downtitration (Participants Entering the Substudy With IGA 0 or 1)

End point title	Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at 16 Weeks After Rerandomization (Week 68) Randomized Downtitration (Participants Entering the Substudy With IGA 0 or 1)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All missing values were imputed using modified last observation carried forward (mLOCF).

APD: Participants who received at least one study medication during Week 52 to Week 200 in Study JAIN and entered the downtitration substudy with IGA 0 or 1. Additionally, those participants who did not meet study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 68

End point values	4 mg Bari to 4 mg Bari LTE Substudy with IGA 0, 1 at Week 52	4 mg Bari to 2 mg Bari LTE Substudy with IGA 0, 1 at Week 52	2 mg Bari to 2 mg Bari LTE Substudy with IGA 0, 1 at Week 52	2 mg Bari to 1 mg Bari LTE Substudy with IGA 0, 1 at Week 52
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	9	10	9
Units: Percentage of participants				
number (confidence interval 95%)	100 (72.2 to 100)	77.8 (45.3 to 93.7)	100 (72.2 to 100)	55.6 (26.7 to 81.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0, 1 or 2 Assessed at 16 Weeks After Rerandomization (Week 104) Randomized Downtitration (Participants Entering the Substudy With IGA 0 or 1)

End point title	Percentage of Participants With a Response of IGA 0, 1 or 2 Assessed at 16 Weeks After Rerandomization (Week 104)

	Randomized Downtitration (Participants Entering the Substudy With IGA 0 or 1)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All missing values were imputed using mLOCF.

APD: Participants who received at least one study medication during Week 52 to Week 200 in Study JAIN and entered the downtitration substudy with IGA 0 or 1. Additionally, those participants who did not meet study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 104

End point values	4 mg Bari to 4 mg Bari LTE Substudy with IGA 0, 1 at Week 52	4 mg Bari to 2 mg Bari LTE Substudy with IGA 0, 1 at Week 52	2 mg Bari to 2 mg Bari LTE Substudy with IGA 0, 1 at Week 52	2 mg Bari to 1 mg Bari LTE Substudy with IGA 0, 1 at Week 52
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	9	10	9
Units: Percentage of participants				
number (confidence interval 95%)	80.0 (49.0 to 94.3)	66.7 (35.4 to 87.9)	100 (72.2 to 100)	33.3 (12.1 to 64.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0 or 1 Assessed at 16 Weeks After Rerandomization (Week 68) Randomized Downtitration (Participants Entering the Substudy With IGA 0 or 1)

End point title	Percentage of Participants With a Response of IGA 0 or 1 Assessed at 16 Weeks After Rerandomization (Week 68) Randomized Downtitration (Participants Entering the Substudy With IGA 0 or 1)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All missing values were imputed using mLOCF.

APD: Participants who received at least one study medication during Week 52 to Week 200 in Study JAIN and entered the downtitration substudy with IGA 0 or 1. Additionally, those participants who did not meet study discontinuation criteria and continued were included in the analysis set.

End point type	Secondary

End point timeframe:

Week 68

End point values	4 mg Bari to 4 mg Bari LTE Substudy with IGA 0, 1 at Week 52	4 mg Bari to 2 mg Bari LTE Substudy with IGA 0, 1 at Week 52	2 mg Bari to 2 mg Bari LTE Substudy with IGA 0, 1 at Week 52	2 mg Bari to 1 mg Bari LTE Substudy with IGA 0, 1 at Week 52
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	9	10	9
Units: Percentage of participants				
number (confidence interval 95%)	60.0 (31.3 to 83.2)	33.3 (12.1 to 64.6)	90.0 (59.6 to 98.2)	55.6 (26.7 to 81.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0 or 1 Assessed at 16 Weeks After Rerandomization (Week 104) Randomized Downtitration (Participants Entering the Substudy With IGA 0 or 1)

End point title	Percentage of Participants With a Response of IGA 0 or 1 Assessed at 16 Weeks After Rerandomization (Week 104) Randomized Downtitration (Participants Entering the Substudy With IGA 0 or 1)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All missing values were imputed using mLOCF.

APD: Participants who received at least one study medication during Week 52 to Week 200 in Study JAIN and entered the downtitration substudy with IGA 0 or 1. Additionally, those participants who did not meet study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 104

End point values	4 mg Bari to 4 mg Bari LTE Substudy with IGA 0, 1 at Week 52	4 mg Bari to 2 mg Bari LTE Substudy with IGA 0, 1 at Week 52	2 mg Bari to 2 mg Bari LTE Substudy with IGA 0, 1 at Week 52	2 mg Bari to 1 mg Bari LTE Substudy with IGA 0, 1 at Week 52
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	10	9	10	9
Units: Percentage of participants				
number (confidence interval 95%)	50 (23.7 to 76.3)	33.3 (12.1 to 64.6)	90.0 (59.6 to 98.2)	22.2 (6.3 to 54.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at Week 68 Participants Not Entered Into Substudy (All Participants)

End point title	Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at Week 68 Participants Not Entered Into Substudy (All Participants)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All missing values were imputed using mLOCF.

APD: Participants who received at least one study medication Week 52 to Week 200 in Study JAIN, and were Responders (IGA 0 or 1) and Partial Responders (IGA 2) at Week 52 but were not eligible for downtitration substudy (i.e. had study drug interrupted at Week 52, or had received high or ultra-high potency TCS in the previous 14 days). Additionally, those participants who did not met study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 68

End point values	LTE 4 mg Baricitinib (Responders/Partial Responders)	LTE 2 mg Baricitinib (Responders/Partial Responders)	LTE 1 mg Baricitinib (Responders/Partial Responders)	LTE Placebo (Responders/Partial Responders)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	22	34	29
Units: Percentage of participants				
number (confidence interval 95%)	100 (64.6 to 100)	86.4 (66.7 to 95.3)	100 (89.8 to 100)	93.1 (78.0 to 98.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at Week 104 Participants Not Entered Into Substudy (All Participants)

End point title	Percentage of Participants With a Response of IGA 0, 1, or 2 Assessed at Week 104 Participants Not Entered Into Substudy (All Participants)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All missing values were imputed using mLOCF.

APD: Participants who received at least one study medication Week 52 to Week 200 in Study JAIN, and were Responders (IGA 0 or 1) and Partial Responders (IGA 2) at Week 52 but were not eligible for downtitration substudy (i.e. had study drug interrupted at Week 52, or had received high or ultra-high potency TCS in the previous 14 days). Additionally, those participants who did not met study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 104

End point values	LTE 4 mg Baricitinib (Responders/Partial Responders)	LTE 2 mg Baricitinib (Responders/Partial Responders)	LTE 1 mg Baricitinib (Responders/Partial Responders)	LTE Placebo (Responders/Partial Responders)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	22	34	29
Units: Percentage of participants				
number (confidence interval 95%)	100 (64.6 to 100)	86.4 (66.7 to 95.3)	97.1 (85.1 to 99.5)	93.1 (78.0 to 98.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0 or 1 Assessed at Week 68 - Participants Not Entered Into Substudy (All Participants)

End point title	Percentage of Participants With a Response of IGA 0 or 1 Assessed at Week 68 - Participants Not Entered Into Substudy (All Participants)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All missing values were imputed using mLOCF.

APD: Participants who received at least one study medication Week 52 to Week 200 in Study JAIN, and were Responders (IGA 0 or 1) and Partial Responders (IGA 2) at Week 52 but were not eligible for downtitration substudy (i.e. had study drug interrupted at Week 52, or had received high or ultra-high potency TCS in the previous 14 days). Additionally, those participants who did not met study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 68

End point values	LTE 4 mg Baricitinib (Responders/Partial Responders)	LTE 2 mg Baricitinib (Responders/Partial Responders)	LTE 1 mg Baricitinib (Responders/Partial Responders)	LTE Placebo (Responders/Partial Responders)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	22	34	29
Units: Percentage of participants				
number (confidence interval 95%)	14.3 (2.6 to 51.3)	50.0 (30.7 to 69.3)	47.1 (31.5 to 63.3)	51.7 (34.4 to 68.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Response of IGA 0 or 1 Assessed at Week 104 - Participants Not Entered into Substudy (All Participants)

End point title	Percentage of Participants With a Response of IGA 0 or 1 Assessed at Week 104 - Participants Not Entered into Substudy (All Participants)

End point description:

The IGA measures the investigator's global assessment of the participant's overall severity of their AD, based on a static, numeric 5-point scale from 0 (clear skin) to 4 (severe disease). The score is based on an overall assessment of the degree of erythema, papulation/induration, oozing/crusting, and lichenification. All missing values were imputed using mLOCF.

APD: Participants who received at least one study medication Week 52 to Week 200 in Study JAIN, and were Responders (IGA 0 or 1) and Partial Responders (IGA 2) at Week 52 but were not eligible for downtitration substudy (i.e. had study drug interrupted at Week 52, or had received high or ultra-high potency TCS in the previous 14 days). Additionally, those participants who did not met study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 104

End point values	LTE 4 mg Baricitinib (Responders/Partial Responders)	LTE 2 mg Baricitinib (Responders/Partial Responders)	LTE 1 mg Baricitinib (Responders/Partial Responders)	LTE Placebo (Responders/Partial Responders)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	22	34	29
Units: Percentage of participants				
number (confidence interval 95%)	42.9 (15.8 to 75.0)	50.0 (30.7 to 69.3)	47.1 (31.5 to 63.3)	48.3 (31.4 to 65.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With A Response of EASI75 Assessed at Week 68 - Participants Not Entered Into Substudy (All Participants)

End point title	Percentage of Participants With A Response of EASI75 Assessed at Week 68 - Participants Not Entered Into Substudy (All Participants)

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: Participants who received at least one study medication Week 52 to Week 200 in Study JAIN, and were Responders (IGA 0 or 1) and Partial Responders (IGA 2) at Week 52 but were not eligible for downtitration substudy.

End point type	Secondary

End point timeframe:

Week 68

End point values	LTE 4 mg Baricitinib (Responders/Partial Responders)	LTE 2 mg Baricitinib (Responders/Partial Responders)	LTE 1 mg Baricitinib (Responders/Partial Responders)	LTE Placebo (Responders/Partial Responders)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	22	34	29
Units: Percentage of participants				
number (confidence interval 95%)	57.1 (25.0 to 84.2)	63.6 (43.0 to 80.3)	76.5 (60.0 to 87.6)	62.1 (44.0 to 77.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With A Response of EASI75 Assessed at Week 104 - Participants Not Entered Into Substudy (All Participants)

End point title	Percentage of Participants With A Response of EASI75 Assessed at Week 104 - Participants Not Entered Into Substudy (All Participants)

End point description:

The EASI assesses objective physician estimates of 2 dimensions of atopic dermatitis - disease extent and clinical signs affected: 0 = 0%; 1 = 1-9%; 2 = 10-29%; 3 = 30-49%; 4 = 50-69%; 5 = 70-89%; 6 = 90-100% and the severity of 4 clinical signs: (1) erythema, (2) edema/papulation, (3) excoriation, and (4) lichenification each on a scale of 0 to 3 (0 = none, absent; 1 = mild; 2 = moderate; 3 = severe) at 4 body sites (head/neck, trunk, upper limbs, and lower limbs). Half scores are allowed between severities 1, 2, and 3. The final EASI score was obtained by weight-averaging these 4 scores and will range from 0 (no disease) to 72 (severe disease). The EASI75 is defined as a ≥ 75% improvement from baseline in the EASI score.

APD: Participants who received at least one study medication Week 52 to Week 200 in Study JAIN, and were Responders (IGA 0 or 1) and Partial Responders (IGA 2) at Week 52 but were not eligible for downtitration substudy.

End point type	Secondary

End point timeframe:

Week 104

End point values	LTE 4 mg Baricitinib (Responders/Partial Responders)	LTE 2 mg Baricitinib (Responders/Partial Responders)	LTE 1 mg Baricitinib (Responders/Partial Responders)	LTE Placebo (Responders/Partial Responders)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	22	34	29
Units: Percentage of participants				
number (confidence interval 95%)	85.7 (48.7 to 97.4)	68.2 (47.3 to 83.6)	70.6 (53.8 to 83.2)	72.4 (54.3 to 85.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Retreatment (Time to IGA ≥3) Randomized Downtitration (All Patients Entering the Substudy)

End point title	Time to Retreatment (Time to IGA ≥3) Randomized Downtitration (All Patients Entering the Substudy)

End point description:

Participants who entered the Substudy and relapsed with an IGA ≥3.

APD: Participants who received at least one study medication during Week 52 to Week 200 in Study JAIN, entered the downtitration substudy and experienced relapse from Week 52 up to Week 200. Additionally, those participants who did not meet study discontinuation criteria and continued will be considered in the analysis set.

End point type	Secondary

End point timeframe:

Week 52 Up to Week 200

End point values	4-mg Bari to 4-mg Bari to 4-mg Bari	4 mg Bari to 2 mg Bari to 4 mg Bari	2 mg Bari to 2 mg Bari to 2 mg Bari	2 mg Bari to 1 mg Bari to 2 mg Bari
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5[27]	11	15	20
Units: Days				
median (full range (min-max))	218 (29 to 9999)	79 (28 to 359)	68 (28 to 364)	71 (29 to 225)

Notes:

[27] - Upper Confidence Level (CI) not estimable due to censoring.

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Baseline up to Week 200

Adverse event reporting additional description:

All randomized participants who received at least 1 dose of investigational product and who did not discontinue from the study for the reason 'Lost to Follow-up' at the first postbaseline visit. Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Placebo

Reporting group description:

Placebo administered orally once daily in combination with topical corticosteroids. Additional Placebo administered orally to maintain the blind.

Reporting group title	2 mg Baricitinib

Reporting group description:

2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	4 mg Baricitinib

Reporting group description:

4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib

Reporting group description:

Long Term Extension (LTE) Substudy 2mg Baricitinib to 1mg Baricitinib (Responders/Partial Responders)
2 mg Baricitinib rerandomized to 1 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib

Reporting group description:

LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib (Responders/Partial Responders)
2 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib

Reporting group description:

LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib (Responders/Partial Responders)
4 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	Long Term Extension Substudy 4mg to 4mg

Reporting group description:

4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE Placebo (Responders/Partial Responders)

Reporting group description:

LTE Placebo (Responders/Partial Responders) - Did Not Enter Substudy
Placebo administered orally once daily (continued previous dose) in combination with topical corticosteroids. Additional placebo administered orally to maintain the blind.

Reporting group title	LTE 1 mg Baricitinib (Responders/Partial Responders)

Reporting group description:

LTE 1 mg Baricitinib (Responders/Partial Responders) - Did Not Enter Substudy
1 mg Baricitinib administered orally once daily (continued previous dose) in combination with topical

corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE 2 mg Baricitinib (Responders/Partial Responders)

Reporting group description:

LTE 2 mg Baricitinib (Responders/Partial Responders) - Did Not Enter Substudy
2 mg Baricitinib administered orally once daily (continued previous dose) in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE 4 mg Baricitinib (Responders/Partial Responders)

Reporting group description:

LTE 4 mg Baricitinib (Responders/Partial Responders) - Did Not Enter Substudy
4 mg Baricitinib administered orally once daily (continued previous dose) in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE Placebo to 2 mg Baricitinib (Non-responders)

Reporting group description:

LTE Placebo to 2 mg Baricitinib (Non-responders) - Did Not Enter Substudy
Placebo rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE Placebo to 4 mg Baricitinib (Non-responders)

Reporting group description:

LTE Placebo to 4 mg Baricitinib (Non-responders) - Did Not Enter Substudy
Placebo rerandomized to 4 mg Baricitinib administered orally once daily (continued previous dose) in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE 1 mg Baricitinib to 2 mg Baricitinib (Non-responders)

Reporting group description:

LTE 1 mg Baricitinib to 2 mg Baricitinib (Non-responders) - Did Not Enter Substudy
1 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LLTE 1 mg Baricitinib to 4 mg Baricitinib (Non-responders)

Reporting group description:

LTE 1 mg Baricitinib to 4 mg Baricitinib (Non-responders) - Did Not Enter Substudy
1 mg Baricitinib rerandomized to 4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE 2 mg Baricitinib to 2 mg Baricitinib (Non-responders)

Reporting group description:

LTE 2 mg Baricitinib to 2 mg Baricitinib (Non-responders) - Did Not Enter Substudy
2 mg Baricitinib rerandomized to 2 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE 2 mg Baricitinib to 4 mg Baricitinib (Non-responders)

Reporting group description:

LTE 2 mg Baricitinib to 4 mg Baricitinib (Non-responders) - Did Not Enter Substudy
2 mg Baricitinib rerandomized to 4 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	LTE 4 mg Baricitinib (Non-responders)

Reporting group description:

LTE 4 mg Baricitinib (Non-responders) - Did Not Enter Substudy
4 mg administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Reporting group title	1mg Baricitinib DBT

Reporting group description:

1 mg Baricitinib administered orally once daily in combination with topical corticosteroids. Placebo administered orally to maintain the blind.

Serious adverse events	Placebo	2 mg Baricitinib	4 mg Baricitinib
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 93 (5.38%)	9 / 184 (4.89%)	10 / 92 (10.87%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma of colon			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bowen's disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemangioma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[1]	0 / 49 (0.00%)	0 / 132 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
hypertensive crisis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
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			
soft tissue inflammation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
adjustment disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
forearm fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injury corneal			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mouth injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scapula fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
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			
brain oedema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral haemorrhage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolic stroke			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tremor			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
corneal erosion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	2 / 93 (2.15%)	1 / 184 (0.54%)	2 / 92 (2.17%)
occurrences causally related to treatment / all	1 / 2	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertrophic scar			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
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			
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
flank pain			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal stenosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tenosynovitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
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			
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
corneal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fracture infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

papilloma viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
periorbital cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 24 (12.50%)	4 / 25 (16.00%)	3 / 16 (18.75%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma of colon			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bowen's disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemangioma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[1]	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
hypertensive crisis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
soft tissue inflammation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
adjustment disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
forearm fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injury corneal			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mouth injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scapula fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
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			
brain oedema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral haemorrhage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (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
embolic stroke			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (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
ischaemic stroke			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tremor			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
corneal erosion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertrophic scar			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
flank pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal stenosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tenosynovitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
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			
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
corneal abscess			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fracture infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papilloma viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
periorbital cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (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
staphylococcal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
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	Long Term Extension Substudy 4mg to 4mg	LTE Placebo (Responders/Partial Responders)	LTE 1 mg Baricitinib (Responders/Partial Responders)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 16 (18.75%)	1 / 29 (3.45%)	1 / 34 (2.94%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma of colon			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bowen's disease			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemangioma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[1]	0 / 8 (0.00%)	0 / 15 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
hypertensive crisis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
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			
soft tissue inflammation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
adjustment disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

ankle fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
forearm fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injury corneal			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (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
meniscus injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (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
mouth injury			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scapula fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
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			
brain oedema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral haemorrhage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolic stroke			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tremor			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
corneal erosion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertrophic scar			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
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			
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
flank pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal stenosis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (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
tenosynovitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
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			
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
corneal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fracture infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papilloma viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
periorbital cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
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	LTE 2 mg Baricitinib (Responders/Partial Responders)	LTE 4 mg Baricitinib (Responders/Partial Responders)	LTE Placebo to 2 mg Baricitinib (Non-responders)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 22 (4.55%)	2 / 7 (28.57%)	1 / 11 (9.09%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma of colon			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bowen's disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemangioma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[1]	0 / 14 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
hypertensive crisis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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			
soft tissue inflammation			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
adjustment disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
forearm fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injury corneal			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mouth injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scapula fracture			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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			
brain oedema			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral haemorrhage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolic stroke			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tremor			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
corneal erosion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (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
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertrophic scar			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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			
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
flank pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal stenosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tenosynovitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
corneal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fracture infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papilloma viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

periorbital cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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	LTE Placebo to 4 mg Baricitinib (Non-responders)	LTE 1 mg Baricitinib to 2 mg Baricitinib (Non-responders)	LLTE 1 mg Baricitinib to 4 mg Baricitinib (Non-responders)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 12 (16.67%)	2 / 13 (15.38%)	3 / 14 (21.43%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma of colon			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bowen's disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemangioma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[1]	0 / 9 (0.00%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
hypertensive crisis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
soft tissue inflammation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
adjustment disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
device dislocation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
forearm fracture			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injury corneal			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mouth injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scapula fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
brain oedema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral haemorrhage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolic stroke			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tremor			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
corneal erosion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal detachment			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertrophic scar			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
bursitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
flank pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal stenosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tenosynovitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
corneal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fracture infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papilloma viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
periorbital cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia bacterial			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	LTE 2 mg Baricitinib to 2 mg Baricitinib (Non-responders)	LTE 2 mg Baricitinib to 4 mg Baricitinib (Non-responders)	LTE 4 mg Baricitinib (Non-responders)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 27 (11.11%)	5 / 26 (19.23%)	4 / 24 (16.67%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma of colon			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bowen's disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
haemangioma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
prostate cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[1]	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

hypertensive crisis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
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			
soft tissue inflammation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
adjustment disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Product issues			
device dislocation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
forearm fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injury corneal			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
meniscus injury			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mouth injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
scapula fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
brain oedema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral haemorrhage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
embolic stroke			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ischaemic stroke			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tremor			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
corneal erosion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertrophic scar			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
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			
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
flank pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc degeneration			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal stenosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tenosynovitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
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			
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (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
corneal abscess			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fracture infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
papilloma viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
periorbital cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
postoperative wound infection			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
staphylococcal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
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	1mg Baricitinib DBT		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 93 (7.53%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
adenocarcinoma of colon			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
bowen's disease			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
breast cancer				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
haemangioma				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
prostate cancer				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed[1]	0 / 58 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
squamous cell carcinoma				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
hypertensive crisis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peripheral arterial occlusive disease				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	0 / 93 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
soft tissue inflammation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
adjustment disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
suicidal ideation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Product issues			
device dislocation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			

ankle fracture				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
fall				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
forearm fracture				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
injury corneal				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ligament rupture				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
meniscus injury				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
mouth injury				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
scapula fracture				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tendon rupture				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
acute myocardial infarction				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardiac arrest				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
coronary artery disease				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myocardial ischaemia				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
brain oedema				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cerebral haemorrhage				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
embolic stroke				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ischaemic stroke				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
transient ischaemic attack				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tremor				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
conjunctivitis allergic				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
corneal erosion				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
retinal detachment				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
dermatitis atopic				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 93 (2.15%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
dyshidrotic eczema				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
eczema				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypertrophic scar				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
nephrolithiasis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
bursitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 93 (2.15%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
flank pain				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
intervertebral disc degeneration				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
spinal stenosis				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tenosynovitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
anal abscess				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cellulitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
covid-19				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
corneal abscess				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
eczema herpeticum				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
erysipelas				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
fracture infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
furuncle				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastroenteritis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
papilloma viral infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ophthalmic herpes simplex				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

perichondritis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
periorbital cellulitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peritonitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia bacterial				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
postoperative wound infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
pyelitis				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sepsis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
staphylococcal infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.

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

Non-serious adverse events	Placebo	2 mg Baricitinib	4 mg Baricitinib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 93 (53.76%)	130 / 184 (70.65%)	75 / 92 (81.52%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
hepatic adenoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
skin papilloma			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	4 / 184 (2.17%)	2 / 92 (2.17%)
occurrences (all)	0	4	2
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	5 / 184 (2.72%)	3 / 92 (3.26%)
occurrences (all)	1	5	3
orthostatic hypotension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
dental implantation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	3 / 184 (1.63%)	0 / 92 (0.00%)
occurrences (all)	0	3	0
intrauterine contraception			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
prostatectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[2]	0 / 49 (0.00%)	0 / 132 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
retinopexy			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
shoulder operation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	2 / 92 (2.17%)
occurrences (all)	0	2	2
tooth restoration			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
uterine polypectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[3]	0 / 44 (0.00%)	0 / 52 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
vasectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[4]	0 / 49 (0.00%)	0 / 132 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	3 / 184 (1.63%)	1 / 92 (1.09%)
occurrences (all)	1	3	1
fatigue			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 93 (3.23%)	2 / 184 (1.09%)	3 / 92 (3.26%)
occurrences (all)	4	2	3
implant site pain			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 93 (3.23%)	6 / 184 (3.26%)	2 / 92 (2.17%)
occurrences (all)	3	6	3
pyrexia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	3 / 184 (1.63%)	0 / 92 (0.00%)
occurrences (all)	0	3	0
swelling face			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	1	1	0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[5]	0 / 44 (0.00%)	0 / 52 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[6]	0 / 44 (0.00%)	0 / 52 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[7]	0 / 44 (0.00%)	0 / 52 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
prostatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[8]	0 / 49 (0.00%)	0 / 132 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
vaginal discharge			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed[9]	0 / 44 (0.00%)	0 / 52 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthmatic crisis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	2	2	0
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 93 (4.30%)	3 / 184 (1.63%)	1 / 92 (1.09%)
occurrences (all)	4	4	2
cough			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	9 / 184 (4.89%)	2 / 92 (2.17%)
occurrences (all)	1	10	2
nasal congestion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
oropharyngeal pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	7 / 184 (3.80%)	3 / 92 (3.26%)
occurrences (all)	1	7	3
rhinitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
depressed mood			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 93 (1.08%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	1	1	0
insomnia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)	3 / 184 (1.63%)	2 / 92 (2.17%)
occurrences (all)	2	4	2
premature ejaculation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[10]	0 / 49 (0.00%)	0 / 132 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
stress			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	1 / 92 (1.09%)
occurrences (all)	0	1	1
somatic symptom disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)	5 / 184 (2.72%)	1 / 92 (1.09%)
occurrences (all)	2	5	1
arthroscopy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	1 / 184 (0.54%)	2 / 92 (2.17%)
occurrences (all)	1	1	2
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	2 / 93 (2.15%)	3 / 184 (1.63%)	2 / 92 (2.17%)
occurrences (all)	2	3	2
blood alkaline phosphatase increased alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
blood creatinine increased alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	2	0	0
blood triglycerides increased alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	1 / 184 (0.54%)	1 / 92 (1.09%)
occurrences (all)	1	1	1
colonoscopy alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
lymphocyte count decreased alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	2 / 92 (2.17%)
occurrences (all)	0	0	2
prostatic specific antigen increased alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[11]	0 / 49 (0.00%)	0 / 132 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
sars-cov-2 test positive alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
sars-cov-2 antibody test positive alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0

weight increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	2 / 184 (1.09%)	2 / 92 (2.17%)
occurrences (all)	1	2	2
Injury, poisoning and procedural complications			
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
ligament sprain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	2 / 92 (2.17%)
occurrences (all)	0	0	2
meniscus injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	0	2	0
post vaccination syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used:			

MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	3 / 184 (1.63%)	0 / 92 (0.00%)
occurrences (all)	0	3	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	0	2	0
headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	8 / 93 (8.60%)	14 / 184 (7.61%)	10 / 92 (10.87%)
occurrences (all)	10	17	13
migraine			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	1	2	0
neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	1	0	1
paraesthesia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
post herpetic neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
tension headache			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 93 (1.08%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
eosinophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
iron deficiency anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
leukopenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	1	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	1 / 92 (1.09%)
occurrences (all)	0	1	1
lymphopenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	0	2	0
neutrophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
deafness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	1	0	1
vertigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	4 / 184 (2.17%)	0 / 92 (0.00%)
occurrences (all)	1	4	0
conjunctival irritation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 93 (3.23%)	3 / 184 (1.63%)	0 / 92 (0.00%)
occurrences (all)	3	3	0
dry eye			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 93 (4.30%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	4	0	0
glaucoma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
keratoconus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
lacrimation increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
noninfective conjunctivitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
vitreous floaters			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 93 (3.23%)	7 / 184 (3.80%)	5 / 92 (5.43%)
occurrences (all)	3	7	6
constipation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	4 / 184 (2.17%)	0 / 92 (0.00%)
occurrences (all)	0	4	0
dental caries			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	0	2	0
diarrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 93 (3.23%)	9 / 184 (4.89%)	6 / 92 (6.52%)
occurrences (all)	3	10	6
dyspepsia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	2 / 92 (2.17%)
occurrences (all)	0	2	3
frequent bowel movements			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
gastritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	1	2	0
nausea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	8 / 184 (4.35%)	2 / 92 (2.17%)
occurrences (all)	0	11	2
stomatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	0	1	0

Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	1 / 184 (0.54%)	1 / 92 (1.09%)
occurrences (all)	1	1	1
actinic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	1 / 92 (1.09%)
occurrences (all)	0	1	2
acne			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	8 / 184 (4.35%)	3 / 92 (3.26%)
occurrences (all)	0	8	3
dermatitis acneiform			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
dermatitis exfoliative generalised			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
dermatitis contact			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	2 / 92 (2.17%)
occurrences (all)	0	0	2
diffuse alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	0	2	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	3 / 184 (1.63%)	1 / 92 (1.09%)
occurrences (all)	0	4	1
hyperhidrosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
milia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
miliaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
onycholysis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
rash papular			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
skin disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)	2 / 184 (1.09%)	2 / 92 (2.17%)
occurrences (all)	2	2	2

Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	3 / 92 (3.26%)
occurrences (all)	0	0	4
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	7 / 184 (3.80%)	5 / 92 (5.43%)
occurrences (all)	1	8	5
back pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	5 / 93 (5.38%)	6 / 184 (3.26%)	6 / 92 (6.52%)
occurrences (all)	6	7	9
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	0	2	0
muscle contracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	1 / 92 (1.09%)
occurrences (all)	0	1	1
myalgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	3 / 184 (1.63%)	1 / 92 (1.09%)
occurrences (all)	1	4	1
muscle spasms			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
neck pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	1	2	0
pain in extremity			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)	5 / 184 (2.72%)	2 / 92 (2.17%)
occurrences (all)	2	6	2
rotator cuff syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
tendon disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	0	2	0
tenosynovitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
bacterial infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	2 / 92 (2.17%)
occurrences (all)	0	1	2
bronchitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	2 / 93 (2.15%)	7 / 184 (3.80%)	1 / 92 (1.09%)
occurrences (all)	2	9	1
candida infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	0	4	0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	2 / 184 (1.09%)	2 / 92 (2.17%)
occurrences (all)	3	3	2
conjunctivitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	3 / 184 (1.63%)	5 / 92 (5.43%)
occurrences (all)	1	4	5
cystitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
dermatophytosis of nail			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
dermatitis infected			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	9 / 184 (4.89%)	1 / 92 (1.09%)
occurrences (all)	0	9	1

ear infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	2 / 92 (2.17%)
occurrences (all)	0	3	4
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	4 / 184 (2.17%)	4 / 92 (4.35%)
occurrences (all)	2	5	5
folliculitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)	9 / 184 (4.89%)	0 / 92 (0.00%)
occurrences (all)	3	10	0
furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 93 (3.23%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	3	1	0
gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	4 / 184 (2.17%)	2 / 92 (2.17%)
occurrences (all)	0	5	2
genital candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
genital infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
herpes simplex			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 93 (1.08%)	5 / 184 (2.72%)	6 / 92 (6.52%)
occurrences (all)	2	5	7
herpes zoster			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	6 / 184 (3.26%)	3 / 92 (3.26%)
occurrences (all)	0	6	3
hordeolum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	2 / 92 (2.17%)
occurrences (all)	0	0	2
impetigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	5 / 184 (2.72%)	1 / 92 (1.09%)
occurrences (all)	1	5	1
influenza			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)	15 / 184 (8.15%)	14 / 92 (15.22%)
occurrences (all)	2	18	15
labyrinthitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	3 / 184 (1.63%)	0 / 92 (0.00%)
occurrences (all)	0	3	0
nasopharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	14 / 93 (15.05%)	36 / 184 (19.57%)	34 / 92 (36.96%)
occurrences (all)	25	48	45
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	3 / 184 (1.63%)	0 / 92 (0.00%)
occurrences (all)	0	3	0

oral herpes			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	6 / 93 (6.45%)	6 / 184 (3.26%)	7 / 92 (7.61%)
occurrences (all)	6	9	13
otitis externa			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	3 / 184 (1.63%)	1 / 92 (1.09%)
occurrences (all)	0	3	1
paronychia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	2 / 92 (2.17%)
occurrences (all)	0	0	2
peritonsillar abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
pharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 93 (4.30%)	4 / 184 (2.17%)	1 / 92 (1.09%)
occurrences (all)	4	4	1
pneumonia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	1 / 184 (0.54%)	0 / 92 (0.00%)
occurrences (all)	0	1	0
post-acute covid-19 syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
pyoderma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	0	2	0
rhinitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	6 / 184 (3.26%)	3 / 92 (3.26%)
occurrences (all)	1	6	3
skin infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	4 / 184 (2.17%)	4 / 92 (4.35%)
occurrences (all)	1	4	5
suspected covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	1	0	1
tonsillitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)	5 / 184 (2.72%)	1 / 92 (1.09%)
occurrences (all)	1	5	1
tooth infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	2 / 184 (1.09%)	0 / 92 (0.00%)
occurrences (all)	0	2	0

urinary tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	4 / 184 (2.17%)	5 / 92 (5.43%)
occurrences (all)	0	7	5
upper respiratory tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	7 / 184 (3.80%)	4 / 92 (4.35%)
occurrences (all)	0	10	5
vaginal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[12]	1 / 44 (2.27%)	0 / 52 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[13]	0 / 44 (0.00%)	2 / 52 (3.85%)	0 / 35 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	1 / 92 (1.09%)
occurrences (all)	0	0	1
folate deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
glucose tolerance impaired			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)	3 / 184 (1.63%)	0 / 92 (0.00%)
occurrences (all)	0	3	0
hyperglycaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	3 / 184 (1.63%)	0 / 92 (0.00%)
occurrences (all)	0	3	0
hyperlipidaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
iron deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)	0 / 184 (0.00%)	0 / 92 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	LTE Substudy 2 mg Baricitinib to 1 mg Baricitinib	LTE Substudy 2 mg Baricitinib to 2 mg Baricitinib	LTE Substudy 4 mg Baricitinib to 2 mg Baricitinib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 24 (70.83%)	16 / 25 (64.00%)	13 / 16 (81.25%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hepatic adenoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
seborrhoeic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 16 (6.25%)
occurrences (all)	0	3	1
orthostatic hypotension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

dental implantation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
intrauterine contraception			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
prostatectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[2]	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
retinopexy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
shoulder operation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
tooth restoration			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
uterine polypectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[3]	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
vasectomy			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed[4]	0 / 21 (0.00%)	0 / 20 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
implant site pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	2 / 16 (12.50%)
occurrences (all)	1	0	2
swelling face			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[5]	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed[6]	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[7]	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
prostatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[8]	1 / 21 (4.76%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
vaginal discharge			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[9]	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthmatic crisis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	2 / 25 (8.00%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
cough			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
nasal congestion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
oropharyngeal pain			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
rhinitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
depressed mood			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
premature ejaculation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[10]	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
stress			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
somatic symptom disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	2	0	1
arthroscopy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
blood creatinine increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
blood triglycerides increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
colonoscopy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
prostatic specific antigen increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[11]	0 / 21 (0.00%)	0 / 20 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
sars-cov-2 test positive			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
sars-cov-2 antibody test positive			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
weight increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
meniscus injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
post vaccination syndrome			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
procedural pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
rib fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	5 / 25 (20.00%)	1 / 16 (6.25%)
occurrences (all)	2	5	1
migraine			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
post herpetic neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tension headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
eosinophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
iron deficiency anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
leukopenia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
neutrophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
deafness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	2
vertigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
conjunctival irritation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
dry eye			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
glaucoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
keratoconus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
lacrimation increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
noninfective conjunctivitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

vitreous floaters			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
dental caries			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
diarrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	2 / 16 (12.50%)
occurrences (all)	0	1	2
dyspepsia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
frequent bowel movements			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
nausea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
stomatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
acne			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
dermatitis acneiform			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dermatitis exfoliative generalised			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
diffuse alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
milia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
miliaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
onycholysis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1

rash papular			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
skin disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
skin ulcer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
urticaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	2 / 16 (12.50%)
occurrences (all)	1	0	2
back pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
muscle contracture			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
muscle spasms			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
neck pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 24 (12.50%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
tendon disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
bacterial infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
candida infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 24 (12.50%)	4 / 25 (16.00%)	1 / 16 (6.25%)
occurrences (all)	3	5	1
cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
cystitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
dermatophytosis of nail			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
dermatitis infected			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
ear infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	2 / 25 (8.00%)	0 / 16 (0.00%)
occurrences (all)	1	3	0
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	2 / 16 (12.50%)
occurrences (all)	1	0	3
folliculitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0

furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
genital candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
genital infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 24 (8.33%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	2	2	0
herpes zoster			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
hordeolum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 24 (8.33%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
impetigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
influenza			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 24 (4.17%)	3 / 25 (12.00%)	1 / 16 (6.25%)
occurrences (all)	1	3	1
labyrinthitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	8 / 24 (33.33%)	3 / 25 (12.00%)	3 / 16 (18.75%)
occurrences (all)	11	4	3
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
oral herpes			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	2 / 25 (8.00%)	0 / 16 (0.00%)
occurrences (all)	1	4	0
otitis externa			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
peritonsillar abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
post-acute covid-19 syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pyoderma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	3
rhinitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
skin infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
suspected covid-19			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
tinea pedis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
tonsillitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
tooth infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	3 / 16 (18.75%)
occurrences (all)	0	0	3
vaginal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[12]	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

vulvovaginal candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[13]	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
folate deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
glucose tolerance impaired			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
hypercholesterolaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
hyperglycaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
hypertriglyceridaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	1 / 25 (4.00%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
hyperlipidaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
iron deficiency			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1

Non-serious adverse events	Long Term Extension Substudy 4mg to 4mg	LTE Placebo (Responders/Partial Responders)	LTE 1 mg Baricitinib (Responders/Partial Responders)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 16 (100.00%)	16 / 29 (55.17%)	25 / 34 (73.53%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
hepatic adenoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	2 / 16 (12.50%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	2	1	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 16 (12.50%)	2 / 29 (6.90%)	0 / 34 (0.00%)
occurrences (all)	2	2	0
orthostatic hypotension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
dental implantation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
intrauterine contraception			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
prostatectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[2]	0 / 8 (0.00%)	0 / 15 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
retinopexy			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
shoulder operation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	1 / 34 (2.94%)
occurrences (all)	0	1	1
tooth restoration			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
uterine polypectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[3]	0 / 8 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
vasectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[4]	0 / 8 (0.00%)	0 / 15 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
fatigue			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
implant site pain			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 16 (12.50%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	2	1	0
pyrexia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
swelling face			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[5]	0 / 8 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[6]	0 / 8 (0.00%)	0 / 14 (0.00%)	3 / 13 (23.08%)
occurrences (all)	0	0	9
ovarian cyst			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[7]	0 / 8 (0.00%)	0 / 14 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
prostatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[8]	0 / 8 (0.00%)	0 / 15 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
vaginal discharge			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed[9]	1 / 8 (12.50%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
asthmatic crisis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 16 (12.50%)	1 / 29 (3.45%)	1 / 34 (2.94%)
occurrences (all)	2	2	1
nasal congestion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	0	2	0
rhinitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	2
insomnia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	1 / 34 (2.94%)
occurrences (all)	0	1	2
premature ejaculation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[10]	0 / 8 (0.00%)	0 / 15 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
stress			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
somatic symptom disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	2
arthroscopy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
blood creatinine increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
colonoscopy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
prostatic specific antigen increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[11]	0 / 8 (0.00%)	0 / 15 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
sars-cov-2 test positive			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
sars-cov-2 antibody test positive			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0

weight increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	1	1	0
ligament sprain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 16 (12.50%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	2	0	0
post vaccination syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	2 / 29 (6.90%)	2 / 34 (5.88%)
occurrences (all)	0	2	2
procedural pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
tooth fracture			
alternative dictionary used:			

MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	2 / 34 (5.88%)
occurrences (all)	0	1	2
migraine			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	5
neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
paraesthesia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	2	0	0
post herpetic neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
tension headache			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
eosinophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
leukopenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
lymphopenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
neutrophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
thrombocytosis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
deafness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
conjunctival irritation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	4 / 29 (13.79%)	1 / 34 (2.94%)
occurrences (all)	1	4	1
dry eye			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
glaucoma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
keratoconus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
lacrimation increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
noninfective conjunctivitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
vitreous floaters			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1
constipation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
diarrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	1 / 34 (2.94%)
occurrences (all)	0	1	1
dyspepsia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
frequent bowel movements			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
gastritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	1 / 29 (3.45%)	1 / 34 (2.94%)
occurrences (all)	1	1	1
nausea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1

Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
actinic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1
acne			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	3 / 34 (8.82%)
occurrences (all)	1	0	4
dermatitis acneiform			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
dermatitis exfoliative generalised			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
diffuse alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	3
hyperhidrosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
milia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
miliaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
onycholysis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
rash papular			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
skin disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	1 / 29 (3.45%)	1 / 34 (2.94%)
occurrences (all)	1	1	1

Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	2 / 34 (5.88%)
occurrences (all)	0	1	2
back pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	2 / 29 (6.90%)	0 / 34 (0.00%)
occurrences (all)	0	3	0
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
muscle contracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	2
muscle spasms			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
neck pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
pain in extremity			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	1 / 29 (3.45%)	1 / 34 (2.94%)
occurrences (all)	1	1	1
rotator cuff syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
tendon disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
tenosynovitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
bacterial infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	3 / 16 (18.75%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	3	0	0
candida infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 16 (25.00%)	4 / 29 (13.79%)	6 / 34 (17.65%)
occurrences (all)	4	5	6
cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
conjunctivitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1
cystitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
dermatophytosis of nail			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
dermatitis infected			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
ear infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	1	1	0

ear infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	1 / 34 (2.94%)
occurrences (all)	0	1	1
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	2 / 34 (5.88%)
occurrences (all)	1	0	2
furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
genital candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
genital infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
herpes simplex			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	3 / 16 (18.75%)	2 / 29 (6.90%)	0 / 34 (0.00%)
occurrences (all)	5	3	0
herpes zoster			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 16 (12.50%)	0 / 29 (0.00%)	3 / 34 (8.82%)
occurrences (all)	2	0	3
hordeolum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
impetigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1
influenza			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 16 (12.50%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	2	1	0
labyrinthitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 16 (18.75%)	3 / 29 (10.34%)	4 / 34 (11.76%)
occurrences (all)	7	3	5
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0

oral herpes			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1
otitis externa			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
peritonsillar abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	2 / 34 (5.88%)
occurrences (all)	0	0	2
pneumonia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
post-acute covid-19 syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
pyoderma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 16 (12.50%)	0 / 29 (0.00%)	2 / 34 (5.88%)
occurrences (all)	2	0	3
skin infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	1	1	0
suspected covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
tooth infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	0	1	0

urinary tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 16 (12.50%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	2	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 29 (3.45%)	0 / 34 (0.00%)
occurrences (all)	0	2	0
vaginal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[12]	0 / 8 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[13]	0 / 8 (0.00%)	0 / 14 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
folate deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
glucose tolerance impaired			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	1 / 34 (2.94%)
occurrences (all)	1	0	1
hyperglycaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
iron deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
obesity			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 29 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 16 (0.00%)	2 / 29 (6.90%)	0 / 34 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	LTE 2 mg Baricitinib (Responders/Partial Responders)	LTE 4 mg Baricitinib (Responders/Partial Responders)	LTE Placebo to 2 mg Baricitinib (Non-responders)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 22 (72.73%)	7 / 7 (100.00%)	6 / 11 (54.55%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
hepatic adenoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	2 / 7 (28.57%)	1 / 11 (9.09%)
occurrences (all)	1	2	1
orthostatic hypotension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

dental implantation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
intrauterine contraception			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
prostatectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[2]	0 / 14 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
retinopexy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
shoulder operation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
tooth restoration			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
uterine polypectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[3]	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
vasectomy			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed[4]	0 / 14 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
implant site pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
influenza like illness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
swelling face			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[5]	1 / 8 (12.50%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed[6]	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[7]	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
prostatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[8]	0 / 14 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
vaginal discharge			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[9]	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthmatic crisis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
cough			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
nasal congestion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
rhinitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
depressed mood			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
premature ejaculation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[10]	1 / 14 (7.14%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
stress			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
somatic symptom disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
arthroscopy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
blood creatinine increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
colonoscopy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
prostatic specific antigen increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[11]	0 / 14 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
sars-cov-2 test positive			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
sars-cov-2 antibody test positive			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
meniscus injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
post vaccination syndrome			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	2 / 22 (9.09%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
procedural pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
migraine			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
post herpetic neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
tension headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
eosinophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
leukopenia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
lymphopenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
neutrophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
deafness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
conjunctival irritation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
dry eye			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
glaucoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
keratoconus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
lacrimation increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
noninfective conjunctivitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

vitreous floaters			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
constipation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
frequent bowel movements			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
nausea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
stomatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
toothache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
acne			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
dermatitis acneiform			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
dermatitis exfoliative generalised			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
diffuse alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
milia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
miliaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
onycholysis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

rash papular			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
skin disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
muscle contracture			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	2
muscle spasms			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
pain in extremity			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	2
rotator cuff syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
tendon disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
tendonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
tenosynovitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
bacterial infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
bronchitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
candida infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 22 (18.18%)	2 / 7 (28.57%)	1 / 11 (9.09%)
occurrences (all)	4	2	1
cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
conjunctivitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
dermatophytosis of nail			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
dermatitis infected			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
ear infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1

furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	2 / 7 (28.57%)	1 / 11 (9.09%)
occurrences (all)	0	2	1
genital candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
genital infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
herpes zoster			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 22 (13.64%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	3	2	0
hordeolum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
impetigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
labyrinthitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	5 / 22 (22.73%)	4 / 7 (57.14%)	1 / 11 (9.09%)
occurrences (all)	5	5	2
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
oral herpes			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 22 (13.64%)	2 / 7 (28.57%)	1 / 11 (9.09%)
occurrences (all)	3	2	3
otitis externa			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
paronychia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
peritonsillar abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
pharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	2 / 7 (28.57%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
pneumonia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
post-acute covid-19 syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
pyoderma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 22 (9.09%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
skin infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
suspected covid-19			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
vaginal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[12]	0 / 8 (0.00%)	0 / 4 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

vulvovaginal candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[13]	1 / 8 (12.50%)	1 / 4 (25.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
folate deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
glucose tolerance impaired			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 22 (4.55%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
iron deficiency			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
vitamin d deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 22 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	LTE Placebo to 4 mg Baricitinib (Non-responders)	LTE 1 mg Baricitinib to 2 mg Baricitinib (Non-responders)	LLTE 1 mg Baricitinib to 4 mg Baricitinib (Non-responders)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 12 (83.33%)	11 / 13 (84.62%)	13 / 14 (92.86%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
hepatic adenoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
skin papilloma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
orthostatic hypotension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dental implantation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
intrauterine contraception			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
prostatectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[2]	0 / 9 (0.00%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
retinopexy			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
shoulder operation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
tooth extraction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tooth restoration			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
uterine polypectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[3]	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
vasectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[4]	0 / 9 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
fatigue			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
implant site pain			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
pyrexia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	2 / 13 (15.38%)	1 / 14 (7.14%)
occurrences (all)	0	3	1
swelling face			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[5]	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[6]	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[7]	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
prostatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[8]	0 / 9 (0.00%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
vaginal discharge			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed[9]	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthmatic crisis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
rhinitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
premature ejaculation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[10]	0 / 9 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
stress			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
somatic symptom disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
arthroscopy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood creatinine increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
colonoscopy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
prostatic specific antigen increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[11]	0 / 9 (0.00%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
sars-cov-2 test positive			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
sars-cov-2 antibody test positive			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

weight increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
meniscus injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
post vaccination syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
procedural pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
rib fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tooth fracture			
alternative dictionary used:			

MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
migraine			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 12 (16.67%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
post herpetic neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
tension headache			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
eosinophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
iron deficiency anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
leukopenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
lymphadenopathy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
lymphopenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
neutrophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
deafness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
ear pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
conjunctival irritation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
dry eye			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
glaucoma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
keratoconus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lacrimation increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
noninfective conjunctivitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
vitreous floaters			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 12 (16.67%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
constipation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
dental caries			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
diarrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
dyspepsia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
frequent bowel movements			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0

Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
actinic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
acne			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
dermatitis acneiform			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dermatitis exfoliative generalised			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
dermatitis contact			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
diffuse alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
milia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
miliaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
onycholysis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rash papular			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
muscle contracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
myalgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
muscle spasms			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pain in extremity			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tendon disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
tenosynovitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bacterial infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
bronchitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
candida infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	3 / 14 (21.43%)
occurrences (all)	0	1	4
cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	3
cystitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
dermatophytosis of nail			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
dermatitis infected			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
ear infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0

ear infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
folliculitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	1 / 13 (7.69%)	1 / 14 (7.14%)
occurrences (all)	2	1	1
furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
genital candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
genital infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
herpes simplex			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	2 / 13 (15.38%)	1 / 14 (7.14%)
occurrences (all)	0	2	1
herpes zoster			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	2 / 13 (15.38%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
hordeolum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
impetigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
influenza			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
labyrinthitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
molluscum contagiosum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
nasopharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	6 / 12 (50.00%)	2 / 13 (15.38%)	1 / 14 (7.14%)
occurrences (all)	7	2	1
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 12 (16.67%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0

oral herpes			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	2 / 13 (15.38%)	0 / 14 (0.00%)
occurrences (all)	3	3	0
otitis externa			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
paronychia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
peritonsillar abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
post-acute covid-19 syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
pyoderma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
pulpitis dental			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
suspected covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
subcutaneous abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
tonsillitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

urinary tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
vaginal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[12]	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[13]	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
folate deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
glucose tolerance impaired			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
iron deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Non-serious adverse events	LTE 2 mg Baricitinib to 2 mg Baricitinib (Non-responders)	LTE 2 mg Baricitinib to 4 mg Baricitinib (Non-responders)	LTE 4 mg Baricitinib (Non-responders)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 27 (66.67%)	18 / 26 (69.23%)	16 / 24 (66.67%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
hepatic adenoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
seborrhoeic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
skin papilloma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
orthostatic hypotension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2

dental implantation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
intrauterine contraception			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
prostatectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[2]	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
retinopexy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
shoulder operation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
tooth extraction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	2 / 26 (7.69%)	2 / 24 (8.33%)
occurrences (all)	0	2	2
tooth restoration			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
uterine polypectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[3]	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
vasectomy			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed[4]	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
implant site pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
pyrexia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	1 / 26 (3.85%)	1 / 24 (4.17%)
occurrences (all)	3	1	1
swelling face			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[5]	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed[6]	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
ovarian cyst			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[7]	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
prostatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[8]	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
vaginal discharge			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[9]	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthmatic crisis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 27 (7.41%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
cough			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
nasal congestion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
oropharyngeal pain			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
rhinitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
depressed mood			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
premature ejaculation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[10]	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
stress			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
somatic symptom disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
arthroscopy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 27 (7.41%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 27 (7.41%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	2	0	1
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
blood creatinine increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
blood triglycerides increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
colonoscopy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
lymphocyte count decreased			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 27 (3.70%)	1 / 26 (3.85%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
prostatic specific antigen increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[11]	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
sars-cov-2 test positive			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
sars-cov-2 antibody test positive			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
meniscus injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
post vaccination syndrome			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	2 / 26 (7.69%)	2 / 24 (8.33%)
occurrences (all)	0	3	5
procedural pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
rib fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	2 / 26 (7.69%)	1 / 24 (4.17%)
occurrences (all)	0	2	1
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
tooth fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	2 / 26 (7.69%)	1 / 24 (4.17%)
occurrences (all)	1	2	3
migraine			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
paraesthesia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
post herpetic neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
tension headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
eosinophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
leukopenia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
lymphadenopathy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
neutrophilia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
deafness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
ear pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
vertigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
conjunctival irritation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
dry eye			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
glaucoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
keratoconus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
lacrimation increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
noninfective conjunctivitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

vitreous floaters			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
constipation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
dental caries			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
dyspepsia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
frequent bowel movements			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
stomatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
toothache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
actinic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
acne			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
dermatitis acneiform			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
dermatitis atopic			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
dermatitis exfoliative generalised			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
diffuse alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
milia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
miliaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
onycholysis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

rash papular			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
skin disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
skin ulcer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
back pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	1 / 26 (3.85%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
muscle contracture			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
rotator cuff syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
tendon disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 27 (7.41%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
tenosynovitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
bacterial infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
bronchitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 27 (7.41%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	2	0	1
candida infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
covid-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 27 (14.81%)	5 / 26 (19.23%)	4 / 24 (16.67%)
occurrences (all)	5	5	5
cellulitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	2 / 26 (7.69%)	1 / 24 (4.17%)
occurrences (all)	0	8	3
conjunctivitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	2
cystitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
dermatophytosis of nail			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
dermatitis infected			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
ear infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
eczema herpeticum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	2 / 26 (7.69%)	2 / 24 (8.33%)
occurrences (all)	0	2	2
erysipelas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
folliculitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 27 (7.41%)	1 / 26 (3.85%)	1 / 24 (4.17%)
occurrences (all)	2	3	3

furuncle			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	2 / 24 (8.33%)
occurrences (all)	1	0	2
gastroenteritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
genital candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
genital infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	2 / 24 (8.33%)
occurrences (all)	1	0	3
herpes zoster			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	4 / 26 (15.38%)	1 / 24 (4.17%)
occurrences (all)	1	4	1
hordeolum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
impetigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
influenza			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	2 / 27 (7.41%)	2 / 26 (7.69%)	1 / 24 (4.17%)
occurrences (all)	2	2	1
labyrinthitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
molluscum contagiosum			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
nasopharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 27 (11.11%)	3 / 26 (11.54%)	2 / 24 (8.33%)
occurrences (all)	3	3	3
ophthalmic herpes simplex			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
oral herpes			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	2
otitis externa			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
paronychia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
peritonsillar abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

perichondritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
post-acute covid-19 syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
pyoderma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	4 / 26 (15.38%)	1 / 24 (4.17%)
occurrences (all)	1	6	1
suspected covid-19			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
tooth infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 27 (3.70%)	0 / 26 (0.00%)	3 / 24 (12.50%)
occurrences (all)	1	0	4
vaginal infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[12]	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
viral infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

vulvovaginal candidiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[13]	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
folate deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
glucose tolerance impaired			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	1 / 26 (3.85%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
hyperglycaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
hypertriglyceridaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 27 (7.41%)	1 / 26 (3.85%)	0 / 24 (0.00%)
occurrences (all)	2	2	0
hyperlipidaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
iron deficiency			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
obesity			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 27 (0.00%)	0 / 26 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	1mg Baricitinib DBT		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	63 / 93 (67.74%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
anogenital warts			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
hepatic adenoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
seborrhoeic keratosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
skin papilloma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		

Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 93 (3.23%)		
occurrences (all)	3		
orthostatic hypotension			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
Surgical and medical procedures			
abscess drainage			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
dental implantation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
intrauterine contraception			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
prostatectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[2]	0 / 58 (0.00%)		
occurrences (all)	0		
retinopexy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
shoulder operation			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
tooth extraction			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
tooth restoration			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
uterine polypectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[3]	0 / 35 (0.00%)		
occurrences (all)	0		
vasectomy			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[4]	0 / 58 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
fatigue			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 93 (3.23%)		
occurrences (all)	3		
implant site pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
influenza like illness			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
pyrexia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 93 (3.23%)		
occurrences (all)	4		
swelling face			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[5]	0 / 35 (0.00%)		
occurrences (all)	0		
dysmenorrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[6]	2 / 35 (5.71%)		
occurrences (all)	3		
ovarian cyst			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[7]	0 / 35 (0.00%)		
occurrences (all)	0		
prostatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[8]	0 / 58 (0.00%)		
occurrences (all)	0		
vaginal discharge			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed[9]	0 / 35 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
asthmatic crisis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
asthma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	2		
cough			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)		
occurrences (all)	2		
nasal congestion			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)		
occurrences (all)	2		
oropharyngeal pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	7 / 93 (7.53%)		
occurrences (all)	10		
rhinitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
depressed mood			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
insomnia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	2 / 93 (2.15%)			
occurrences (all)	3			
premature ejaculation				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed[10]	0 / 58 (0.00%)			
occurrences (all)	0			
stress				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
somatic symptom disorder				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
Investigations				
alanine aminotransferase increased				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
arthroscopy				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
aspartate aminotransferase increased				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
blood creatine phosphokinase increased				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 93 (3.23%)			
occurrences (all)	3			
blood alkaline phosphatase increased				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
blood creatinine increased				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
blood triglycerides increased				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
colonoscopy				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
lymphocyte count decreased				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
prostatic specific antigen increased				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed[11]	0 / 58 (0.00%)			
occurrences (all)	0			
sars-cov-2 test positive				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
sars-cov-2 antibody test positive				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
weight increased				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			

Injury, poisoning and procedural complications			
ligament rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
ligament sprain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)		
occurrences (all)	3		
meniscus injury			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
post vaccination syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
procedural pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
rib fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)		
occurrences (all)	2		
tendon rupture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
tooth fracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
Cardiac disorders			

angina pectoris			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	8 / 93 (8.60%)		
occurrences (all)	15		
migraine			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
paraesthesia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
post herpetic neuralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
tension headache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			

anaemia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
eosinophilia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
iron deficiency anaemia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
leukopenia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
lymphadenopathy				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
lymphopenia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	2			
neutrophilia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
thrombocytosis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
Ear and labyrinth disorders				

deafness			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
ear pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
vertigo			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
conjunctival irritation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
conjunctivitis allergic			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
dry eye			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
glaucoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
keratoconus			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
lacrimation increased			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
noninfective conjunctivitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
retinal detachment			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
vitreous floaters			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)		
occurrences (all)	3		
constipation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
dental caries			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
diarrhoea			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	2 / 93 (2.15%)		
occurrences (all)	2		
dyspepsia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)		
occurrences (all)	3		
frequent bowel movements			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
gastritis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
nausea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)		
occurrences (all)	2		
stomatitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
toothache			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	2 / 93 (2.15%)			
occurrences (all)	2			
actinic keratosis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
acne				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	4 / 93 (4.30%)			
occurrences (all)	5			
dermatitis acneiform				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
dermatitis atopic				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
dermatitis exfoliative generalised				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
dermatitis contact				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
diffuse alopecia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
dyshidrotic eczema				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 93 (2.15%)			
occurrences (all)	2			

hyperhidrosis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
milia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
miliaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
onycholysis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
rash papular			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
skin disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
skin ulcer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
urticaria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
Renal and urinary disorders			

dysuria			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 93 (4.30%)		
occurrences (all)	4		
back pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	6 / 93 (6.45%)		
occurrences (all)	9		
bursitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 93 (3.23%)		
occurrences (all)	4		
muscle contracture			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
myalgia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	3 / 93 (3.23%)		
occurrences (all)	4		
muscle spasms			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
neck pain			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
pain in extremity			
alternative dictionary used:			

MedDRA 25.1			
subjects affected / exposed	2 / 93 (2.15%)		
occurrences (all)	2		
rotator cuff syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
tendon disorder			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
tendonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
tenosynovitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
anal abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
bacterial infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
bronchitis			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	3 / 93 (3.23%)			
occurrences (all)	3			
candida infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
covid-19				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
cellulitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
conjunctivitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
cystitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
dermatophytosis of nail				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
dermatitis infected				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
ear infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			

ear infection bacterial				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
eczema herpeticum				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
erysipelas				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
folliculitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	9 / 93 (9.68%)			
occurrences (all)	11			
furuncle				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
gastroenteritis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 93 (2.15%)			
occurrences (all)	2			
genital candidiasis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
genital infection bacterial				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
herpes simplex				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
herpes zoster				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	4 / 93 (4.30%)			
occurrences (all)	4			
hordeolum				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
impetigo				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
influenza				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 93 (3.23%)			
occurrences (all)	4			
labyrinthitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
molluscum contagiosum				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
nasopharyngitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	16 / 93 (17.20%)			
occurrences (all)	20			
ophthalmic herpes simplex				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			

oral herpes				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	5 / 93 (5.38%)			
occurrences (all)	7			
otitis externa				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
paronychia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
peritonsillar abscess				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
perichondritis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
pharyngitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
pneumonia				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 93 (2.15%)			
occurrences (all)	2			
post-acute covid-19 syndrome				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
pyoderma				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
pulpitis dental				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 93 (2.15%)			
occurrences (all)	2			
rhinitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
skin infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	3 / 93 (3.23%)			
occurrences (all)	4			
suspected covid-19				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
subcutaneous abscess				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
tinea pedis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	2 / 93 (2.15%)			
occurrences (all)	2			
tonsillitis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
tooth infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			

urinary tract infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	1 / 93 (1.08%)			
occurrences (all)	1			
upper respiratory tract infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	4 / 93 (4.30%)			
occurrences (all)	5			
vaginal infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed[12]	0 / 35 (0.00%)			
occurrences (all)	0			
viral infection				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
vulvovaginal candidiasis				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed[13]	0 / 35 (0.00%)			
occurrences (all)	0			
Metabolism and nutrition disorders				
decreased appetite				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
folate deficiency				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
glucose tolerance impaired				
alternative dictionary used: MedDRA 25.1				
subjects affected / exposed	0 / 93 (0.00%)			
occurrences (all)	0			
hypercholesterolaemia				
alternative dictionary used: MedDRA 25.1				

subjects affected / exposed	1 / 93 (1.08%)		
occurrences (all)	1		
hyperglycaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
hypertriglyceridaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
hyperlipidaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
iron deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
obesity			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		
vitamin d deficiency			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 93 (0.00%)		
occurrences (all)	0		

Notes:

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.
[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants At Risk adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 May 2019	Amendment (c): Key secondary endpoints were changed.
19 September 2019	Amendment (d): Update the Primary Endpoint from IGA 0,1 to EASI 75.
06 December 2019	Amendment (e): Updated risk information as well as the addition of a new bridging extension post week 104 (V22) of up to 96 additional weeks (for a total of 200 weeks).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported