Clinical trial results:
A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study of the Efficacy and Safety of INCB054707 in Participants With Hidradenitis Suppurativa

Summary

EudraCT number	2020-001981-13
Trial protocol	FR
Global end of trial date	16 August 2023

Results information

Result version number	v1 (current)
This version publication date	30 August 2024
First version publication date	30 August 2024

Trial information

Trial identification

Sponsor protocol code	INCB 54707-204

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cutoff Drive, Wilmington, United States, 19803
Public contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com
Scientific contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	16 August 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 August 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study was conducted to evaluate the efficacy and safety of INCB054707 in participants with hidradenitis suppurativa over a 16-week Placebo-Controlled Treatment Period followed by a 36-week Open-Label Extension Period. All eligible participants were invited to continue treatment for an additional 48-week Long-Term Extension Period (also open label).

Protection of trial subjects:

This study was to be performed in accordance with the ethical principles that have their origin in the Declaration of Helsinki and conducted in adherence to the study Protocol, applicable Good Clinical Practices, and applicable laws and country-specific regulations in which the study was conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 August 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 10
Country: Number of subjects enrolled	Germany: 9
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	Poland: 19
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	United States: 161
Worldwide total number of subjects	209
EEA total number of subjects	38

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)	205
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 209 participants were enrolled at 36 study centers: 26 in North America and 10 in Europe.

Period 1

Period 1 title	16-Week Placebo-Controlled Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received oral placebo once daily (QD) for 16 weeks in the Placebo-controlled Treatment Period.

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:

matching placebo taken once daily

Arm title	Povorcitinib 15 mg

Arm description:

Participants received oral povorcitinib 15 milligrams (mg) QD for 16 weeks in the Placebo-controlled Treatment Period.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	INCB054707
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 15-mg tablet taken once daily

Arm title	Povorcitinib 45 mg

Arm description:

Participants received oral povorcitinib 45 mg QD for 16 weeks in the Placebo-controlled Treatment Period.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	INCB054707
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Three 15-mg tablets taken once daily

Arm title	Povorcitinib 75 mg

Arm description:

Participants received oral povorcitinib 75 mg QD for 16 weeks in the Placebo-controlled Treatment Period.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	INCB054707
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Five 15-mg tablets taken once daily

Number of subjects in period 1	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg
Started	52	52	52
Completed	48	47	45
Not completed	4	5	7
Consent withdrawn by subject	1	3	4
Adverse event, non-fatal	2	-	1
Lost to follow-up	1	1	2
Protocol deviation	-	1	-

Number of subjects in period 1	Povorcitinib 75 mg
Started	53
Completed	51
Not completed	2
Consent withdrawn by subject	1
Adverse event, non-fatal	-
Lost to follow-up	1
Protocol deviation	-

Period 2

Period 2 title	36-Week Open-Label Extension Period
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo to povorcitinib 75 mg

Arm description:

Participants received oral placebo once daily (QD) for 16 weeks in the Placebo-controlled Treatment Period. At Week 16, eligible participants who opted to enter the 36-week Open-Label Extension (OLE) Period received povorcitinib 75 milligrams (mg) QD.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	INCB054707
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Five 15-mg tablets taken once daily

Arm title	Povorcitinib 15 mg to 75 mg

Arm description:

Participants received oral povorcitinib 15 milligrams (mg) QD for 16 weeks in the Placebo-controlled Treatment Period. At Week 16, eligible participants who opted to enter the 36-week Open-Label Extension Period received povorcitinib 75 mg QD.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	INCB054707
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Five 15-mg tablets taken once daily

Arm title	Povorcitinib 45 mg to 75 mg

Arm description:

Participants received oral povorcitinib 45 mg QD for 16 weeks in the Placebo-controlled Treatment Period. At Week 16, eligible participants who opted to enter the 36-week Open-Label Extension Period received povorcitinib 75 mg QD.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	INCB054707
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Five 15-mg tablets taken once daily

Arm title	Povorcitinib 75 mg

Arm description:

Participants received oral povorcitinib 75 mg QD for 16 weeks in the Placebo-controlled Treatment Period. At Week 16, eligible participants who opted to enter the 36-week Open-Label Extension Period received povorcitinib 75 mg QD.

Arm type	Experimental

Investigational medicinal product name	povorcitinib
Investigational medicinal product code	INCB054707
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Five 15-mg tablets taken once daily

Number of subjects in period 2[1]	Placebo to povorcitinib 75 mg	Povorcitinib 15 mg to 75 mg	Povorcitinib 45 mg to 75 mg
Started	43	44	42
Completed	26	32	30
Not completed	17	12	12
Non-compliance with Study Drug	1	-	-
Consent withdrawn by subject	11	5	2
Physician decision	-	2	-
Adverse event, non-fatal	1	3	-
Pregnancy	2	-	-
Lost to follow-up	1	2	7
Sponsor Request	-	-	1
Lack of Efficacy/Depression and Facial Acne	1	-	-
Lack of efficacy	-	-	1
Protocol deviation	-	-	1

Number of subjects in period 2[1]	Povorcitinib 75 mg
Started	46
Completed	31
Not completed	15
Non-compliance with Study Drug	-
Consent withdrawn by subject	3
Physician decision	1
Adverse event, non-fatal	4
Pregnancy	-
Lost to follow-up	5
Sponsor Request	-
Lack of Efficacy/Depression and Facial Acne	-
Lack of efficacy	2
Protocol deviation	-

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: Not all participants who completed the Placebo-Controlled Period decided to continue to the Open-Label Extension Period.

Period 3

Period 3 title	48-Week Long-Term Extension Period
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Povorcitinib 45 mg

Arm description:

At the completion of the Open-Label Extension (OLE) Period, all eligible participants had the option to continue treatment for an additional 48 weeks. Participants received povorcitinib 45 mg QD during the Long-Term Extension (LTE) Period based on the number of hidradenitis suppurativa (HS) lesions they had at each study visit. In some cases, the study doctor had the opportunity to choose a dose that was different from 45 mg or 75 mg.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	INCB054707
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Three 15-mg tablets taken once daily

Arm title	Povorcitinib 75 mg

Arm description:

At the completion of the OLE Period, all eligible participants had the option to continue treatment for an additional 48 weeks. Participants received povorcitinib 75 mg QD during the LTE Period based on the number of HS lesions they had at each study visit. In some cases, the study doctor had the opportunity to choose a dose that was different from 45 mg or 75 mg.

Arm type	Experimental
Investigational medicinal product name	povorcitinib
Investigational medicinal product code	INCB054707
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Five 15-mg tablets taken once daily

Number of subjects in period 3[2]	Povorcitinib 45 mg	Povorcitinib 75 mg
Started	45	52
Completed	33	33
Not completed	12	19
Site Closure	3	3

Adverse event, serious fatal	-	1
Consent withdrawn by subject	5	3
Received Rescue for Lesions	-	1
Adverse event, non-fatal	-	5
Lost to follow-up	4	2
Sponsor Request	-	4

Notes:

[2] - 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: Not all participants who completed the Open-Label Extension Period decided to continue to the Long-Term Extension Period.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received oral placebo once daily (QD) for 16 weeks in the Placebo-controlled Treatment Period.	
Reporting group title	Povorcitinib 15 mg
Reporting group description:	
Participants received oral povorcitinib 15 milligrams (mg) QD for 16 weeks in the Placebo-controlled Treatment Period.	
Reporting group title	Povorcitinib 45 mg
Reporting group description:	
Participants received oral povorcitinib 45 mg QD for 16 weeks in the Placebo-controlled Treatment Period.	
Reporting group title	Povorcitinib 75 mg
Reporting group description:	
Participants received oral povorcitinib 75 mg QD for 16 weeks in the Placebo-controlled Treatment Period.	

Reporting group values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg
Number of subjects	52	52	52
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	51	51	51
From 65-84 years	1	1	1
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	35.2	38.2	37.3
standard deviation	± 9.96	± 10.85	± 12.51
Gender Categorical Units: Subjects			
Female	43	37	39
Male	9	15	13
Race Units: Subjects			
White/Caucasian	40	36	35
Black/African American	10	13	12
Asian	1	2	2
American Indian/Alaska Native	0	0	1
Captured as Other	1	1	2
Ethnicity			

Units: Subjects			
Hispanic or Latino	10	5	7
Not Hispanic or Latino	41	47	44
Unknown	1	0	0
Captured as Other	0	0	1
Mean abscess and inflammatory nodule (AN) count			
Units: abscesses and inflammatory nodules			
arithmetic mean	11.2	11.8	12.9
standard deviation	± 5.85	± 7.10	± 12.34
Mean abscess, inflammatory nodule (IN), and draining fistula (DF) (ANF) count			
Units: abscesses, INs, and DFs			
arithmetic mean	13.6	14.1	15.1
standard deviation	± 6.36	± 10.08	± 13.51
Mean International Hidradenitis Suppurativa Severity Score System (IHS4) score			
The IHS4 is a composite, dynamic score and validated tool used to determine Hidradenitis Suppurativa severity. It employs a weighted scale using the number of inflammatory nodules, the number of abscesses, and the number of draining tunnels (fistulas or sinuses), with respective weight factors of 1, 2, and 4. Scores: mild=0-3; moderate=4-10; severe ≥11.			
Units: scores on a scale			
arithmetic mean	22.9	22.4	23.5
standard deviation	± 17.02	± 23.24	± 22.79

Reporting group values	Povorcitinib 75 mg	Total	
Number of subjects	53	209	
Age Categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	52	205	
From 65-84 years	1	4	
85 years and over	0	0	
Age Continuous			
Units: years			
arithmetic mean	37.5		
standard deviation	± 10.83	-	
Gender Categorical			
Units: Subjects			
Female	39	158	
Male	14	51	
Race			
Units: Subjects			
White/Caucasian	36	147	
Black/African American	16	51	

Asian	1	6	
American Indian/Alaska Native	0	1	
Captured as Other	0	4	
Ethnicity Units: Subjects			
Hispanic or Latino	6	28	
Not Hispanic or Latino	47	179	
Unknown	0	1	
Captured as Other	0	1	
Mean abscess and inflammatory nodule (AN) count Units: abscesses and inflammatory nodules			
arithmetic mean	10.6		
standard deviation	± 7.24	-	
Mean abscess, inflammatory nodule (IN), and draining fistula (DF) (ANF) count Units: abscesses, INs, and DFs			
arithmetic mean	12.2		
standard deviation	± 8.94	-	
Mean International Hidradenitis Suppurativa Severity Score System (IHS4) score			
The IHS4 is a composite, dynamic score and validated tool used to determine Hidradenitis Suppurativa severity. It employs a weighted scale using the number of inflammatory nodules, the number of abscesses, and the number of draining tunnels (fistulas or sinuses), with respective weight factors of 1, 2, and 4. Scores: mild=0-3; moderate=4-10; severe ≥11.			
Units: scores on a scale			
arithmetic mean	18.9		
standard deviation	± 17.25	-	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received oral placebo once daily (QD) for 16 weeks in the Placebo-controlled Treatment Period.	
Reporting group title	Povorcitinib 15 mg
Reporting group description:	
Participants received oral povorcitinib 15 milligrams (mg) QD for 16 weeks in the Placebo-controlled Treatment Period.	
Reporting group title	Povorcitinib 45 mg
Reporting group description:	
Participants received oral povorcitinib 45 mg QD for 16 weeks in the Placebo-controlled Treatment Period.	
Reporting group title	Povorcitinib 75 mg
Reporting group description:	
Participants received oral povorcitinib 75 mg QD for 16 weeks in the Placebo-controlled Treatment Period.	
Reporting group title	Placebo to povorcitinib 75 mg
Reporting group description:	
Participants received oral placebo once daily (QD) for 16 weeks in the Placebo-controlled Treatment Period. At Week 16, eligible participants who opted to enter the 36-week Open-Label Extension (OLE) Period received povorcitinib 75 milligrams (mg) QD.	
Reporting group title	Povorcitinib 15 mg to 75 mg
Reporting group description:	
Participants received oral povorcitinib 15 milligrams (mg) QD for 16 weeks in the Placebo-controlled Treatment Period. At Week 16, eligible participants who opted to enter the 36-week Open-Label Extension Period received povorcitinib 75 mg QD.	
Reporting group title	Povorcitinib 45 mg to 75 mg
Reporting group description:	
Participants received oral povorcitinib 45 mg QD for 16 weeks in the Placebo-controlled Treatment Period. At Week 16, eligible participants who opted to enter the 36-week Open-Label Extension Period received povorcitinib 75 mg QD.	
Reporting group title	Povorcitinib 75 mg
Reporting group description:	
Participants received oral povorcitinib 75 mg QD for 16 weeks in the Placebo-controlled Treatment Period. At Week 16, eligible participants who opted to enter the 36-week Open-Label Extension Period received povorcitinib 75 mg QD.	
Reporting group title	Povorcitinib 45 mg
Reporting group description:	
At the completion of the Open-Label Extension (OLE) Period, all eligible participants had the option to continue treatment for an additional 48 weeks. Participants received povorcitinib 45 mg QD during the Long-Term Extension (LTE) Period based on the number of hidradenitis suppurativa (HS) lesions they had at each study visit. In some cases, the study doctor had the opportunity to choose a dose that was different from 45 mg or 75 mg.	
Reporting group title	Povorcitinib 75 mg
Reporting group description:	
At the completion of the OLE Period, all eligible participants had the option to continue treatment for an additional 48 weeks. Participants received povorcitinib 75 mg QD during the LTE Period based on the number of HS lesions they had at each study visit. In some cases, the study doctor had the opportunity to choose a dose that was different from 45 mg or 75 mg.	

Primary: Mean change from Baseline in abscess and inflammatory nodule (AN) count at Week 16

End point title	Mean change from Baseline in abscess and inflammatory nodule (AN) count at Week 16

End point description:

Change from Baseline was calculated as the post-Baseline value minus the Baseline value. The mixed model repeated measure (MMRM) included the fixed effects of treatment group (placebo and povorcitinib 15, 45, and 75 mg), stratification factors (disease severity [Hurley Stage I, II, and III] and geographical region [North America and outside of North America]), visit (Weeks 2, 4, 6, 8, 12, and 16), treatment by visit interaction, and covariates of Baseline measurement and Baseline measurement by visit interaction. The variance-covariance matrix of the within-participant errors in MMRM are modeled as unstructured. Analysis was conducted in members of the Intent-to-Treat (ITT) Population: all randomized participants. Treatment groups for this population were defined according to the treatment assignment at randomization.

End point type	Primary

End point timeframe:

Baseline; Week 16

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43[1]	45[2]	43[3]	46[4]
Units: abscesses and inflammatory nodules				
least squares mean (standard error)	-2.5 (± 0.88)	-5.2 (± 0.86)	-6.9 (± 0.88)	-6.3 (± 0.85)

Notes:

[1] - Only participants with available data were analyzed.

[2] - Only participants with available data were analyzed.

[3] - Only participants with available data were analyzed.

[4] - Only participants with available data were analyzed.

Statistical analyses

Statistical analysis title	Placebo versus povorcitinib 15 mg
Comparison groups	Placebo v Povorcitinib 15 mg
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0277
Method	MMRM
Parameter estimate	Least squares mean (LSM) difference
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.2
upper limit	-0.3
Variability estimate	Standard error of the mean
Dispersion value	1.23

Statistical analysis title	Placebo versus povorcitinib 45 mg
Comparison groups	Placebo v Povorcitinib 45 mg
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0006
Method	MMRM
Parameter estimate	LSM difference
Point estimate	-4.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	-1.9
Variability estimate	Standard error of the mean
Dispersion value	1.25

Statistical analysis title	Placebo verus povorcitinib 75 mg
Comparison groups	Placebo v Povorcitinib 75 mg
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0021
Method	MMRM
Parameter estimate	LSM difference
Point estimate	-3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.2
upper limit	-1.4
Variability estimate	Standard error of the mean
Dispersion value	1.22

Secondary: Percentage of participants who achieved a hidradenitis suppurativa clinical response (HiSCR) at Week 16

End point title	Percentage of participants who achieved a hidradenitis suppurativa clinical response (HiSCR) at Week 16

End point description:

HiSCR, the key secondary endpoint, was defined as at least a 50% decrease from Baseline in AN count with no increase in the number of abscesses or draining fistulas. 95% confidence interval (CI) was based on the Clopper-Pearson exact method. Missing post-Baseline values were imputed as nonresponders.

End point type	Secondary

End point timeframe:

Baseline; Week 16

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52[5]	52[6]	52[7]	53[8]
Units: percentage of participants				
number (confidence interval 95%)	28.8 (17.1 to 43.1)	48.1 (34.0 to 62.4)	44.2 (30.5 to 58.7)	45.3 (31.6 to 59.6)

Notes:

[5] - ITT Population

[6] - ITT Population

[7] - ITT Population

[8] - ITT Population

Statistical analyses

Statistical analysis title	Placebo versus povorcitinib 15 mg
Comparison groups	Placebo v Povorcitinib 15 mg
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	= 0.0445
Method	Wald test
Parameter estimate	Odds ratio (OR)
Point estimate	2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	5.3

Notes:

[9] - Logistic regression model with treatment group and stratification factors (disease severity and geographical region).

Statistical analysis title	Placebo verus povorcitinib 75 mg
Comparison groups	Placebo v Povorcitinib 75 mg
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority[10]
P-value	= 0.0829
Method	Wald test
Parameter estimate	Odds ratio (OR)
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	4.7

Notes:

[10] - Logistic regression model with treatment group and stratification factors (disease severity and geographical region).

Statistical analysis title	Placebo versus povorcitinib 45 mg
Comparison groups	Placebo v Povorcitinib 45 mg
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	= 0.0998
Method	Wald test
Parameter estimate	Odds ratio (OR)
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	4.6

Notes:

[11] - Logistic regression model with treatment group and stratification factors (disease severity and geographical region).

Secondary: Percentage of participants who achieved a HiSCR at Weeks 2 through 12

End point title	Percentage of participants who achieved a HiSCR at Weeks 2 through 12

End point description:

HiSCR was defined as at least a 50% decrease from Baseline in AN count with no increase in the number of abscesses or draining fistulas. 95% CI was based on the Clopper-Pearson exact method. Missing post-Baseline values were imputed as nonresponders.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 6, 8, and 12

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52[12]	52[13]	52[14]	53[15]
Units: percentage of participants				
number (confidence interval 95%)				
Week 2	15.4 (6.9 to 28.1)	25.0 (14.0 to 38.9)	34.6 (22.0 to 49.1)	34.0 (21.5 to 48.3)
Week 4	25.0 (14.0 to 38.9)	36.5 (23.6 to 51.0)	44.2 (30.5 to 58.7)	49.1 (35.1 to 63.2)
Week 6	17.3 (8.2 to 30.3)	32.7 (20.3 to 47.1)	48.1 (34.0 to 62.4)	52.8 (38.6 to 66.7)
Week 8	28.8 (17.1 to 43.1)	36.5 (23.6 to 51.0)	44.2 (30.5 to 58.7)	52.8 (38.6 to 66.7)
Week 12	30.8 (18.7 to 45.1)	42.3 (28.7 to 56.8)	48.1 (34.0 to 62.4)	58.5 (44.1 to 71.9)

Notes:

[12] - ITT Population

[13] - ITT Population

[14] - ITT Population

[15] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who achieved HiSCR75 from Weeks 2 to 16

End point title	Percentage of participants who achieved HiSCR75 from Weeks 2 to 16

End point description:

HiSCR75 was defined as at least a 75% decrease from Baseline in AN count with no increase in the number of abscesses or draining fistulas. 95% CI was based on the Clopper-Pearson exact method. Missing post-Baseline values were imputed as nonresponders.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 6, 8, 12, and 16

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52[16]	52[17]	52[18]	53[19]
Units: percentage of participants				
number (confidence interval 95%)				
Week 2	1.9 (0.0 to 10.3)	9.6 (3.2 to 21.0)	13.5 (5.6 to 25.8)	18.9 (9.4 to 32.0)
Week 4	7.7 (2.1 to 18.5)	15.4 (6.9 to 28.1)	21.2 (11.1 to 34.7)	15.1 (6.7 to 27.6)
Week 6	9.6 (3.2 to 21.0)	17.3 (8.2 to 30.3)	28.8 (17.1 to 43.1)	24.5 (13.8 to 38.3)
Week 8	19.2 (9.6 to 32.5)	23.1 (12.5 to 36.8)	30.8 (18.7 to 45.1)	35.8 (23.1 to 50.2)
Week 12	19.2 (9.6 to 32.5)	26.9 (15.6 to 41.0)	32.7 (20.3 to 47.1)	39.6 (26.5 to 54.0)
Week 16	17.3 (8.2 to 30.3)	30.8 (18.7 to 45.1)	28.8 (17.1 to 43.1)	30.2 (18.3 to 44.3)

Notes:

[16] - ITT Population

[17] - ITT Population

[18] - ITT Population

[19] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in the severity of the disease, as assessed by the International Hidradenitis Suppurativa Severity Score System (IHS4) score, from Weeks 2 to 16

End point title	Mean change from Baseline in the severity of the disease, as assessed by the International Hidradenitis Suppurativa Severity Score System (IHS4) score, from Weeks 2 to 16

End point description:

Change from Baseline was calculated as the post-Baseline value minus the Baseline value. The IHS4 is a composite, dynamic score and validated tool used to determine Hidradenitis Suppurativa severity. It employs a weighted scale using the number of inflammatory nodules, the number of abscesses, and the number of draining tunnels (fistulas or sinuses), with respective weight factors of 1, 2, and 4. Scores: mild=0-3; moderate=4-10; severe ≥11. MMRM included the fixed effects of treatment group (placebo and povorcitinib 15, 45, and 75 mg), stratification factors (disease severity [Hurley Stage I, II, and III] and geographical region [North America and outside of North America]), visit (Weeks 2, 4, 6, 8, 12, and 16), treatment by visit interaction, and covariates of Baseline measurement and Baseline measurement by visit interaction. The variance-covariance matrix of the within-participant errors in MMRM are modeled as unstructured.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 6, 8, 12, and 16

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52[20]	52[21]	52[22]	53[23]
Units: scores on a scale				
least squares mean (standard error)				
Week 2, n=47, 51, 48, 52	-2.4 (± 1.17)	-3.8 (± 1.13)	-6.7 (± 1.16)	-6.1 (± 1.12)
Week 4, n=49, 50, 50, 52	-2.1 (± 1.52)	-3.9 (± 1.49)	-9.3 (± 1.51)	-9.3 (± 1.47)
Week 6, n=45, 47, 48, 49	-3.1 (± 1.77)	-4.7 (± 1.73)	-10.7 (± 1.75)	-10.6 (± 1.71)
Week 8, n=45, 50, 47, 51	-3.0 (± 1.85)	-4.0 (± 1.79)	-11.8 (± 1.83)	-10.7 (± 1.78)
Week 12, n=45, 45, 45, 49	-3.1 (± 1.80)	-5.5 (± 1.76)	-11.8 (± 1.79)	-11.9 (± 1.73)
Week 16, n=43, 45, 43, 36	-3.1 (± 1.96)	-5.6 (± 1.92)	-11.0 (± 1.96)	-12.1 (± 1.90)

Notes:

[20] - ITT Population. Only participants with available data were analyzed.

[21] - ITT Population. Only participants with available data were analyzed.

[22] - ITT Population. Only participants with available data were analyzed.

[23] - ITT Population. Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who achieved AN50, AN75, AN90, and AN100 from Weeks 2 to 16

End point title	Percentage of participants who achieved AN50, AN75, AN90, and AN100 from Weeks 2 to 16

End point description:

AN50, AN75, AN90, and AN100 were defined as at least a 50%, 75%, 90%, and 100% decrease, respectively, from Baseline in AN count. 95% CI was based on the Clopper-Pearson exact method. Missing post-Baseline values were imputed as nonresponders.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 6, 8, 12, and 16

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52[24]	52[25]	52[26]	53[27]
Units: percentage of participants				
number (confidence interval 95%)				
AN50, Week 2	15.4 (6.9 to 28.1)	25.0 (14.0 to 38.9)	34.6 (22.0 to 49.1)	39.6 (26.5 to 54.0)
AN50, Week 4	30.8 (18.7 to 45.1)	44.2 (30.5 to 58.7)	46.2 (32.2 to 60.5)	58.5 (44.1 to 71.9)
AN50, Week 6	32.7 (20.3 to 47.1)	46.2 (32.2 to 60.5)	51.9 (37.6 to 66.0)	56.6 (42.3 to 70.2)
AN50, Week 8	36.5 (23.6 to 51.0)	55.8 (41.3 to 69.5)	53.8 (39.5 to 67.8)	54.7 (40.4 to 68.4)
AN50, Week 12	44.2 (30.5 to 58.7)	51.9 (37.6 to 66.0)	55.8 (41.3 to 69.5)	62.3 (47.9 to 75.2)
AN50, Week 16	36.5 (23.6 to 51.0)	55.8 (41.3 to 69.5)	57.7 (43.2 to 71.3)	52.8 (38.6 to 66.7)
AN75, Week 2	1.9 (0.0 to 10.3)	9.6 (3.2 to 21.0)	13.5 (5.6 to 25.8)	20.8 (10.8 to 34.1)
AN75, Week 4	7.7 (2.1 to 18.5)	15.4 (6.9 to 28.1)	23.1 (12.5 to 36.8)	18.9 (9.4 to 32.0)
AN75, Week 6	13.5 (5.6 to 25.8)	25.0 (14.0 to 38.9)	32.7 (20.3 to 47.1)	26.4 (15.3 to 40.3)
AN75, Week 8	21.2 (11.1 to 34.7)	28.8 (17.1 to 43.1)	32.7 (20.3 to 47.1)	37.7 (24.8 to 52.1)
AN75, Week 12	23.1 (12.5 to 36.8)	32.7 (20.3 to 47.1)	36.5 (23.6 to 51.0)	39.6 (26.5 to 54.0)
AN75, Week 16	17.3 (8.2 to 30.3)	36.5 (23.6 to 51.0)	36.5 (23.6 to 51.0)	34.0 (21.5 to 48.3)
AN90, Week 2	0.0 (0.0 to 6.8)	3.8 (0.5 to 13.2)	1.9 (0.0 to 10.3)	11.3 (4.3 to 23.0)
AN90, Week 4	0.0 (0.0 to 6.8)	5.8 (1.2 to 15.9)	7.7 (2.1 to 18.5)	5.7 (1.2 to 15.7)
AN90, Week 6	5.8 (1.2 to 15.9)	5.8 (1.2 to 15.9)	11.5 (4.4 to 23.4)	9.4 (3.1 to 20.7)
AN90, Week 8	5.8 (1.2 to 15.9)	15.4 (6.9 to 28.1)	19.2 (9.6 to 32.5)	18.9 (9.4 to 32.0)
AN90, Week 12	5.8 (1.2 to 15.9)	17.3 (8.2 to 30.3)	13.5 (5.6 to 25.8)	20.8 (10.8 to 34.1)
AN90, Week 16	3.8 (0.5 to 13.2)	17.3 (8.2 to 30.3)	19.2 (9.6 to 32.5)	18.9 (9.4 to 32.0)
AN100, Week 2	0.0 (0.0 to 6.8)	3.8 (0.5 to 13.2)	1.9 (0.0 to 10.3)	7.5 (2.1 to 18.2)
AN100, Week 4	0.0 (0.0 to 6.8)	3.8 (0.5 to 13.2)	5.8 (1.2 to 15.9)	5.7 (1.2 to 15.7)
AN100, Week 6	0.0 (0.0 to 6.8)	3.8 (0.5 to 13.2)	7.7 (2.1 to 18.5)	9.4 (3.1 to 20.7)
AN100, Week 8	3.8 (0.5 to 13.2)	13.5 (5.6 to 25.8)	11.5 (4.4 to 23.4)	17.0 (8.1 to 29.8)
AN100, Week 12	3.8 (0.5 to 13.2)	13.5 (5.6 to 25.8)	11.5 (4.4 to 23.4)	18.9 (9.4 to 32.0)
AN100, Week 16	3.8 (0.5 to 13.2)	15.4 (6.9 to 28.1)	11.5 (4.4 to 23.4)	17.0 (8.1 to 29.8)

Notes:

[24] - ITT Population

[25] - ITT Population

[26] - ITT Population

[27] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in AN count at Weeks 2 to 12

End point title	Mean change from Baseline in AN count at Weeks 2 to 12

End point description:

Change from Baseline was calculated as the post-Baseline value minus the Baseline value. MMRM included the fixed effects of treatment group (placebo and povorcitinib 15, 45, and 75 mg), stratification factors (disease severity [Hurley Stage I, II, and III] and geographical region [North America and outside of North America]), visit (Weeks 2, 4, 6, 8, 12, and 16), treatment by visit interaction, and covariates of Baseline measurement and Baseline measurement by visit interaction. The variance-covariance matrix of the within-participant errors in MMRM are modeled as unstructured.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 6, 8, and 12

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52[28]	52[29]	52[30]	53[31]
Units: abscesses and inflammatory nodules				
least squares mean (standard error)				
Week 2, n=47, 51, 48, 52	-1.7 (± 0.69)	-2.7 (± 0.66)	-3.4 (± 0.69)	-4.0 (± 0.66)
Week 4, n=49, 50, 50, 52	-3.0 (± 0.71)	-3.6 (± 0.70)	-4.8 (± 0.71)	-5.3 (± 0.69)
Week 6, n=45, 47, 48, 49	-2.7 (± 0.77)	-4.8 (± 0.76)	-5.3 (± 0.77)	-6.2 (± 0.75)
Week 8, n=45, 50, 47, 51	-2.7 (± 0.82)	-4.7 (± 0.79)	-6.4 (± 0.82)	-5.7 (± 0.79)
Week 12, n=45, 45, 45, 49	-2.8 (± 0.84)	-5.0 (± 0.82)	-6.7 (± 0.84)	-6.5 (± 0.81)

Notes:

[28] - ITT Population. Only participants with available data were analyzed.

[29] - ITT Population. Only participants with available data were analyzed.

[30] - ITT Population. Only participants with available data were analyzed.

[31] - ITT Population. Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with a total AN count of 0 to 2 from Weeks 2 to 16

End point title	Percentage of participants with a total AN count of 0 to 2 from Weeks 2 to 16

End point description:

Total AN count was assessed throughout the study.

End point type	Secondary
End point timeframe:	
Weeks 2, 4, 6, 8, 12, and 16	

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52[32]	52[33]	52[34]	53[35]
Units: percentage of participants				
number (not applicable)				
Week 2, n=47, 51, 48, 52	4.3	9.8	16.7	23.1
Week 4, n=49, 50, 50, 52	14.3	20.0	20.0	23.1
Week 6, n=45, 47, 48, 49	13.3	19.1	31.3	38.8
Week 8, n=45, 50, 47, 51	28.9	30.0	38.3	41.2
Week 12, n=45, 45, 45, 49	28.9	33.3	46.7	38.8
Week 16, n=43, 45, 43, 46	25.6	44.4	51.2	37.0

Notes:

[32] - ITT Population. Only participants with available data were analyzed.

[33] - ITT Population. Only participants with available data were analyzed.

[34] - ITT Population. Only participants with available data were analyzed.

[35] - ITT Population, Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in draining fistula count from Weeks 2 to 16

End point title	Mean change from Baseline in draining fistula count from Weeks 2 to 16
End point description:	
Change from Baseline was calculated as the post-Baseline value minus the Baseline value.	
End point type	Secondary
End point timeframe:	
Baseline; Weeks 2, 4, 6, 8, 12, and 16	

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52[36]	52[37]	52[38]	53[39]
Units: draining fistulas				
arithmetic mean (standard deviation)				
Baseline, n=52, 52, 52, 53	2.4 (± 3.97)	2.3 (± 4.44)	2.2 (± 4.04)	1.6 (± 2.85)
Change from Baseline at Week 2, n=47, 51, 48, 52	-0.2 (± 1.23)	-0.2 (± 1.01)	-0.6 (± 1.62)	-0.2 (± 1.30)
Change from Baseline at Week 4, n=49, 50, 50, 52	0.0 (± 1.80)	0.0 (± 1.11)	-0.8 (± 2.59)	-0.6 (± 2.44)
Change from Baseline at Week 6, n=45, 47, 48, 49	-0.2 (± 2.14)	0.1 (± 1.85)	-1.0 (± 2.95)	-0.8 (± 2.62)

Change from Baseline at Week 8, n=45, 50, 47, 51	-0.2 (± 2.46)	0.2 (± 2.10)	-1.1 (± 2.82)	-0.8 (± 2.70)
Change from Baseline at Week 12, n=45, 45, 45, 49	-0.3 (± 2.17)	0.0 (± 2.71)	-1.0 (± 2.87)	-1.0 (± 2.61)
Change from Baseline at Week 16, n=43, 45, 43, 46	-0.3 (± 2.05)	0.1 (± 3.25)	-0.8 (± 3.20)	-1.1 (± 2.57)

Notes:

[36] - ITT Population. Only participants with available data were analyzed.

[37] - ITT Population. Only participants with available data were analyzed.

[38] - ITT Population. Only participants with available data were analyzed.

[39] - ITT Population. Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in abscess, inflammatory nodule (IN), and draining fistula (DF) (ANF) count from Weeks 2 to 16

End point title	Mean change from Baseline in abscess, inflammatory nodule (IN), and draining fistula (DF) (ANF) count from Weeks 2 to 16

End point description:

Change from Baseline was calculated as the post-Baseline value minus the Baseline value. MMRM included the fixed effects of treatment group (placebo and povorcitinib 15, 45, and 75 mg), stratification factors (disease severity [Hurley Stage I, II, and III] and geographical region [North America and outside of North America]), visit (Weeks 2, 4, 6, 8, 12, and 16), treatment by visit interaction, and covariates of Baseline measurement and Baseline measurement by visit interaction. The variance-covariance matrix of the within-participant errors in MMRM are modeled as unstructured.

End point type	Secondary

End point timeframe:

Baseline; Weeks 2, 4, 6, 8, 12, and 16

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52[40]	52[41]	52[42]	53[43]
Units: abscesses, INs, and DFs				
least squares mean (standard error)				
Week 2, n=47, 51, 48, 52	-1.8 (± 0.74)	-2.9 (± 0.72)	-4.0 (± 0.74)	-4.4 (± 0.71)
Week 4, n=49, 50, 50, 52	-2.7 (± 0.83)	-3.5 (± 0.82)	-5.7 (± 0.82)	-6.2 (± 0.80)
Week 6, n=45, 47, 48, 49	-2.6 (± 0.92)	-4.7 (± 0.90)	-6.4 (± 0.92)	-7.1 (± 0.89)
Week 8, n=45, 50, 47, 51	-2.6 (± 0.96)	-4.4 (± 0.93)	-7.5 (± 0.96)	-6.8 (± 0.92)
Week 12, n=45, 45, 45, 49	-2.7 (± 0.99)	-5.0 (± 0.97)	-7.7 (± 0.98)	-7.6 (± 0.95)
Week 16, n=43, 45, 43, 46	-2.4 (± 1.06)	-5.1 (± 1.03)	-7.7 (± 1.05)	-7.6 (± 1.02)

Notes:

[40] - ITT Population. Only participants with available data were analyzed.

[41] - ITT Population. Only participants with available data were analyzed.

[42] - ITT Population. Only participants with available data were analyzed.

[43] - ITT Population. Only participants with available data were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Placebo-Controlled Period: Number of participants with treatment-emergent adverse events (TEAEs)

End point title	Placebo-Controlled Period: Number of participants with treatment-emergent adverse events (TEAEs)

End point description:

An adverse event (AE) was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug-related. An AE could have been any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study treatment. A TEAE was defined as any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study drug until the end of the safety follow-up. Analysis was conducted in members of the Safety Population, defined as all participants who received at least 1 dose of povorcitinib or placebo during the Placebo-controlled Period.

End point type	Secondary

End point timeframe:

up to Week 16

End point values	Placebo	Povorcitinib 15 mg	Povorcitinib 45 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52[44]	52[45]	52[46]	53[47]
Units: participants	34	31	30	32

Notes:

[44] - Safety Population

[45] - Safety Population

[46] - Safety Population

[47] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Open-Label Extension Period: Number of participants with TEAEs

End point title	Open-Label Extension Period: Number of participants with TEAEs

End point description:

An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug-related. An AE could have been any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study treatment. A TEAE was defined as any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study drug until the end of the safety follow-up. Analysis was conducted in members of the Open-Label Evaluable (OLE) Population, defined as all participants who received at least 1 dose of povorcitinib 75 mg during the OLE Period.

End point type	Secondary

End point timeframe:

Week 17 to Week 52

End point values	Placebo to povorcitinib 75 mg	Povorcitinib 15 mg to 75 mg	Povorcitinib 45 mg to 75 mg	Povorcitinib 75 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43[48]	44[49]	42[50]	46[51]
Units: participants	32	35	35	33

Notes:

[48] - OLE Population

[49] - OLE Population

[50] - OLE Population

[51] - OLE Population

Statistical analyses

No statistical analyses for this end point

Secondary: Long-Term Extension Period: Number of participants with TEAEs

End point title	Long-Term Extension Period: Number of participants with TEAEs

End point description:

An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug-related. An AE could have been any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study treatment. A TEAE was defined as any AE either reported for the first time or the worsening of a pre-existing event after the first dose of study drug until the end of the safety follow-up. Analysis was conducted in members of the Long-Term Evaluable (LTE) Population, defined as all participants who received at least 1 dose of povorcitinib during the LTE Period.

End point type	Secondary

End point timeframe:

Week 53 to Week 100

End point values	Povorcitinib 45 mg	Povorcitinib 75 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45[52]	52[53]		
Units: participants	25	39		

Notes:

[52] - LTE Population

[53] - LTE Population

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

up to Week 100

Adverse event reporting additional description:

Treatment-emergent adverse events (TEAEs), defined as AEs either reported for the first time or the worsening of pre-existing events after the first dose of study drug until the end of the safety follow-up, have been reported.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26

Reporting groups

Reporting group title	PC Pd: Placebo/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg

Reporting group description:

Participants who took placebo during the 16-week Placebo-controlled (PC) Period (Pd), took povorcitinib (povo) 75 milligrams (mg) during the 36-week Open-Label Extension (OLE) Period, and took povorcitinib ≤45 mg at the beginning of the 48-week Long-term Extension (LTE) Period

Reporting group title	PC Pd: Placebo/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg

Reporting group description:

Participants who took placebo during the 16-week PC Period, took povorcitinib 75 mg during the 36-week OLE Period, and took povorcitinib ≥60 mg at the beginning of the 48-week LTE Period

Reporting group title	PC Pd: Povo 15 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg

Reporting group description:

Participants who took povorcitinib 15 mg during the 16-week PC Period, took povorcitinib 75 mg during the 36-week OLE Period, and took povorcitinib ≤45 mg at the beginning of the 48-week LTE Period

Reporting group title	PC Pd: Povo 15 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg

Reporting group description:

Participants who took povorcitinib 15 mg during the 16-week PC Period, took povorcitinib 75 mg during the 36-week OLE Period, and took povorcitinib ≥60 mg at the beginning of the 48-week LTE Period

Reporting group title	PC Pd: Povo 45 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg

Reporting group description:

Participants who took povorcitinib 45 mg during the 16-week PC Period, took povorcitinib 75 mg during the 36-week OLE Period, and took povorcitinib ≤45 mg at the beginning of the 48-week LTE Period

Reporting group title	PC Pd: Povo 45 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg

Reporting group description:

Participants who took povorcitinib 45 mg during the 16-week PC Period, took povorcitinib 75 mg during the 36-week OLE Period, and took povorcitinib ≥60 mg at the beginning of the 48-week LTE Period

Reporting group title	PC Pd: Povo 75 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg

Reporting group description:

Participants who took povorcitinib 75 mg during the 16-week PC Period, took povorcitinib 75 mg during the 36-week OLE Period, and took povorcitinib ≤45 mg at the beginning of the 48-week LTE Period

Reporting group title	PC Pd: Povo 75 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg

Reporting group description:

Participants who took povorcitinib 75 mg during the 16-week PC Period, took povorcitinib 75 mg during the 36-week OLE Period, and took povorcitinib ≥60 mg at the beginning of the 48-week LTE Period

Reporting group title	PC Period: Placebo/OLE Period: Placebo to Povorcitinib 75 mg

Reporting group description:

Participants who took placebo during the 16-week PC Period, took povorcitinib 75 mg during the 36-week OLE Period, and did not enter the 48-week LTE Period

Reporting group title	PC Pd: Povorcitinib 15 mg/OLE Pd: Povorcitinib 15 mg to 75 mg

Reporting group description:

Participants who took povorcitinib 15 mg during the 16-week PC Period, took povorcitinib 75 mg during

the 36-week OLE Period, and did not enter the 48-week LTE Period	
Reporting group title	PC Pd: Povorcitinib 45 mg/OLE Pd: Povorcitinib 45 mg to 75 mg
Reporting group description:	
Participants who took povorcitinib 45 mg during the 16-week PC Period, took povorcitinib 75 mg during the 36-week OLE Period, and did not enter the 48-week LTE Period	
Reporting group title	PC Period: Povorcitinib 75 mg/OLE Period: Povorcitinib 75 mg
Reporting group description:	
Participants who took povorcitinib 75 mg during the 16-week PC Period, took povorcitinib 75 mg during the 36-week OLE Period, and did not enter the 48-week LTE Period	
Reporting group title	PC Period: Placebo
Reporting group description:	
Participants who took placebo during the 16-week PC Period, and did not enter the 36-week OLE Period	
Reporting group title	PC Period: Povorcitinib 15 mg
Reporting group description:	
Participants who took povorcitinib 15 mg during the 16-week PC Period, and did not enter the 36-week OLE Period	
Reporting group title	PC Period: Povorcitinib 45 mg
Reporting group description:	
Participants who took povorcitinib 45 mg during the 16-week PC Period, and did not enter the 36-week OLE Period	
Reporting group title	PC Period: Povorcitinib 75 mg
Reporting group description:	
Participants who took povorcitinib 75 mg during the 16-week PC Period, and did not enter the 36-week OLE Period	

Serious adverse events	PC Pd: Placebo/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg	PC Pd: Placebo/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg	PC Pd: Povo 15 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
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)			
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
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			
Fall			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
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			
Interstitial lung disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
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			
Hidradenitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
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			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
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	PC Pd: Povo 15 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg	PC Pd: Povo 45 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg	PC Pd: Povo 45 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	4 / 16 (25.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung adenocarcinoma stage IV			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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
Metastatic neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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 / 1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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
Rib fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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 failure congestive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (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

Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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			
Interstitial lung disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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			
Hidradenitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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			
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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			
Abscess limb			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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
Bacterial infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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
Diverticulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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
Perirectal abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (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	PC Pd: Povo 75 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg	PC Pd: Povo 75 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg	PC Period: Placebo/OLE Period: Placebo to Povorcitinib 75 mg
Total subjects affected by serious adverse events			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	3 / 21 (14.29%)
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)			
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Metastatic neoplasm			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Rib fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Atrial fibrillation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Cardiac failure congestive			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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

Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Interstitial lung disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Pulmonary embolism			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Musculoskeletal and connective tissue			

disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Perirectal abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Sepsis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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
Metabolism and nutrition disorders			
Diabetic ketoacidosis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (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

Serious adverse events	PC Pd: Povorcitinib 15 mg/OLE Pd: Povorcitinib 15 mg to 75 mg	PC Pd: Povorcitinib 45 mg/OLE Pd: Povorcitinib 45 mg to 75 mg	PC Period: Povorcitinib 75 mg/OLE Period: Povorcitinib 75 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 20 (15.00%)	1 / 15 (6.67%)	4 / 22 (18.18%)
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)			
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
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			
Fall			
subjects affected / exposed	1 / 20 (5.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
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			
Interstitial lung disease			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (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
Skin and subcutaneous tissue disorders			
Hidradenitis			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
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			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sepsis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PC Period: Placebo	PC Period: Povorcitinib 15 mg	PC Period: Povorcitinib 45 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	1 / 8 (12.50%)
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)			
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute myocardial infarction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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			
Interstitial lung disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 8 (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
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (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
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 8 (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
Perirectal abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
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	PC Period: Povorcitinib 75 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic neoplasm			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fall			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Interstitial lung disease			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacterial infection			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Perirectal abscess			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	PC Pd: Placebo/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg	PC Pd: Placebo/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg	PC Pd: Povo 15 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 9 (88.89%)	13 / 13 (100.00%)	10 / 12 (83.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Cervix neoplasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fibroadenoma of breast			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Skin papilloma			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Drug withdrawal syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 9 (22.22%)	3 / 13 (23.08%)	2 / 12 (16.67%)
occurrences (all)	2	4	2
Feeling abnormal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Mite allergy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			

Abnormal uterine bleeding			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Adenomyosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast enlargement			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital ulceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Pelvic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Uterine polyp			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Emphysema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Obstructive sleep apnoea syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngeal erythema			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Productive cough			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Throat irritation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 9 (11.11%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Bipolar disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Depressive symptom			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Panic attack			

subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tachyphrenia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood glucose increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	3 / 12 (25.00%)
occurrences (all)	0	1	3
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood testosterone increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood oestrogen decreased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram abnormal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Human papilloma virus test positive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Transaminases increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arteriovenous fistula site haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle strain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Neck injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rib fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Wound			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pulmonary valve incompetence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Cerebral disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 9 (22.22%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Dysgeusia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 9 (0.00%)	3 / 13 (23.08%)	3 / 12 (25.00%)
occurrences (all)	0	4	5
Memory impairment			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Sciatica			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Small fibre neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Speech disorder			

subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tension headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Increased tendency to bruise			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mast cell activation syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Episcleritis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Foreign body sensation in eyes			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Anal fissure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Diarrhoea			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Gingival recession			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 9 (22.22%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Odynophagia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	2 / 9 (22.22%)	2 / 13 (15.38%)	1 / 12 (8.33%)
occurrences (all)	2	2	2
Acne cystic			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 9 (0.00%)	3 / 13 (23.08%)	0 / 12 (0.00%)
occurrences (all)	0	3	0
Diffuse alopecia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyshidrotic eczema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hand dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 9 (0.00%)	2 / 13 (15.38%)	1 / 12 (8.33%)
occurrences (all)	0	6	1
Hirsutism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Perioral dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Rash			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rosacea			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin fissures			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin lesion inflammation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Telangiectasia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperoestrogenism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Arthritis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	2 / 13 (15.38%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Exostosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 9 (11.11%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Tendonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abscess limb			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abscess soft tissue			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Acarodermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
COVID-19 pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	4 / 9 (44.44%)	6 / 13 (46.15%)	2 / 12 (16.67%)
occurrences (all)	4	7	2
Carbuncle			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Cellulitis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Diarrhoea infectious			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear infection staphylococcal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eyelid boil			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	2 / 9 (22.22%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gastric infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	5
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Helicobacter infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Impetigo			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Kidney infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nail infection			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 9 (11.11%)	2 / 13 (15.38%)	1 / 12 (8.33%)
occurrences (all)	1	2	2
Onychomycosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 9 (0.00%)	2 / 13 (15.38%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Penile abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Perineal abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pilonidal disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	1 / 9 (11.11%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Pneumonia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	2 / 13 (15.38%)	1 / 12 (8.33%)
occurrences (all)	0	2	1
Skin candida			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sweat gland infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
Tooth infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Trichomoniasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	1 / 9 (11.11%)	2 / 13 (15.38%)	2 / 12 (16.67%)
occurrences (all)	1	3	2
Urinary tract infection			
subjects affected / exposed	1 / 9 (11.11%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	1	4	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Insulin resistance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vitamin B complex deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PC Pd: Povo 15 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg	PC Pd: Povo 45 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg	PC Pd: Povo 45 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	9 / 11 (81.82%)	16 / 16 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cervix neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Fibroadenoma of breast			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 12 (16.67%)	1 / 11 (9.09%)	2 / 16 (12.50%)
occurrences (all)	2	1	2
Feeling abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			

subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Vaccination site pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Xerosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Mite allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Adenomyosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Benign prostatic hyperplasia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Breast enlargement			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Genital ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Ovarian cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Uterine polyp			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Emphysema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Obstructive sleep apnoea syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Pharyngeal erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Throat irritation			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Bipolar disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Depressive symptom			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tachyphrenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Blood glucose increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	3 / 16 (18.75%)
occurrences (all)	0	0	4
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Blood testosterone increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood oestrogen decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Crystal urine present			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Electrocardiogram abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Haemoglobin decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Heart rate increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Human papilloma virus test positive			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Urine analysis abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Arteriovenous fistula site haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Breast injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neck injury			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rib fracture			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Road traffic accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Mitral valve incompetence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pulmonary valve incompetence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Tricuspid valve incompetence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Cerebral disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Memory impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Small fibre neuropathy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Speech disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Increased tendency to bruise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Mast cell activation syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Episcleritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Faeces discoloured			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gingival recession			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Lip ulceration			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Odynophagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hypertransaminasaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	2 / 12 (16.67%)	1 / 11 (9.09%)	2 / 16 (12.50%)
occurrences (all)	2	2	2
Acne cystic			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Actinic keratosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dermal cyst			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	4
Dermatitis acneiform			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dermatitis atopic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diffuse alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dyshidrotic eczema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Eczema asteatotic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hand dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			

subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Hirsutism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Papule			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Perioral dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Rosacea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin lesion inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Telangiectasia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urticaria			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Urinary tract inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hyperoestrogenism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Exostosis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abscess limb			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abscess soft tissue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Acarodermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Acute sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	2 / 12 (16.67%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	2	0	1
Breast abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Breast cellulitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
COVID-19 pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	7 / 12 (58.33%)	5 / 11 (45.45%)	7 / 16 (43.75%)
occurrences (all)	8	5	7
Carbuncle			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	4	0	0
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Ear infection			
subjects affected / exposed	1 / 12 (8.33%)	1 / 11 (9.09%)	2 / 16 (12.50%)
occurrences (all)	1	2	2
Ear infection staphylococcal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Eye abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eyelid boil			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	2
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Gastric infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	2 / 12 (16.67%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	4
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Impetigo			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Kidney infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 12 (16.67%)	1 / 11 (9.09%)	3 / 16 (18.75%)
occurrences (all)	2	2	5
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Oral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Penile abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Perineal abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pilonidal disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	3 / 16 (18.75%)
occurrences (all)	0	0	3
Skin candida			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Subcutaneous abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Sweat gland infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Trichomoniasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 12 (25.00%)	1 / 11 (9.09%)	3 / 16 (18.75%)
occurrences (all)	3	1	4
Urinary tract infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	2
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Glucose tolerance impaired			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Hyperlipidaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 11 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Insulin resistance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Obesity			

subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Vitamin B complex deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 11 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PC Pd: Povo 75 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≤45 mg	PC Pd: Povo 75 mg/OLE Pd: Povo 75 mg/LTE Pd: Povo ≥60 mg	PC Period: Placebo/OLE Period: Placebo to Povorcitinib 75 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 13 (76.92%)	10 / 11 (90.91%)	16 / 21 (76.19%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cervix neoplasm			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fibroadenoma of breast			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 13 (7.69%)	2 / 11 (18.18%)	2 / 21 (9.52%)
occurrences (all)	2	2	2

General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 13 (7.69%)	2 / 11 (18.18%)	2 / 21 (9.52%)
occurrences (all)	1	2	2
Feeling abnormal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Swelling			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Mite allergy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Adenomyosis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Amenorrhoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Breast enlargement			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Genital ulceration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Ovarian cyst			
subjects affected / exposed	0 / 13 (0.00%)	2 / 11 (18.18%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Pelvic pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Uterine polyp			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Emphysema			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Obstructive sleep apnoea syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Pharyngeal erythema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Attention deficit hyperactivity disorder			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Bipolar disorder			
subjects affected / exposed	2 / 13 (15.38%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	3	0	0
Depression			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Depressive symptom			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Panic attack			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tachyphrenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Blood glucose increased			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood testosterone increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Blood pressure increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Blood oestrogen decreased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram abnormal			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Haemoglobin decreased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Heart rate increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Human papilloma virus test positive			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Platelet count decreased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	1 / 21 (4.76%)
occurrences (all)	0	3	1
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 13 (0.00%)	2 / 11 (18.18%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Transaminases increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Arteriovenous fistula site haemorrhage			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Breast injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	2
Eye injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Muscle strain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Neck injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Sunburn			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pulmonary valve incompetence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Cerebral disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	3 / 21 (14.29%)
occurrences (all)	1	1	3
Memory impairment			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Small fibre neuropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Iron deficiency anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Mast cell activation syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Episcleritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Anal fissure			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Aphthous ulcer			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	2 / 13 (15.38%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Dry mouth			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gingival recession			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	2 / 21 (9.52%)
occurrences (all)	0	1	2
Odynophagia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 13 (7.69%)	4 / 11 (36.36%)	4 / 21 (19.05%)
occurrences (all)	1	4	4
Acne cystic			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Alopecia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Dermatitis			

subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Dermatitis contact			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Diffuse alopecia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dyshidrotic eczema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hand dermatitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hidradenitis			
subjects affected / exposed	1 / 13 (7.69%)	2 / 11 (18.18%)	0 / 21 (0.00%)
occurrences (all)	1	2	0
Hirsutism			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Intertrigo			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Perioral dermatitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Rosacea			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Skin lesion inflammation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Telangiectasia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0

Pollakiuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Urinary tract inflammation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperoestrogenism			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Arthritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
Exostosis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abscess limb			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Abscess soft tissue			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Acarodermatitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Acute sinusitis			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Bacterial vaginosis			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	1 / 21 (4.76%)
occurrences (all)	1	4	1

Breast abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Breast cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
COVID-19 pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	4 / 13 (30.77%)	7 / 11 (63.64%)	2 / 21 (9.52%)
occurrences (all)	5	7	2
Carbuncle			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	2 / 13 (15.38%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Ear infection staphylococcal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Eye abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Eyelid boil			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 13 (0.00%)	2 / 11 (18.18%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Fungal infection			
subjects affected / exposed	0 / 13 (0.00%)	2 / 11 (18.18%)	0 / 21 (0.00%)
occurrences (all)	0	3	0
Gastroenteritis			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Gastric infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Genital herpes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	2	0	1
Gingivitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Helicobacter infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Kidney infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Nail infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	2 / 11 (18.18%)	0 / 21 (0.00%)
occurrences (all)	1	2	0
Onychomycosis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Oral infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Paronychia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Penile abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Perineal abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pilonidal disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	2 / 13 (15.38%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Rhinitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Skin candida			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Subcutaneous abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Sweat gland infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Suspected COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Tinea pedis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Trichomoniasis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 13 (23.08%)	2 / 11 (18.18%)	3 / 21 (14.29%)
occurrences (all)	5	3	3
Urinary tract infection			
subjects affected / exposed	1 / 13 (7.69%)	3 / 11 (27.27%)	3 / 21 (14.29%)
occurrences (all)	1	4	3
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Diabetes mellitus			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Glucose tolerance impaired			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Hyponatraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Insulin resistance			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Obesity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vitamin B complex deficiency			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	1 / 21 (4.76%)
occurrences (all)	2	1	1

Non-serious adverse events	PC Pd: Povorcitinib 15 mg/OLE Pd: Povorcitinib 15 mg to 75 mg	PC Pd: Povorcitinib 45 mg/OLE Pd: Povorcitinib 45 mg to 75 mg	PC Period: Povorcitinib 75 mg/OLE Period: Povorcitinib 75 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 20 (85.00%)	15 / 15 (100.00%)	15 / 22 (68.18%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cervix neoplasm			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fibroadenoma of breast			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Drug withdrawal syndrome			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 20 (10.00%)	2 / 15 (13.33%)	4 / 22 (18.18%)
occurrences (all)	2	2	4
Feeling abnormal			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Nodule			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Swelling			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Vaccination site pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Xerosis			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Mite allergy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Adenomyosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Breast enlargement			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Dysmenorrhoea			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Genital ulceration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Haemorrhagic ovarian cyst			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Menstruation irregular			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Uterine polyp			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Emphysema			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Obstructive sleep apnoea syndrome			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pharyngeal erythema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Throat irritation			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Bipolar disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Depression			

subjects affected / exposed	0 / 20 (0.00%)	3 / 15 (20.00%)	2 / 22 (9.09%)
occurrences (all)	0	3	2
Depressive symptom			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Generalised anxiety disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Panic attack			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tachyphrenia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 20 (5.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 20 (5.00%)	2 / 15 (13.33%)	0 / 22 (0.00%)
occurrences (all)	1	2	0
Blood cholesterol increased			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Blood glucose increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			

subjects affected / exposed	1 / 20 (5.00%)	2 / 15 (13.33%)	2 / 22 (9.09%)
occurrences (all)	1	2	3
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood testosterone increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Blood oestrogen decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram abnormal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Haemoglobin decreased			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Heart rate increased			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Human papilloma virus test positive			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Urine analysis abnormal			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Arteriovenous fistula site haemorrhage			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Breast injury			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Burns second degree			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
Eye injury			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	1 / 20 (5.00%)	1 / 15 (6.67%)	1 / 22 (4.55%)
occurrences (all)	2	1	1
Muscle strain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Neck injury			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Thermal burn			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Wound			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pulmonary valve incompetence			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Cerebral disorder			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	4 / 20 (20.00%)	2 / 15 (13.33%)	2 / 22 (9.09%)
occurrences (all)	7	2	2
Memory impairment			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Small fibre neuropathy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
Increased tendency to bruise			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Mast cell activation syndrome			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0

Thrombocytopenia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Episcleritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Anal fissure			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Cheilitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Constipation			

subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Diarrhoea			
subjects affected / exposed	3 / 20 (15.00%)	2 / 15 (13.33%)	1 / 22 (4.55%)
occurrences (all)	3	2	1
Dry mouth			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gingival recession			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 20 (15.00%)	0 / 15 (0.00%)	2 / 22 (9.09%)
occurrences (all)	5	0	2
Odynophagia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	3 / 20 (15.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	3	0	1
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 20 (5.00%)	3 / 15 (20.00%)	4 / 22 (18.18%)
occurrences (all)	1	3	4
Acne cystic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Dermal cyst			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Dermatitis atopic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			

subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Diffuse alopecia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dyshidrotic eczema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Ecchymosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hand dermatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	3 / 20 (15.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	3	0	2
Hirsutism			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Papule			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Perioral dermatitis			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Rosacea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin lesion inflammation			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Telangiectasia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Renal cyst			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Urinary tract inflammation			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Hyperoestrogenism			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 20 (10.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	2	0	1
Arthritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 20 (10.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Exostosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Neck pain			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Tendonitis			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Abscess limb			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Abscess soft tissue			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Abscess			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Acarodermatitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Breast abscess			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Breast cellulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
COVID-19 pneumonia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	3 / 20 (15.00%)	5 / 15 (33.33%)	5 / 22 (22.73%)
occurrences (all)	3	5	5
Carbuncle			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ear infection staphylococcal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye abscess			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Eyelid boil			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Folliculitis			
subjects affected / exposed	3 / 20 (15.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	3	0	1
Fungal infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Gastric infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Hordeolum			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Kidney infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Nail infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 20 (15.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Onychomycosis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Penile abscess			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Perineal abscess			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Pilonidal disease			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	1 / 20 (5.00%)	2 / 15 (13.33%)	0 / 22 (0.00%)
occurrences (all)	1	2	0
Skin candida			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sweat gland infection			
subjects affected / exposed	1 / 20 (5.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Suspected COVID-19			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1

Tooth abscess			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Trichomoniasis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 20 (10.00%)	2 / 15 (13.33%)	3 / 22 (13.64%)
occurrences (all)	2	2	3
Urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	3 / 15 (20.00%)	1 / 22 (4.55%)
occurrences (all)	0	3	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Diabetes mellitus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Glucose tolerance impaired			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			

subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	2 / 20 (10.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Hypokalaemia			
subjects affected / exposed	1 / 20 (5.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Increased appetite			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Insulin resistance			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 15 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vitamin B complex deficiency			
subjects affected / exposed	0 / 20 (0.00%)	1 / 15 (6.67%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			
subjects affected / exposed	0 / 20 (0.00%)	2 / 15 (13.33%)	0 / 22 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	PC Period: Placebo	PC Period: Povorcitinib 15 mg	PC Period: Povorcitinib 45 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 9 (77.78%)	7 / 8 (87.50%)	4 / 8 (50.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cervix neoplasm			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fibroadenoma of breast			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	1 / 9 (11.11%)	1 / 8 (12.50%)	2 / 8 (25.00%)
occurrences (all)	1	1	2
Feeling abnormal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Influenza like illness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Mite allergy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Adenomyosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Breast enlargement			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Genital ulceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Menstruation irregular			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pelvic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Uterine polyp			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Emphysema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Obstructive sleep apnoea syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pharyngeal erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bipolar disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Depressive symptom			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachyphrenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood testosterone increased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood oestrogen decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram abnormal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Heart rate increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Human papilloma virus test positive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Platelet count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Arteriovenous fistula site haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Breast injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Eye injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fall			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neck injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Bundle branch block right			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Mitral valve incompetence			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pulmonary valve incompetence			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Cerebral disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Dysgeusia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Memory impairment			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sciatica			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Small fibre neuropathy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Mast cell activation syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry eye			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Episcleritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gingival recession			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Odynophagia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Acne cystic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Diffuse alopecia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Dyshidrotic eczema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eczema asteatotic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hand dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hirsutism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Papule			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Perioral dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Rosacea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin lesion inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Telangiectasia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract inflammation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperoestrogenism			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Exostosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tendonitis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abscess limb			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abscess soft tissue			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abscess			
subjects affected / exposed	1 / 9 (11.11%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Acarodermatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Breast cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
COVID-19 pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

COVID-19			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Carbuncle			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ear infection staphylococcal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eyelid boil			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

Gastroenteritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastric infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Onychomycosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Penile abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Perineal abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pilonidal disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Pharyngitis streptococcal			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sweat gland infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Tooth infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Trichomoniasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 9 (0.00%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Diabetes mellitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Insulin resistance			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitamin B complex deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 9 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PC Period: Povorcitinib 75 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Cervix neoplasm			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Fibroadenoma of breast			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Skin papilloma			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Essential hypertension			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Haematoma			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Drug withdrawal syndrome			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Feeling abnormal			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Malaise			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Nodule			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Oedema			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Swelling			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Vaccination site pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Xerosis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Mite allergy			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Seasonal allergy			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			

Abnormal uterine bleeding				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Adenomyosis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Amenorrhoea				
subjects affected / exposed	1 / 7 (14.29%)			
occurrences (all)	1			
Benign prostatic hyperplasia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Breast enlargement				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Dysmenorrhoea				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Erectile dysfunction				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Genital ulceration				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Haemorrhagic ovarian cyst				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Heavy menstrual bleeding				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Menstruation irregular				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Ovarian cyst				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			

Pelvic pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Uterine polyp			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Emphysema			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Obstructive sleep apnoea syndrome			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Pharyngeal erythema			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Productive cough			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Rhinitis allergic			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Sinus congestion			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Throat irritation			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Bipolar disorder			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Depressive symptom			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Generalised anxiety disorder			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Panic attack			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Tachyphrenia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood cholesterol increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood glucose increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood testosterone increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood pressure increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood oestrogen decreased			

subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Blood triglycerides increased				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
C-reactive protein increased				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Crystal urine present				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Electrocardiogram abnormal				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Haemoglobin decreased				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Heart rate increased				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Human papilloma virus test positive				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Neutrophil count decreased				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Platelet count decreased				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
SARS-CoV-2 test positive				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			

Transaminases increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Urine analysis abnormal			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Arteriovenous fistula site haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Breast injury			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Burns second degree			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Eye injury			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Muscle strain			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Neck injury			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Procedural pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Rib fracture			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Road traffic accident			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Sunburn			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Thermal burn			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Wound			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Bundle branch block right			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Mitral valve incompetence			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Pulmonary valve incompetence			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		

Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Tricuspid valve incompetence			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Ventricular extrasystoles			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Cerebral disorder			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Memory impairment			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Small fibre neuropathy			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Speech disorder			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Tension headache			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Increased tendency to bruise			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Mast cell activation syndrome			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Episcleritis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Foreign body sensation in eyes			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Anal fissure			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Aphthous ulcer			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Cheilitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Dry mouth			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Faeces discoloured			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		

Gingival recession subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Irritable bowel syndrome subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Lip ulceration subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Nausea subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Odynophagia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Toothache subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Vomiting subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Hepatobiliary disorders Hepatic steatosis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Acne cystic			

subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Actinic keratosis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Alopecia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Dermal cyst				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Dermatitis acneiform				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Dermatitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Dermatitis atopic				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Dermatitis contact				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Diffuse alopecia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Dry skin				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Dyshidrotic eczema				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Eczema				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Ecchymosis				

subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Eczema asteatotic				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Hand dermatitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Hidradenitis				
subjects affected / exposed	1 / 7 (14.29%)			
occurrences (all)	1			
Hirsutism				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Intertrigo				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Papule				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Perioral dermatitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Pruritus				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Rash				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Rosacea				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Seborrhoeic dermatitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Skin fissures				

subjects affected / exposed occurrences (all) Skin lesion inflammation subjects affected / exposed occurrences (all) Telangiectasia subjects affected / exposed occurrences (all) Urticaria subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0		
Renal and urinary disorders Nephrolithiasis subjects affected / exposed occurrences (all) Pollakiuria subjects affected / exposed occurrences (all) Renal cyst subjects affected / exposed occurrences (all) Urinary tract inflammation subjects affected / exposed occurrences (all)	 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0		
Endocrine disorders Goitre subjects affected / exposed occurrences (all) Hyperoestrogenism subjects affected / exposed occurrences (all) Hypothyroidism subjects affected / exposed occurrences (all)	 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0		
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Arthritis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Exostosis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Tendonitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Abscess limb			

subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Abscess soft tissue				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Abscess				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Acarodermatitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Acute sinusitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Bacterial vaginosis				
subjects affected / exposed	1 / 7 (14.29%)			
occurrences (all)	1			
Breast abscess				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Breast cellulitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Bronchitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
COVID-19 pneumonia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
COVID-19				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Carbuncle				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Cellulitis				

subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Conjunctivitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Cystitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Diarrhoea infectious				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Ear infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Ear infection staphylococcal				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Eye abscess				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Eyelid boil				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Folliculitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Fungal infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Gastric infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Gastroenteritis viral				

subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Gastrointestinal bacterial overgrowth				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Genital herpes				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Genital herpes simplex				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Gingivitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Herpes simplex				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Herpes zoster				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Helicobacter infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Hordeolum				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Impetigo				
subjects affected / exposed	1 / 7 (14.29%)			
occurrences (all)	1			
Influenza				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Kidney infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Nail infection				

subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Onychomycosis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Oral herpes				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Oral infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Otitis media				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Paronychia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Penile abscess				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Perineal abscess				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Pilonidal disease				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Pharyngitis streptococcal				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	1 / 7 (14.29%)			
occurrences (all)	1			
Pneumonia				

subjects affected / exposed	1 / 7 (14.29%)			
occurrences (all)	1			
Rhinitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Skin candida				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Subcutaneous abscess				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Sweat gland infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Suspected COVID-19				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Tinea pedis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Tooth abscess				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Tonsillitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Tooth infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Trichomoniasis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences (all)	0			
Upper respiratory tract infection				

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Diabetes mellitus			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Glucose tolerance impaired			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hypercholesterolaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hyperglycaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hyperlipidaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		

Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Increased appetite			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Insulin resistance			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Obesity			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Vitamin B complex deficiency			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 September 2021	The primary purpose of the amendment was to obtain additional long-term safety and efficacy data through 104 weeks; and to incorporate changes from country-specific amendments for Germany (dated 04 DEC 2020) and Canada (dated 08 MAR 2021).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported