Clinical trial results:
A Phase 3 Randomised, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel Group, Multi-Center Study Investigating the Efficacy and Safety of PF-04965842 and Dupilumab in Comparison with Placebo in Adult Subjects on Background Topical Therapy, With Moderate to Severe Atopic Dermatitis

Summary

EudraCT number	2018-002573-21
Trial protocol	SK BG CZ LV FR HU AT GB ES IT
Global end of trial date	06 March 2020

Results information

Result version number	v1 (current)
This version publication date	12 March 2021
First version publication date	12 March 2021

Trial information

Trial identification

Sponsor protocol code	B7451029

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03720470
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 May 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of 100 milligram (mg) and 200 mg once daily (QD) of PF-04965842 versus placebo in adult subjects on background topical therapy with moderate to severe atopic dermatitis.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 October 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 38
Country: Number of subjects enrolled	Bulgaria: 16
Country: Number of subjects enrolled	Canada: 36
Country: Number of subjects enrolled	Chile: 30
Country: Number of subjects enrolled	Czechia: 55
Country: Number of subjects enrolled	Germany: 55
Country: Number of subjects enrolled	Hungary: 15
Country: Number of subjects enrolled	Italy: 3
Country: Number of subjects enrolled	Japan: 76
Country: Number of subjects enrolled	Korea, Republic of: 33
Country: Number of subjects enrolled	Latvia: 9
Country: Number of subjects enrolled	Mexico: 13
Country: Number of subjects enrolled	Poland: 182
Country: Number of subjects enrolled	Slovakia: 15
Country: Number of subjects enrolled	Spain: 6
Country: Number of subjects enrolled	Taiwan: 16
Country: Number of subjects enrolled	United Kingdom: 67
Country: Number of subjects enrolled	United States: 172
Worldwide total number of subjects	837
EEA total number of subjects	356

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)	783
From 65 to 84 years	54
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study had treatment period of 20 weeks. The first part of this treatment period consists of a 16-week period where subjects received PF-04965842, dupilumab and placebo. The randomisation and double-blind was maintained during the final 4 weeks of the treatment period, but subjects only received PF-04965842 and placebo.

Period 1

Period 1 title	Treatment Period: First Part 16 Weeks
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo up to Week (Wk)16

Arm description:

Subjects were randomised to receive oral placebo matched to PF-04965842 once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 till Week 16.

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

Dosage and administration details:

Subjects received oral placebo matched to PF-04965842 once daily every other week from Day 1 till Week 16.

Arm title	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20

Arm description:

Subjects were randomised to receive PF-04965842 100 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, followed by administration of PF-04965842 100 mg tablet orally once daily post Week 16 up to Week 20.

Arm type	Experimental
Investigational medicinal product name	Abrocitinib100 mg+Placebo Inj.
Investigational medicinal product code	PF-04965842
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Subcutaneous use

Dosage and administration details:

Subjects were received PF-04965842 100 mg tablet with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16.

Arm title	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20

Arm description:

Subjects were randomised to receive PF-04965842 200 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, followed by administration of PF-04965842 200 mg tablet orally once daily post Week 16 up to Week 20.

Arm type	Experimental

Investigational medicinal product name	Abrocitinib 200 mg+Placebo Inj.
Investigational medicinal product code	PF-04965842
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Subcutaneous use

Dosage and administration details:

Subjects received PF-04965842 200 mg tablet with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16.

Arm title	Dupilumab 300mg+Oral Placebo up to Wk16>Oral Placebo Wk 16-20

Arm description:

Subjects were randomised to receive dupilumab 300 mg subcutaneous injection every other week with oral placebo matched to PF-04965842 once daily from Day 1 to Week 16, followed by administration of oral placebo matched to PF-04965842 once daily post Week 16 up to Week 20.

Arm type	Experimental
Investigational medicinal product name	Dupilumab 300mg+ Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Injection
Routes of administration	Oral use, Subcutaneous use

Dosage and administration details:

Subjects received dupilumab 300 mg subcutaneous injection every other week with oral placebo matched to PF-04965842 once daily from Day 1 to Week 16.

Number of subjects in period 1	Placebo up to Week (Wk)16	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Started	131	238	226
Full Analysis Set	131	238	226
Completed	117	217	208
Not completed	14	21	18
Consent withdrawn by subject	5	9	3
Adverse event, non-fatal	5	5	8
Protocol deviation	2	2	2
Pregnancy	-	-	1
Unspecified	1	1	2
Medication Error Without Associated Adverse Event	-	1	1
Lost to follow-up	1	2	1
Lack of efficacy	-	1	-

Number of subjects in period 1	Dupilumab 300mg+Oral Placebo up to Wk16>Oral Placebo Wk 16-20
Started	242
Full Analysis Set	242

Completed	223
Not completed	19
Consent withdrawn by subject	6
Adverse event, non-fatal	6
Protocol deviation	1
Pregnancy	1
Unspecified	2
Medication Error Without Associated Adverse Event	-
Lost to follow-up	2
Lack of efficacy	1

Period 2

Period 2 title	Treatment Period: Final 4 Weeks
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20

Arm description:

Subjects who were randomised to receive oral placebo matched to PF-04965842 with subcutaneous injectable placebo matched to dupilumab till Week 16, received PF-04965842 100 mg tablet orally once daily post Week 16 up to Week 20.

Arm type	Experimental
Investigational medicinal product name	Abrocitinib 100 mg
Investigational medicinal product code	PF-04965842
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received PF-04965842 100 mg tablet orally once daily post Week 16 up to Week 20.

Arm title	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20

Arm description:

Subjects who were randomised to receive oral placebo matched to PF-04965842 with subcutaneous injectable placebo matched to dupilumab till Week 16, received PF-04965842 200 mg tablet orally once daily post Week 16 up to Week 20.

Arm type	Experimental
Investigational medicinal product name	Abrocitinib 200 mg
Investigational medicinal product code	PF-04965842
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received PF-04965842 200 mg tablet orally once daily post Week 16 up to Week 20.

Arm title	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20

Arm description:

Subjects were randomised to receive PF-04965842 100 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, followed by administration of PF-04965842 100 mg tablet orally once daily post Week 16 up to Week 20.

Arm type	Experimental
Investigational medicinal product name	Abrocitinib 100mg
Investigational medicinal product code	PF-04965842
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received of PF-04965842 100 mg tablet orally once daily post Week 16 up to Week 20.

Arm title	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20

Arm description:

Subjects were randomised to receive PF-04965842 200 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, followed by administration of PF-04965842 200 mg tablet orally once daily post Week 16 up to Week 20.

Arm type	Experimental
Investigational medicinal product name	Abrocitinib 200 mg
Investigational medicinal product code	PF-04965842
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received PF-04965842 200 mg tablet orally once daily post Week 16 up to Week 20.

Arm title	Dupilumab 300mg+Oral Placebo up to Wk>Oral Placebo Wk 16-20

Arm description:

Subjects were randomised to receive dupilumab 300 mg subcutaneous injection every other week with oral placebo matched to PF-04965842 once daily from Day 1 to Week 16, followed by administration of oral placebo matched to PF-04965842 once daily post Week 16 up to Week 20.

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:

Subjects received oral placebo matched to PF-04965842 once daily post Week 16 up to Week 20.

Number of subjects in period 2	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20
Started	60	57	217
Treated/ Safety Analysis Set	60	57	217
Full Analysis Set	60	57	217

Completed	58	55	210
Not completed	2	2	7
Consent withdrawn by subject	1	-	2
Adverse event, non-fatal	-	-	2
Protocol deviation	-	1	-
Pregnancy	-	-	-
Unspecified	1	-	2
Lost to follow-up	-	-	1
Lack of efficacy	-	1	-

Number of subjects in period 2	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20	Dupilumab 300mg+Oral Placebo up to Wk>Oral Placebo Wk 16-20
Started	208	223
Treated/ Safety Analysis Set	208	223
Full Analysis Set	208	223
Completed	204	218
Not completed	4	5
Consent withdrawn by subject	2	2
Adverse event, non-fatal	1	1
Protocol deviation	-	-
Pregnancy	-	1
Unspecified	1	-
Lost to follow-up	-	1
Lack of efficacy	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Placebo up to Week (Wk)16
Reporting group description:	
Subjects were randomised to receive oral placebo matched to PF-04965842 once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 till Week 16.	
Reporting group title	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20
Reporting group description:	
Subjects were randomised to receive PF-04965842 100 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, followed by administration of PF-04965842 100 mg tablet orally once daily post Week 16 up to Week 20.	
Reporting group title	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Reporting group description:	
Subjects were randomised to receive PF-04965842 200 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, followed by administration of PF-04965842 200 mg tablet orally once daily post Week 16 up to Week 20.	
Reporting group title	Dupilumab 300mg+Oral Placebo up to Wk16>Oral Placebo Wk 16-20
Reporting group description:	
Subjects were randomised to receive dupilumab 300 mg subcutaneous injection every other week with oral placebo matched to PF-04965842 once daily from Day 1 to Week 16, followed by administration of oral placebo matched to PF-04965842 once daily post Week 16 up to Week 20.	

Reporting group values	Placebo up to Week (Wk)16	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Number of subjects	131	238	226
Age Categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	121	224	211
>=65 years	10	14	15
Sex: Female, Male Units: Subjects			
Female	54	118	122
Male	77	120	104
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	1	0
Asian	31	48	53
Native Hawaiian or Other Pacific Islander	1	0	1
Black or African American	6	6	9
White	87	182	161
More than one race	1	1	1
Unknown or Not Reported	3	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	16	35	36

Not Hispanic or Latino	113	200	187
Unknown or Not Reported	2	3	3

Reporting group values	Dupilumab 300mg+Oral Placebo up to Wk16>Oral Placebo Wk 16-20	Total	
Number of subjects	242	837	
Age Categorical Units: Subjects			
<=18 years	0	0	
Between 18 and 65 years	227	783	
>=65 years	15	54	
Sex: Female, Male Units: Subjects			
Female	134	428	
Male	108	409	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	5	
Asian	46	178	
Native Hawaiian or Other Pacific Islander	0	2	
Black or African American	14	35	
White	176	606	
More than one race	2	5	
Unknown or Not Reported	2	6	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	37	124	
Not Hispanic or Latino	201	701	
Unknown or Not Reported	4	12	

End points reporting groups

Reporting group title	Placebo up to Week (Wk)16
Reporting group description:	
Subjects were randomised to receive oral placebo matched to PF-04965842 once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 till Week 16.	
Reporting group title	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20
Reporting group description:	
Subjects were randomised to receive PF-04965842 100 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, followed by administration of PF-04965842 100 mg tablet orally once daily post Week 16 up to Week 20.	
Reporting group title	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Reporting group description:	
Subjects were randomised to receive PF-04965842 200 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, followed by administration of PF-04965842 200 mg tablet orally once daily post Week 16 up to Week 20.	
Reporting group title	Dupilumab 300mg+Oral Placebo up to Wk16>Oral Placebo Wk 16-20
Reporting group description:	
Subjects were randomised to receive dupilumab 300 mg subcutaneous injection every other week with oral placebo matched to PF-04965842 once daily from Day 1 to Week 16, followed by administration of oral placebo matched to PF-04965842 once daily post Week 16 up to Week 20.	
Reporting group title	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20
Reporting group description:	
Subjects who were randomised to receive oral placebo matched to PF-04965842 with subcutaneous injectable placebo matched to dupilumab till Week 16, received PF-04965842 100 mg tablet orally once daily post Week 16 up to Week 20.	
Reporting group title	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20
Reporting group description:	
Subjects who were randomised to receive oral placebo matched to PF-04965842 with subcutaneous injectable placebo matched to dupilumab till Week 16, received PF-04965842 200 mg tablet orally once daily post Week 16 up to Week 20.	
Reporting group title	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20
Reporting group description:	
Subjects were randomised to receive PF-04965842 100 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, followed by administration of PF-04965842 100 mg tablet orally once daily post Week 16 up to Week 20.	
Reporting group title	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Reporting group description:	
Subjects were randomised to receive PF-04965842 200 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, followed by administration of PF-04965842 200 mg tablet orally once daily post Week 16 up to Week 20.	
Reporting group title	Dupilumab 300mg+Oral Placebo up to Wk>Oral Placebo Wk 16-20
Reporting group description:	
Subjects were randomised to receive dupilumab 300 mg subcutaneous injection every other week with oral placebo matched to PF-04965842 once daily from Day 1 to Week 16, followed by administration of oral placebo matched to PF-04965842 once daily post Week 16 up to Week 20.	
Subject analysis set title	PF-04965842 100 mg + Placebo Injection up to Week 16
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects were randomised to receive PF-04965842 100 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16.	

Subject analysis set title	PF-04965842 200 mg + Placebo Injection up to Week 16
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects were randomised to receive PF-04965842 200 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16.

Subject analysis set title	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects were randomised to receive dupilumab 300 mg subcutaneous injection every other week with oral placebo matched to PF-04965842 once daily from Day 1 to Week 16.

Primary: Percentage of Subjects Achieving Investigator's Global Assessment (IGA) Response of Clear (0) or Almost Clear (1) and a Reduction of Greater Than or Equal to (>=) 2 Points From Baseline at Week 12

End point title	Percentage of Subjects Achieving Investigator's Global Assessment (IGA) Response of Clear (0) or Almost Clear (1) and a Reduction of Greater Than or Equal to (>=) 2 Points From Baseline at Week 12[1]

End point description:

IGA assessed severity of atopic dermatitis (AD) on a 5 point scale (0 to 4, higher scores indicate more severity). Scores: 0= clear, no inflammatory signs of AD; 1= almost clear, AD not fully cleared- light pink residual lesions (except post-inflammatory hyperpigmentation), just perceptible erythema, papulation/induration lichenification, excoriation, and no oozing/crusting; 2= mild AD with light red lesions, slight but definite erythema, papulation/induration, lichenification, excoriation and no oozing/crusting; 3= moderate AD with red lesions, moderate erythema, papulation/induration, lichenification, excoriation and slight oozing/crusting; 4= severe AD with deep dark red lesions, severe erythema, papulation/induration, lichenification, excoriation and moderate to severe oozing/crusting. Assessment excluded scalp, palms and sole. FAS analysed till Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Baseline (the last measurement prior to first dosing on Day 1), Week 12

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 12.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	129	235	219	241
Units: Percentage of subjects				
number (confidence interval 95%)	14.0 (8.0 to 19.9)	36.6 (30.4 to 42.8)	48.4 (41.8 to 55.0)	36.5 (30.4 to 42.6)

Statistical analyses

Statistical analysis title	PF-04965842 versus placebo

Statistical analysis description:

Difference in percentage (PF-04965842 versus placebo) and confidence interval (CI) for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	Placebo up to Week (Wk)16 v PF-04965842 100 mg + Placebo

	Injection up to Week 16
Number of subjects included in analysis	364
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	23.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.7
upper limit	31.4

Statistical analysis title	PF-04965842 versus placebo

Statistical analysis description:

Difference in percentage (PF-04965842 versus placebo) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	Placebo up to Week (Wk)16 v PF-04965842 200 mg + Placebo Injection up to Week 16
Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	34.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.1
upper limit	43.5

Primary: Percentage of Subjects Achieving Eczema Area and Severity Index (EASI) Response >=75 Percent (%) Improvement From Baseline at Week 12

End point title	Percentage of Subjects Achieving Eczema Area and Severity Index (EASI) Response >=75 Percent (%) Improvement From Baseline at Week 12[2]

End point description:

EASI evaluates severity of subjects with AD (excluded scalp, palms, soles) based on severity of AD clinical signs and % of body surface area (BSA) affected. Severity of clinical signs of AD (erythema, induration/papulation, excoriation and lichenification) scored separately for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin] and lower limbs [including buttocks]) on 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % BSA with AD in body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+Exl+Ll); (A =EASI area score) ranged from 0.0 to 72.0, higher scores = greater severity of AD. FAS analysed till Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Baseline, Week 12

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 12.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	129	235	219	241
Units: Percentage of subjects				
number (confidence interval 95%)	27.1 (19.5 to 34.8)	58.7 (52.4 to 65.0)	70.3 (64.3 to 76.4)	58.1 (51.9 to 64.3)

Statistical analyses

Statistical analysis title	PF-04965842 versus placebo

Statistical analysis description:

Difference in percentage (PF-04965842 versus placebo) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	Placebo up to Week (Wk)16 v PF-04965842 100 mg + Placebo Injection up to Week 16
Number of subjects included in analysis	364
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	31.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.2
upper limit	41.6

Statistical analysis title	PF-04965842 versus placebo

Statistical analysis description:

Difference in percentage (PF-04965842 versus placebo) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	Placebo up to Week (Wk)16 v PF-04965842 200 mg + Placebo Injection up to Week 16

Number of subjects included in analysis	348
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	43.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.7
upper limit	52.7

Secondary: Percentage of Subjects With at Least 4 Points Improvement in the Numerical Rating Scale (NRS) for Severity of Pruritus From Baseline at Day 2-15, Week 2, 4, 8, 12 and 16

End point title	Percentage of Subjects With at Least 4 Points Improvement in the Numerical Rating Scale (NRS) for Severity of Pruritus From Baseline at Day 2-15, Week 2, 4, 8, 12 and 16[3]

End point description:

Subjects were asked to assess their worst pruritus/itching due to AD over the past 24 hours on an NRS scale ranged from 0 (no itching) to 10 (worst possible itching), where higher scores indicated greater severity. FAS analysed till Week 16. Here, "Number Analyzed" (n) signifies the number of subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Baseline, Day 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15 and Week 2, 4, 8, 12, 16

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 2 (n=117, 220, 203, 206)	5.1 (1.1 to 9.1)	5.9 (2.8 to 9.0)	7.4 (3.8 to 11.0)	2.4 (0.3 to 4.5)
Day 3 (n=114, 214, 203, 213)	7.9 (2.9 to 12.8)	8.4 (4.7 to 12.1)	14.8 (9.9 to 19.7)	3.3 (0.9 to 5.7)
Day 4 (n=116, 216, 199, 216)	6.0 (1.7 to 10.4)	11.6 (7.3 to 15.8)	18.6 (13.2 to 24.0)	5.6 (2.5 to 8.6)
Day 5 (n=119, 211, 196, 210)	7.6 (2.8 to 12.3)	14.2 (9.5 to 18.9)	26.5 (20.3 to 32.7)	9.5 (5.6 to 13.5)
Day 6 (n=119, 213, 207, 214)	10.9 (5.3 to 16.5)	15.0 (10.2 to 19.8)	25.1 (19.2 to 31.0)	14.0 (9.4 to 18.7)
Day 7 (n=108, 214, 208, 216)	11.1 (5.2 to 17.0)	20.1 (14.7 to 25.5)	28.8 (22.7 to 35.0)	13.4 (8.9 to 18.0)
Day 8 (n=118, 210, 207, 212)	14.4 (8.1 to 20.7)	21.4 (15.9 to 27.0)	33.3 (26.9 to 39.8)	16.5 (11.5 to 21.5)

Day 9 (n=115, 204, 208, 209)	13.0 (6.9 to 19.2)	24.0 (18.2 to 29.9)	34.1 (27.7 to 40.6)	14.8 (10.0 to 19.7)
Day 10 (n=114, 203, 207, 210)	13.2 (7.0 to 19.4)	25.6 (19.6 to 31.6)	34.3 (27.8 to 40.8)	17.1 (12.0 to 22.2)
Day 11 (n=118, 201, 210, 210)	12.7 (6.7 to 18.7)	25.4 (19.4 to 31.4)	39.5 (32.9 to 46.1)	20.5 (15.0 to 25.9)
Day 12 (n=117, 204, 202, 215)	12.0 (6.1 to 17.8)	25.5 (19.5 to 31.5)	44.1 (37.2 to 50.9)	21.9 (16.3 to 27.4)
Day 13 (n=114, 196, 203, 212)	13.2 (7.0 to 19.4)	30.6 (24.2 to 37.1)	43.8 (37.0 to 50.7)	23.6 (17.9 to 29.3)
Day 14 (n=121, 210, 199, 212)	15.7 (9.2 to 22.2)	31.4 (25.1 to 37.7)	45.7 (38.8 to 52.7)	24.5 (18.7 to 30.3)
Day 15 (n=117, 207, 208, 211)	11.1 (5.4 to 16.8)	30.4 (24.2 to 36.7)	49.0 (42.2 to 55.8)	26.5 (20.6 to 32.5)
Week 2 (n=130, 236, 226, 239)	13.8 (7.9 to 19.8)	31.8 (25.8 to 37.7)	49.1 (42.6 to 55.6)	26.4 (20.8 to 31.9)
Week 4 (n=124, 224, 214, 232)	20.2 (13.1 to 27.2)	44.6 (38.1 to 51.2)	59.3 (52.8 to 65.9)	45.3 (38.9 to 51.7)
Week 8 (n=122, 221, 214, 229)	27.0 (19.2 to 34.9)	47.5 (40.9 to 54.1)	64.0 (57.6 to 70.4)	50.7 (44.2 to 57.1)
Week 12 (n=121, 221, 217, 224)	28.9 (20.8 to 37.0)	47.5 (40.9 to 54.1)	63.1 (56.7 to 69.6)	54.5 (47.9 to 61.0)
Week 16 (n=94, 168, 172, 189)	28.7 (19.6 to 37.9)	47.0 (39.5 to 54.6)	62.8 (55.6 to 70.0)	57.1 (50.1 to 64.2)

Statistical analyses

Statistical analysis title	PF-04965842 versus placebo

Statistical analysis description:

Week 2: Difference in percentage (PF-04965842 versus placebo) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	Placebo up to Week (Wk)16 v PF-04965842 100 mg + Placebo Injection up to Week 16
Number of subjects included in analysis	369
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	17.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.5
upper limit	26.3

Statistical analysis title	PF-04965842 versus placebo

Statistical analysis description:

Week 2: Difference in percentage (PF-04965842 versus placebo) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	Placebo up to Week (Wk)16 v PF-04965842 200 mg + Placebo Injection up to Week 16
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	34.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	26
upper limit	43.7

Statistical analysis title	PF-04965842 versus dupilumab

Statistical analysis description:

Week 2: Difference in percentage (PF-04965842 versus dupilumab) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	PF-04965842 100 mg + Placebo Injection up to Week 16 v Dupilumab 300 mg + Oral Placebo up to Week 16
Number of subjects included in analysis	480
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2084
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	13.4

Statistical analysis title	PF-04965842 versus dupilumab

Statistical analysis description:

Week 2: Difference in percentage (PF-04965842 versus dupilumab) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	PF-04965842 200 mg + Placebo Injection up to Week 16 v Dupilumab 300 mg + Oral Placebo up to Week 16
Number of subjects included in analysis	468
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	22.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	13.5
upper limit	30.7

Secondary: Percentage of Subjects Achieving IGA Response of Clear (0) or Almost Clear (1) and a Reduction of >=2 Points From Baseline at Week 2, 4, 8 and 16

End point title	Percentage of Subjects Achieving IGA Response of Clear (0) or Almost Clear (1) and a Reduction of >=2 Points From Baseline at Week 2, 4, 8 and 16[4]

End point description:

IGA assessed severity of AD on a 5 point scale (0 to 4, higher scores indicate more severity). Scores: 0= clear, no inflammatory signs of AD; 1= almost clear, AD not fully cleared- light pink residual lesions (except post-inflammatory hyperpigmentation), just perceptible erythema, papulation/induration lichenification, excoriation, and no oozing/crusting; 2= mild AD with light red lesions, slight but definite erythema, papulation/induration, lichenification, excoriation and no oozing/crusting; 3= moderate AD with red lesions, moderate erythema, papulation/induration, lichenification, excoriation and slight oozing/crusting; 4= severe AD with deep dark red lesions, severe erythema, papulation/induration, lichenification, excoriation and moderate to severe oozing/crusting. Assessment excluded sole, palms and scalp. FAS analysed till Week 16. Here, "n" signifies the number of subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4, 8 and 16

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 2 (n=128, 230, 223, 236)	6.3 (2.1 to 10.4)	15.2 (10.6 to 19.9)	18.4 (13.3 to 23.5)	4.7 (2.0 to 7.4)
Week 4 (n=129, 234, 223, 238)	6.2 (2.0 to 10.4)	25.2 (19.6 to 30.8)	31.4 (25.3 to 37.5)	18.9 (13.9 to 23.9)
Week 8 (n=129, 232, 225, 239)	10.1 (4.9 to 15.3)	35.8 (29.6 to 41.9)	50.7 (44.1 to 57.2)	28.5 (22.7 to 34.2)
Week 16 (n=124, 230, 221, 232)	12.9 (7.0 to 18.8)	34.8 (28.6 to 40.9)	47.5 (40.9 to 54.1)	38.8 (32.5 to 45.1)

Statistical analyses

Statistical analysis title	PF-04965842 versus placebo

Statistical analysis description:

Week 16: Difference in percentage (PF-04965842 versus placebo) and CI for difference were calculated

based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	Placebo up to Week (Wk)16 v PF-04965842 100 mg + Placebo Injection up to Week 16
Number of subjects included in analysis	369
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	22.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.7
upper limit	30.5

Statistical analysis title	PF-04965842 versus placebo

Statistical analysis description:

Week 16: Difference in percentage (PF-04965842 versus placebo) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	Placebo up to Week (Wk)16 v PF-04965842 200 mg + Placebo Injection up to Week 16
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	35
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.3
upper limit	43.7

Statistical analysis title	PF-04965842 versus dupilumab

Statistical analysis description:

Week 16: Difference in percentage (PF-04965842 versus dupilumab) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	PF-04965842 100 mg + Placebo Injection up to Week 16 v Dupilumab 300 mg + Oral Placebo up to Week 16

Number of subjects included in analysis	480
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in Percentage
Point estimate	-3.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.2
upper limit	5.2

Statistical analysis title	PF-04965842 versus dupilumab

Statistical analysis description:

Week 16: Difference in percentage (PF-04965842 versus dupilumab) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	PF-04965842 200 mg + Placebo Injection up to Week 16 v Dupilumab 300 mg + Oral Placebo up to Week 16
Number of subjects included in analysis	468
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in Percentage
Point estimate	9.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	18.5

Secondary: Percentage of Subjects Achieving EASI Response >=75% Improvement From Baseline at Week 2, 4, 8 and 16

End point title	Percentage of Subjects Achieving EASI Response >=75% Improvement From Baseline at Week 2, 4, 8 and 16[5]

End point description:

EASI evaluates severity of subjects' AD (excluded scalp, palms, soles) based on severity of AD clinical signs and % of body surface area (BSA) affected. Severity of clinical signs of AD (erythema, induration/papulation, excoriation and lichenification) scored separately for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin] and lower limbs [including buttocks]) on 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % BSA with AD in body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+Exl+Ll); (A =EASI area score) ranged from 0.0 to 72.0, higher scores = greater severity of AD. FAS analysed till Week 16. Here, "n" signifies the number of subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4, 8 and 16

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 2 (n= 128, 228, 223, 235)	10.9 (5.5 to 16.3)	25.4 (19.8 to 31.1)	30.0 (24.0 to 36.1)	14.0 (9.6 to 18.5)
Week 4 (n= 128, 233, 223, 238)	15.6 (9.3 to 21.9)	44.6 (38.3 to 51.0)	57.4 (50.9 to 63.9)	38.2 (32.1 to 44.4)
Week 8 (n= 129, 232, 224, 239)	18.6 (11.9 to 25.3)	55.6 (49.2 to 62.0)	67.9 (61.7 to 74.0)	52.7 (46.4 to 59.0)
Week 16 (n= 124, 229, 221, 232)	30.6 (22.5 to 38.8)	60.3 (53.9 to 66.6)	71.0 (65.1 to 77.0)	65.5 (59.4 to 71.6)

Statistical analyses

Statistical analysis title	PF-04965842 versus placebo

Statistical analysis description:

Difference in percentage (PF-04965842 versus placebo) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	Placebo up to Week (Wk)16 v PF-04965842 100 mg + Placebo Injection up to Week 16
Number of subjects included in analysis	369
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	24.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	14
upper limit	34.1

Statistical analysis title	PF-04965842 versus placebo

Statistical analysis description:

Difference in percentage (PF-04965842 versus placebo) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	Placebo up to Week (Wk)16 v PF-04965842 200 mg + Placebo

	Injection up to Week 16
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	30.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.3
upper limit	39.8

Statistical analysis title	PF-04965842 versus dupilumab

Statistical analysis description:

Week 16: Difference in percentage (PF-04965842 versus dupilumab) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	Placebo up to Week (Wk)16 v Dupilumab 300 mg + Oral Placebo up to Week 16
Number of subjects included in analysis	373
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in Percentage
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.6
upper limit	4.2

Statistical analysis title	PF-04965842 versus dupilumab

Statistical analysis description:

Week 16: Difference in percentage (PF-04965842 versus dupilumab) and CI for difference were calculated based on the weighted average of difference by disease severity group using the normal approximation of binomial proportions. P-value was adjusted by baseline disease severity.

Comparison groups	PF-04965842 100 mg + Placebo Injection up to Week 16 v Dupilumab 300 mg + Oral Placebo up to Week 16
Number of subjects included in analysis	480
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in Percentage
Point estimate	3.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	9.6

Secondary: Percentage of Subjects Achieving EASI Response >=50% Improvement From Baseline at Week 2, 4, 8, 12 and 16

End point title	Percentage of Subjects Achieving EASI Response >=50% Improvement From Baseline at Week 2, 4, 8, 12 and 16[6]

End point description:

EASI evaluates severity of subjects' AD (excluded scalp, palms, soles) based on severity of AD clinical signs and % of BSA affected. Severity of clinical signs of AD (erythema, induration/papulation, excoriation and lichenification) scored separately for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin] and lower limbs [including buttocks]) on 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % BSA with AD in body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+Exl+Ll); (A =EASI area score) ranged from 0.0 to 72.0, higher scores = greater severity of AD. FAS analysed till Week 16. Here, "n" signifies the number of subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4, 8, 12 and 16

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 2 (n=128, 228, 223, 235)	21.9 (14.7 to 29.0)	53.1 (46.6 to 59.5)	60.5 (54.1 to 67.0)	35.7 (29.6 to 41.9)
Week 4 (n=128, 233, 223, 238)	39.8 (31.4 to 48.3)	73.4 (67.7 to 79.1)	78.5 (73.1 to 83.9)	66.8 (60.8 to 72.8)
Week 8 (n=129, 232, 224, 239)	48.8 (40.2 to 57.5)	78.9 (73.6 to 84.1)	88.4 (84.2 to 92.6)	77.4 (72.1 to 82.7)
Week 12 (n=129, 235, 219, 241)	52.7 (44.1 to 61.3)	75.3 (69.8 to 80.8)	86.3 (81.7 to 90.9)	80.9 (76.0 to 85.9)
Week 16 (n=124, 229, 221, 232)	57.3 (48.6 to 66.0)	81.2 (76.2 to 86.3)	87.3 (82.9 to 91.7)	84.1 (79.3 to 88.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving EASI Response >=90% Improvement From Baseline at Week 2, 4, 8, 12 and 16

End point title	Percentage of Subjects Achieving EASI Response >=90% Improvement From Baseline at Week 2, 4, 8, 12 and 16[7]

End point description:

EASI evaluates severity of subjects' AD (excluded scalp, palms, soles) based on severity of AD clinical signs and % of BSA affected. Severity of clinical signs of AD (erythema, induration/papulation, excoriation and lichenification) scored separately for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin] and lower limbs [including buttocks]) on 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % BSA with AD in body region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+Exl+Ll); (A =EASI area score) ranged from 0.0 to 72.0, higher scores = greater severity of AD. FAS analysed till Week 16. Here, "n" signifies the number of subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4, 8, 12 and 16

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 2 (n=128, 228, 223, 235)	2.3 (0.0 to 5.0)	8.3 (4.7 to 11.9)	11.2 (7.1 to 15.4)	2.6 (0.5 to 4.6)
Week 4 (n=128, 233, 223, 238)	6.3 (2.1 to 10.4)	20.2 (15.0 to 25.3)	32.3 (26.2 to 38.4)	12.2 (8.0 to 16.3)
Week 8 (n=129, 232, 224, 239)	7.8 (3.1 to 12.4)	30.6 (24.7 to 36.5)	47.3 (40.8 to 53.9)	24.3 (18.8 to 29.7)
Week 12 (n=129, 235, 219, 241)	10.1 (4.9 to 15.3)	36.6 (30.4 to 42.8)	46.1 (39.5 to 52.7)	34.9 (28.8 to 40.9)
Week 16 (n=124, 229, 221, 232)	11.3 (5.7 to 16.9)	38.0 (31.7 to 44.3)	48.9 (42.3 to 55.5)	38.8 (32.5 to 45.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving EASI Response =100% Improvement From Baseline at Week 2, 4, 8, 12 and 16

End point title	Percentage of Subjects Achieving EASI Response =100% Improvement From Baseline at Week 2, 4, 8, 12 and 16[8]

End point description:

EASI evaluates severity of subjects' AD (excluded scalp, palms, soles) based on severity of AD clinical signs and % of BSA affected. Severity of clinical signs of AD (erythema, induration/papulation, excoriation and lichenification) scored separately for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin] and lower limbs [including buttocks]) on 4-point scale: 0= absent; 1= mild; 2= moderate; 3= severe. EASI area score was based upon % BSA with AD in body

region: 0 (0%), 1 (>0 to <10%), 2 (10 to <30%), 3 (30 to <50%), 4 (50 to <70%), 5 (70 to <90%) and 6 (90 to 100%). Total EASI score =0.1*Ah*(Eh+Ih+Exh+Lh) + 0.2*Au*(Eu+Iu+ExU+Lu) + 0.3*At*(Et+It+Ext+Lt) + 0.4*Al*(El+Il+Exl+Ll); (A =EASI area score) ranged from 0.0 to 72.0, higher scores = greater severity of AD. FAS analysed till Week 16. Here, "n" signifies the number of subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4, 8, 12 and 16

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 2 (n=128, 228, 223, 235)	0 (0.0 to 2.8)	1.3 (0.0 to 2.8)	4.5 (1.8 to 7.2)	0.4 (0.0 to 1.3)
Week 4 (n=128, 233, 223, 238)	0 (0.0 to 2.8)	2.6 (0.5 to 4.6)	7.2 (3.8 to 10.6)	2.5 (0.5 to 4.5)
Week 8 (n=129, 232, 224, 239)	0 (0.0 to 2.8)	6.0 (3.0 to 9.1)	11.6 (7.4 to 15.8)	2.1 (0.3 to 3.9)
Week 12 (n=129, 235, 219, 241)	1.6 (0.0 to 3.7)	8.1 (4.6 to 11.6)	12.3 (8.0 to 16.7)	6.6 (3.5 to 9.8)
Week 16 (n=124, 229, 221, 232)	4.0 (0.6 to 7.5)	12.7 (8.4 to 17.0)	13.6 (9.1 to 18.1)	5.2 (2.3 to 8.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Time From Baseline to First Achieve at Least 4 Points Improvement in the Severity of Pruritus NRS

End point title	Time From Baseline to First Achieve at Least 4 Points Improvement in the Severity of Pruritus NRS[9]

End point description:

Subjects were asked to assess their worst pruritus/itching due to AD over the past 24 hours on an NRS scale ranged from 0 (no itching) to 10 (worst possible itching), where higher scores indicated greater severity. FAS analysed till Week 16. Subjects with a baseline numeric rating scale score for severity of pruritus >=4 were included in the analysis. Here, "99999" signifies median and upper limit for 95% CI could not be estimated because there were insufficient number of subjects with event.

End point type	Secondary

End point timeframe:

Baseline up to Week 16

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	130	236	226	240
Units: Days				
median (confidence interval 95%)	99999 (84.0 to 99999)	29.0 (16.0 to 56.0)	13.0 (10.0 to 16.0)	31.0 (29.0 to 57.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Percentage Body Surface Area (BSA) at Week 2, 4, 8, 12 and 16

End point title	Change From Baseline in Percentage Body Surface Area (BSA) at Week 2, 4, 8, 12 and 16[10]

End point description:

4 body regions were evaluated: head and neck, upper limbs, trunk (including axillae and groin) and lower limbs (including buttocks). Scalp, palms and soles were excluded. BSA was calculated using handprint method. Number of handprints (size of subject's hand with fingers in a closed position) fitting in the affected area of a body region was estimated. Maximum number of handprints were 10 for head and neck, 20 for upper limbs, 30 for trunk and 40 for lower limbs. Surface area of body region equivalent to 1 handprint: 1 handprint was equal to 10% for head and neck, 5% for upper limbs, 3.33% for trunk and 2.5% for lower limbs. Percent BSA for a body region was calculated as = total number of handprints in a body region * % surface area equivalent to 1 handprint. Overall % BSA for an individual: arithmetic mean of % BSA of all 4 body regions, ranges from 0 to 100%, with higher values representing greater severity of AD. FAS analysed till Week 16.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4, 8, 12 and 16

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: Percentage BSA				
least squares mean (confidence interval 95%)				
Change at Week 2	-7.6 (-10.4 to -4.8)	-19.5 (-21.6 to -17.4)	-21.4 (-23.5 to -19.3)	-14.0 (-16.1 to -11.9)
Change at Week 4	-14.3 (-17.2 to -11.4)	-26.8 (-29.0 to -24.7)	-30.7 (-32.9 to -28.4)	-24.0 (-26.2 to -21.9)
Change at Week 8	-16.2 (-19.0 to -13.4)	-30.3 (-32.4 to -28.2)	-36.4 (-38.6 to -34.3)	-29.8 (-31.8 to -27.7)
Change at Week 12	-17.1 (-20.1 to -14.1)	-31.6 (-33.8 to -29.4)	-37.4 (-39.6 to -35.1)	-32.5 (-34.7 to -30.3)

Change at Week 16	-19.6 (-22.6 to -16.6)	-32.9 (-35.1 to -30.7)	-39.0 (-41.3 to -36.8)	-34.4 (-36.6 to -32.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage BSA at Week 18 and 20

End point title	Percentage BSA at Week 18 and 20

End point description:

4 body regions were evaluated: head and neck, upper limbs, trunk (including axillae and groin) and lower limbs (including buttocks). Scalp, palms and soles were excluded. BSA was calculated using handprint method. Number of handprints (size of subject's hand with fingers in closed position) fitting in the affected area of body region was estimated. Maximum number of handprints were 10 for head and neck, 20 for upper limbs, 30 for trunk and 40 for lower limbs. Surface area (SA) of body region equivalent to 1 handprint: 1 handprint=10% for head and neck, 5% for upper limbs, 3.33% for trunk and 2.5% for lower limbs. %BSA for body region was calculated as=total number of handprints in body region*% SA equivalent to 1 handprint. Overall %BSA for individual: arithmetic mean of %BSA of all 4 body regions, ranges from 0-100%, with higher values representing greater severity of AD. FAS analysed post Week 16. Here, "n" signifies the number of subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Week 18 and 20

End point values	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	57	217	208
Units: Percentage BSA				
arithmetic mean (standard deviation)				
Week 18 (n=55, 51, 200, 198, 204)	22.0 (± 23.67)	20.8 (± 22.7)	14.8 (± 19.3)	9.8 (± 13.6)
Week 20 (n=57, 56, 212, 197, 214)	18.0 (± 21.2)	16.0 (± 19.7)	14.2 (± 19.0)	10.3 (± 14.2)

End point values	Dupilumab 300mg+Oral Placebo up to Wk>Oral Placebo Wk 16-20			
Subject group type	Reporting group			
Number of subjects analysed	223			
Units: Percentage BSA				

arithmetic mean (standard deviation)				
Week 18 (n=55, 51, 200, 198, 204)	13.2 (± 16.4)			
Week 20 (n=57, 56, 212, 197, 214)	13.2 (± 16.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient Global Assessment (PtGA) at Week 2, 4, 8, 12 and 16

End point title	Change From Baseline in Patient Global Assessment (PtGA) at Week 2, 4, 8, 12 and 16[11]

End point description:

Subject responded to the following question: "Overall, how would you describe your Atopic Dermatitis right now?" on a scale: 0= clear; 1= almost clear; 2= mild; 3= moderate; and 4= severe. Higher scores indicated more severity. FAS analysed till Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4, 8, 12 and 16

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	241
Units: units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 2	-0.5 (-0.6 to -0.3)	-0.8 (-0.9 to -0.7)	-1.0 (-1.1 to -0.9)	-0.7 (-0.8 to -0.6)
Change at Week 4	-0.5 (-0.7 to -0.4)	-1.0 (-1.1 to -0.9)	-1.4 (-1.5 to -1.3)	-1.1 (-1.2 to -0.9)
Change at Week 8	-0.6 (-0.7 to -0.4)	-1.1 (-1.3 to -1.0)	-1.5 (-1.6 to -1.4)	-1.3 (-1.4 to -1.1)
Change at Week 12	-0.7 (-0.8 to -0.5)	-1.2 (-1.3 to -1.1)	-1.6 (-1.7 to -1.5)	-1.3 (-1.4 to -1.2)
Change at Week 16	-0.7 (-0.9 to -0.6)	-1.2 (-1.3 to -1.0)	-1.6 (-1.7 to -1.5)	-1.4 (-1.5 to -1.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Dermatology Life Quality Index (DLQI) at

Week 2, 12 and 16

End point title	Change From Baseline in Dermatology Life Quality Index (DLQI) at Week 2, 12 and 16[12]

End point description:

DLQI is a 10-item questionnaire that measures the impact of skin disease. Each question was evaluated on a 4-point scale ranging from 0 (not at all) to 3 (very much); where higher scores indicated more impact on quality of life. Scores from all 10 questions added up to give DLQI total score range from 0 (not at all) to 30 (very much). Higher scores indicated more impact on quality of life of subjects. FAS analysed till Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 12 and 16

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	241
Units: units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 2	-4.5 (-5.5 to -3.5)	-6.7 (-7.5 to -6.0)	-8.5 (-9.2 to -7.8)	-6.7 (-7.4 to -5.9)
Change at Week 12	-6.2 (-7.1 to -5.3)	-8.7 (-9.4 to -8.0)	-11.0 (-11.7 to -10.3)	-9.9 (-10.6 to -9.2)
Change at Week 16	-6.2 (-7.1 to -5.3)	-9.0 (-9.7 to -8.4)	-11.7 (-12.4 to -11.1)	-10.8 (-11.4 to -10.1)

Statistical analyses

No statistical analyses for this end point

Secondary: DLQI at Week 20

End point title	DLQI at Week 20

End point description:

DLQI is a 10-item questionnaire that measures the impact of skin disease. Each question was evaluated on a 4-point scale ranging from 0 (not at all) to 3 (very much); where higher scores indicated more impact on quality of life. Scores from all 10 questions added up to give DLQI total score range from 0 (not at all) to 30 (very much). Higher scores indicated more impact on quality of life of subjects. FAS analysed post Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 20

End point values	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	55	210	198
Units: units on a scale				
arithmetic mean (standard deviation)	5.3 (± 5.3)	5.8 (± 5.7)	6.3 (± 5.8)	4.3 (± 4.7)

End point values	Dupilumab 300mg+Oral Placebo up to Wk>Oral Placebo Wk 16-20			
Subject group type	Reporting group			
Number of subjects analysed	216			
Units: units on a scale				
arithmetic mean (standard deviation)	5.6 (± 4.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EuroQol Quality of Life 5-Dimension 5-Level Scale (EQ-5D-5L) Index Value at Week 12 and 16

End point title	Change From Baseline in EuroQol Quality of Life 5-Dimension 5-Level Scale (EQ-5D-5L) Index Value at Week 12 and 16[13]

End point description:

EQ-5D-5L: standardised subject completed questionnaire consisted of 2 components: a health state profile and optional VAS. EQ-5D health state profile had 5 dimensions: mobility, self-care, usual activities, pain/discomfort, anxiety/depression. Each dimension has 5 levels: 1=no problems, 2=slight problems, 3=moderate problems, 4=severe problems, and 5=extreme problems. Responses to 5 dimensions comprised a health state/a single utility index value. E.g. if a subject responded "no problems" for each 5 dimensions, then health state was coded as "11111" with predefined index value to it. Every health state (coded as combination of responses on each of 5 dimensions) had a unique predefined utility index value assigned to it, by EuroQol. US value sets (with all possible health states) was used for adults in study, range from 1 to -0.109. Higher (positive) scores = better health state. . FAS analysed till Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12 and 16

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	241
Units: units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 12	0.051 (0.032 to 0.070)	0.101 (0.087 to 0.115)	0.127 (0.113 to 0.141)	0.104 (0.091 to 0.118)
Change at Week 16	0.067 (0.047 to 0.087)	0.093 (0.079 to 0.107)	0.133 (0.119 to 0.148)	0.113 (0.099 to 0.127)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L Visual Analogue Scale (VAS) Score at Week 12 and 16

End point title	Change From Baseline in EQ-5D-5L Visual Analogue Scale (VAS) Score at Week 12 and 16[14]

End point description:

EQ-5D-5L consists of two components: a health state profile and an optional VAS. EQ-5D VAS was used to record a subject's rating for his/her current health-related quality of life state and captured on a vertical VAS (0-100), where 0 = worst imaginable health state and 100 = best imaginable health state. FAS analysed till Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12 and 16

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	241
Units: units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 12	7.975 (5.161 to 10.789)	11.337 (9.272 to 13.401)	17.373 (15.270 to 19.476)	14.939 (12.900 to 16.978)
Change at Week 16	7.840 (4.952 to 10.727)	11.223 (9.129 to 13.318)	16.711 (14.581 to 18.841)	14.405 (12.315 to 16.496)

Statistical analyses

No statistical analyses for this end point

Secondary: EQ-5D-5L- Index Value at Week 20

End point title	EQ-5D-5L- Index Value at Week 20

End point description:

EQ-5D-5L: standardised subject completed questionnaire consisted of 2 components: a health state profile and optional VAS. EQ-5D health state profile had 5 dimensions: mobility, self-care, usual activities, pain/discomfort, anxiety/depression. Each dimension has 5 levels: 1=no problems, 2=slight problems, 3=moderate problems, 4=severe problems, and 5=extreme problems. Responses to 5 dimensions comprised a health state/a single utility index value. E.g. if a subject responded "no problems" for each 5 dimensions, then health state was coded as "11111" with predefined index value to it. Every health state (coded as combination of responses on each of 5 dimensions) had a unique predefined utility index value assigned to it, by EuroQol. US value sets (with all possible health states) was used for adults in study, range from 1 to -0.109. Higher (positive) scores = better health state. FAS analysed post Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 20

End point values	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	55	210	197
Units: units on a scale				
arithmetic mean (standard deviation)	0.905 (± 0.097)	0.894 (± 0.122)	0.883 (± 0.124)	0.917 (± 0.109)

End point values	Dupilumab 300mg+Oral Placebo up to Wk>Oral Placebo Wk 16-20			
Subject group type	Reporting group			
Number of subjects analysed	216			
Units: units on a scale				
arithmetic mean (standard deviation)	0.890 (± 0.109)			

Statistical analyses

No statistical analyses for this end point

Secondary: EQ-5D-5L- VAS Score at Week 20

End point title	EQ-5D-5L- VAS Score at Week 20

End point description:

EQ-5D-5L consists of two components: a health state profile and an optional VAS. EQ-5D VAS was used to record a subject's rating for his/her current health-related quality of life state and captured on a vertical VAS (0-100), where 0 = worst imaginable health state and 100 = best imaginable health state. FAS analysed post Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 20

End point values	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	55	210	197
Units: units on a scale				
arithmetic mean (standard deviation)	78.2 (± 16.3)	78.5 (± 20.2)	76.7 (± 19.5)	82.1 (± 17.1)

End point values	Dupilumab 300mg+Oral Placebo up to Wk>Oral Placebo Wk 16-20			
Subject group type	Reporting group			
Number of subjects analysed	216			
Units: units on a scale				
arithmetic mean (standard deviation)	79.6 (± 18.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hospital Anxiety and Depression Scale (HADS) – Anxiety Scale at Week 12 and 16

End point title	Change From Baseline in Hospital Anxiety and Depression Scale (HADS) – Anxiety Scale at Week 12 and 16[15]

End point description:

HADS: subject rated 14-item questionnaire. HADS consisted of 2 subscales: HADS-Anxiety (HADS-A) scale and HADS-Depression (HADS-D) scale, both of these subscales comprised of 7 items each. Each item was rated on a 4-point scale, score range from 0 to 3, where higher scores indicates more anxiety/depression symptoms. HADS-A assesses state of generalised anxiety (anxious mood, restlessness, anxious thoughts, panic attacks). HADS-D assesses state of lost interest and diminished pleasure response (lowering of hedonic tone). HADS-A: sum of all 7 items resulted in score range of 0 (no presence of anxiety) to 21 (severe feeling of anxiety); higher score indicating greater severity of anxiety. FAS analysed till Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12 and 16

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 12	-0.4 (-0.9 to 0.1)	-1.2 (-1.5 to -0.8)	-1.6 (-2.0 to -1.2)	-1.4 (-1.7 to -1.0)
Change at Week 16	-0.4 (-0.9 to 0.1)	-1.2 (-1.6 to -0.8)	-2.0 (-2.4 to -1.6)	-1.5 (-1.9 to -1.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in HADS – Depression Scale at Week 12 and 16

End point title	Change From Baseline in HADS – Depression Scale at Week 12 and 16[16]

End point description:

HADS: subject rated 14-item questionnaire. HADS consisted of 2 subscales: HADS-A scale and HADS-D scale, both of these subscales comprised of 7 items each. Each item was rated on a 4-point scale, score range from 0 to 3, where higher scores indicates more anxiety/depression symptoms. HADS-A assesses state of generalised anxiety (anxious mood, restlessness, anxious thoughts, panic attacks). HADS-D assesses state of lost interest and diminished pleasure response (lowering of hedonic tone). HADS-D: sum of all 7 items resulted in score range of 0 (no presence of depression) to 21 (severe feeling of depression); higher score indicating greater severity of depression symptoms. FAS analysed till Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12 and 16

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 12	-0.3 (-0.7 to 0.2)	-1.3 (-1.6 to -0.9)	-1.6 (-1.9 to -1.2)	-1.3 (-1.6 to -0.9)
Change at Week 16	-0.3 (-0.8 to 0.2)	-1.0 (-1.4 to -0.7)	-1.6 (-1.9 to -1.2)	-1.2 (-1.5 to -0.8)

Statistical analyses

No statistical analyses for this end point

Secondary: HADS – Anxiety Scale at Week 20

End point title	HADS – Anxiety Scale at Week 20

End point description:

HADS: subject rated 14-item questionnaire. HADS consisted of 2 subscales: HADS-A scale and HADS-D scale, both of these subscales comprised of 7 items each. Each item was rated on a 4-point scale, score range from 0 to 3, where higher scores indicates more anxiety/depression symptoms. HADS-A assesses state of generalised anxiety (anxious mood, restlessness, anxious thoughts, panic attacks). HADS-D assesses state of lost interest and diminished pleasure response (lowering of hedonic tone). HADS-A: sum of all 7 items resulted in score range of 0 (no presence of anxiety) to 21 (severe feeling of anxiety); higher score indicating greater severity of anxiety. FAS analysed post Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 20

End point values	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	55	209	197
Units: units on a scale				

arithmetic mean (standard deviation)	3.4 (± 3.2)	4.5 (± 4.5)	4.0 (± 3.8)	3.1 (± 3.1)

End point values	Dupilumab 300mg+Oral Placebo up to Wk>Oral Placebo Wk 16-20			
Subject group type	Reporting group			
Number of subjects analysed	215			
Units: units on a scale				
arithmetic mean (standard deviation)	3.7 (± 3.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: HADS – Depression Scale at Week 20

End point title	HADS – Depression Scale at Week 20

End point description:

HADS: subject rated 14-item questionnaire. HADS consisted of 2 subscales: HADS-A scale and HADS-D scale, both of these subscales comprised of 7 items each. Each item was rated on a 4-point scale, score range from 0 to 3, where higher scores indicates more anxiety/depression symptoms. HADS-A assesses state of generalised anxiety (anxious mood, restlessness, anxious thoughts, panic attacks). HADS-D assesses state of lost interest and diminished pleasure response (lowering of hedonic tone). HADS-D: sum of all 7 items resulted in score range of 0 (no presence of depression) to 21 (severe feeling of depression); higher score indicating greater severity of depression symptoms. FAS analysed post Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 20

End point values	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	55	209	197
Units: units on a scale				
arithmetic mean (standard deviation)	2.6 (± 3.4)	3.6 (± 3.7)	2.8 (± 3.2)	2.2 (± 3.1)

End point values	Dupilumab 300mg+Oral Placebo up to			

	Wk>Oral Placebo Wk 16-20			
Subject group type	Reporting group			
Number of subjects analysed	215			
Units: units on a scale				
arithmetic mean (standard deviation)	2.7 (± 3.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient-Oriented Eczema Measure (POEM) at Week 12 and 16

End point title	Change From Baseline in Patient-Oriented Eczema Measure (POEM) at Week 12 and 16[17]

End point description:

POEM is a 7-item subject reported outcome (PRO) measure used to assess the impact of AD (dryness, itching, flaking, cracking, sleep loss, bleeding and weeping) over the past week. Each item is scored as following: "no days (0)", "1-2 days (1)", "3-4 days (2)", "5-6 days (3)" and "every day (4)". The score ranges from 0 to 28, where higher score indicated greater severity. FAS analysed till Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12 and 16

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	241
Units: units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 12	-5.1 (-6.3 to -3.9)	-9.6 (-10.5 to -8.6)	-12.6 (-13.6 to -11.7)	-10.8 (-11.7 to -9.9)
Change at Week 16	-5.0 (-6.3 to -3.8)	-9.2 (-10.1 to -8.2)	-12.5 (-13.4 to -11.6)	-10.8 (-11.8 to -9.9)

Statistical analyses

No statistical analyses for this end point

Secondary: POEM at Week 20

End point title	POEM at Week 20

End point description:

POEM is a 7-item subject reported outcome (PRO) measure used to assess the impact of AD (dryness, itching, flaking, cracking, sleep loss, bleeding and weeping) over the past week. Each item is scored as following: "no days (0)", "1-2 days (1)", "3-4 days (2)", "5-6 days (3)" and "every day (4)". The score ranges from 0 to 28, where higher score indicated greater severity. FAS analysed post Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 20

End point values	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	55	209	196
Units: units on a scale				
arithmetic mean (standard deviation)	10.7 (± 6.8)	9.6 (± 7.8)	11.6 (± 7.7)	8.6 (± 7.0)

End point values	Dupilumab 300mg+Oral Placebo up to Wk>Oral Placebo Wk 16-20			
Subject group type	Reporting group			
Number of subjects analysed	215			
Units: units on a scale				
arithmetic mean (standard deviation)	11.0 (± 6.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Pruritus and Symptoms Assessment for Atopic Dermatitis (PSAAD) Total Score Week 1 to Week 16

End point title	Change From Baseline in Pruritus and Symptoms Assessment for Atopic Dermatitis (PSAAD) Total Score Week 1 to Week 16[18]

End point description:

PSAAD is a daily subject reported symptom electronic diary. Subjects rated their symptoms of AD over the past 24 hours, using 11 items (itchy skin, painful skin, dry skin, flaky skin, cracked skin, bumpy skin, red skin, discolored skin [lighter or darker], bleeding from skin, seeping or oozing fluid from skin [other than blood], and skin swelling). Subject had to think about all the areas of their body affected by their skin condition and chose the number that best described their experience for each of the 11 items, from 0 (no symptoms) to 10 (extreme symptoms), higher scores signified worse skin condition. Total PSAAD score = arithmetic mean of 11 items, 0 (no symptoms) to 10 (extreme symptoms), where higher score = worse skin condition. FAS analysed till Week 16. Here, 'Number of Subjects Analysed' =

subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 1 to Week 16

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	130	237	225	241
Units: units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 1	-0.5 (-0.8 to -0.3)	-1.1 (-1.3 to -0.9)	-1.3 (-1.5 to -1.2)	-0.9 (-1.1 to -0.8)
Change at Week 2	-0.9 (-1.2 to -0.7)	-1.8 (-2.0 to -1.6)	-2.3 (-2.5 to -2.1)	-1.6 (-1.8 to -1.4)
Change at Week 3	-1.1 (-1.4 to -0.8)	-2.2 (-2.4 to -2.0)	-2.8 (-3.0 to -2.6)	-2.1 (-2.3 to -1.9)
Change at Week 4	-1.4 (-1.7 to -1.1)	-2.4 (-2.6 to -2.2)	-3.0 (-3.3 to -2.8)	-2.4 (-2.7 to -2.2)
Change at Week 5	-1.5 (-1.8 to -1.2)	-2.6 (-2.8 to -2.4)	-3.2 (-3.5 to -3.0)	-2.7 (-2.9 to -2.5)
Change at Week 6	-1.5 (-1.8 to -1.2)	-2.6 (-2.8 to -2.4)	-3.3 (-3.6 to -3.1)	-2.8 (-3.1 to -2.6)
Change at Week 7	-1.6 (-1.9 to -1.2)	-2.7 (-2.9 to -2.4)	-3.4 (-3.6 to -3.1)	-2.9 (-3.2 to -2.7)
Change at Week 8	-1.5 (-1.9 to -1.2)	-2.7 (-2.9 to -2.4)	-3.4 (-3.7 to -3.2)	-3.0 (-3.2 to -2.7)
Change at Week 9	-1.7 (-2.0 to -1.4)	-2.7 (-2.9 to -2.4)	-3.5 (-3.8 to -3.3)	-3.1 (-3.3 to -2.8)
Change at Week 10	-1.7 (-2.0 to -1.4)	-2.7 (-2.9 to -2.4)	-3.5 (-3.8 to -3.3)	-3.1 (-3.4 to -2.9)
Change at Week 11	-1.6 (-1.9 to -1.3)	-2.7 (-2.9 to -2.4)	-3.5 (-3.8 to -3.3)	-3.2 (-3.4 to -2.9)
Change at Week 12	-1.6 (-2.0 to -1.3)	-2.7 (-3.0 to -2.5)	-3.6 (-3.8 to -3.3)	-3.2 (-3.5 to -3.0)
Change at Week 13	-1.7 (-2.0 to -1.4)	-2.8 (-3.1 to -2.6)	-3.7 (-3.9 to -3.4)	-3.3 (-3.6 to -3.1)
Change at Week 14	-1.6 (-1.9 to -1.3)	-2.8 (-3.1 to -2.6)	-3.6 (-3.9 to -3.4)	-3.4 (-3.6 to -3.2)
Change at Week 15	-1.7 (-2.0 to -1.4)	-2.9 (-3.1 to -2.6)	-3.6 (-3.8 to -3.4)	-3.4 (-3.6 to -3.1)
Change at Week 16	-1.7 (-2.0 to -1.3)	-2.8 (-3.1 to -2.6)	-3.6 (-3.8 to -3.4)	-3.4 (-3.6 to -3.2)

Statistical analyses

No statistical analyses for this end point

Secondary: PSAAD Total Score at Week 18 and 20

End point title	PSAAD Total Score at Week 18 and 20

End point description:

PSAAD is a daily subject reported symptom electronic diary. Subjects rated their symptoms of AD over the past 24 hours, using 11 items (itchy skin, painful skin, dry skin, flaky skin, cracked skin, bumpy skin, red skin, discolored skin [lighter or darker], bleeding from skin, seeping or oozing fluid from skin [other than blood], and skin swelling). Subject had to think about all the areas of their body affected by their skin condition and chose the number that best described their experience for each of the 11 items, from 0 (no symptoms) to 10 (extreme symptoms), higher scores signified worse skin condition. Total PSAAD score = arithmetic mean of 11 items, 0 (no symptoms) to 10 (extreme symptoms), where higher score = worse skin condition. FAS analysed post Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint and "n" signifies the number of subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Week 18 and 20

End point values	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54	54	202	202
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 18 (n=54, 54, 202, 202,218)	2.6 (± 1.9)	3.0 (± 2.4)	2.2 (± 1.9)	1.7 (± 1.7)
Week 20 (n=54, 53, 201, 199,213)	2.5 (± 2.0)	2.6 (± 2.3)	2.2 (± 1.9)	1.8 (± 1.8)

End point values	Dupilumab 300mg+Oral Placebo up to Wk>Oral Placebo Wk 16-20			
Subject group type	Reporting group			
Number of subjects analysed	218			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 18 (n=54, 54, 202, 202,218)	1.8 (± 1.5)			
Week 20 (n=54, 53, 201, 199,213)	2.0 (± 1.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Scoring Atopic Dermatitis (SCORAD)

Response >=50% Improvement From Baseline at Week 2, 4, 8, 12 and 16

End point title	Percentage of Subjects With Scoring Atopic Dermatitis (SCORAD) Response >=50% Improvement From Baseline at Week 2, 4, 8, 12 and 16[19]

End point description:

SCORAD:scoring index for AD combining extent (A), severity (B), subjective symptoms (C). A: rule of 9 was used to calculate BSA affected by AD as a % of whole BSA for each body region-head and neck 9%, upper limbs 9% each, lower limbs 18% each, anterior trunk 18%, back 18%, 1% for genitals; score for each region was added to give A(0-100). B: severity of each sign (erythema; edema; oozing; excoriation; skin thickening; dryness) was assessed as none=0, mild=1, moderate=2, severe=3; scores were summed to give B(0-18). C: pruritus and sleep, each of these 2 were scored by subject/caregiver using VAS where "0"=no itch/no sleeplessness; "10"=the worst imaginable itch/sleeplessness, higher scores=worse symptoms. Scores for itch and sleeplessness were added to give C (0-20). The SCORAD was calculated: A/5 + 7*B/2 + C;range=0-103;higher values=worse outcome. FAS analysed till Week 16. Here, "n" signifies the number of subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4, 8, 12 and 16

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 2 (n=128, 233, 224, 237)	10.2 (4.9 to 15.4)	23.6 (18.2 to 29.1)	38.4 (32.0 to 44.8)	15.6 (11.0 to 20.2)
Week 4 (n=129, 234, 224, 238)	18.6 (11.9 to 25.3)	45.7 (39.3 to 52.1)	61.6 (55.2 to 68.0)	45.8 (39.5 to 52.1)
Week 8 (n=129, 234, 225, 239)	20.2 (13.2 to 27.1)	53.4 (47.0 to 59.8)	71.6 (65.7 to 77.5)	56.9 (50.6 to 63.2)
Week 12 (n=128, 234, 224, 238)	27.3 (19.6 to 35.1)	56.8 (50.5 to 63.2)	72.3 (66.5 to 78.2)	64.3 (58.2 to 70.4)
Week 16 (n=123, 228, 221, 231)	33.3 (25.0 to 41.7)	56.1 (49.7 to 62.6)	68.8 (62.7 to 74.9)	67.5 (61.5 to 73.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With SCORAD Response >=75% Improvement From Baseline at Week 2, 4, 8 12 and 16

End point title	Percentage of Subjects With SCORAD Response >=75% Improvement From Baseline at Week 2, 4, 8 12 and 16[20]

End point description:

SCORAD:scoring index for AD combining extent (A), severity (B), subjective symptoms (C). A: rule of 9 was used to calculate BSA affected by AD as a % of whole BSA for each body region-head and neck 9%, upper limbs 9% each, lower limbs 18% each, anterior trunk 18%, back 18%, 1% for genitals; score for each region was added to give A(0-100). B: severity of each sign (erythema; edema; oozing;

excoriation; skin thickening; dryness) was assessed as none=0, mild=1, moderate=2, severe=3; scores were summed to give B(0-18). C: pruritus and sleep, each of these 2 were scored by subject/caregiver using VAS where "0"=no itch/no sleeplessness; "10"=the worst imaginable itch/sleeplessness, higher scores=worse symptoms. Scores for itch and sleeplessness were added to give C (0-20). The SCORAD was calculated: A/5 + 7*B/2 + C;range=0-103;higher values=worse outcome. FAS analysed till Week 16. Here, "n" signifies the number of subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4, 8 12 and 16

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 2 (n=128, 233, 224, 237)	1.6 (0.0 to 3.7)	6.4 (3.3 to 9.6)	8.5 (4.8 to 12.1)	0.8 (0.0 to 2.0)
Week 4 (n=129, 234, 224, 238)	3.1 (0.1 to 6.1)	12.4 (8.2 to 16.6)	25.4 (19.7 to 31.2)	7.1 (3.9 to 10.4)
Week 8 (n=129, 234, 225, 239)	3.1 (0.1 to 6.1)	19.2 (14.2 to 24.3)	41.3 (34.9 to 47.8)	16.3 (11.6 to 21.0)
Week 12 (n=128, 234, 224, 238)	6.3 (2.1 to 10.4)	25.6 (20.0 to 31.2)	39.3 (32.9 to 45.7)	26.1 (20.5 to 31.6)
Week 16 (n=123, 228, 221, 231)	10.6 (5.1 to 16.0)	26.8 (21.0 to 32.5)	40.3 (33.8 to 46.7)	29.4 (23.6 to 35.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in SCORAD Visual Analogue Scale (VAS) of Itch and Sleep Loss at Week 2, 4, 8 12 and 16

End point title	Change From Baseline in SCORAD Visual Analogue Scale (VAS) of Itch and Sleep Loss at Week 2, 4, 8 12 and 16[21]

End point description:

SCORAD:scoring index for AD combining extent (A), severity (B), subjective symptoms (C). A: rule of 9 was used to calculate BSA affected by AD as a % of whole BSA for each body region-head and neck 9%, upper limbs 9% each, lower limbs 18% each, anterior trunk 18%, back 18%, 1% for genitals; score for each region was added to give A(0-100). B: severity of each sign (erythema; edema; oozing; excoriation; skin thickening; dryness) was assessed as none=0, mild=1, moderate=2, severe=3; scores were summed to give B(0-18). C: pruritus and sleep, each of these 2 were scored by subject/caregiver using VAS where "0"=no itch/no sleeplessness; "10"=the worst imaginable itch/sleeplessness, higher scores=worse symptoms. Scores for itch and sleeplessness were added to give C (0-20). The SCORAD was calculated: A/5 + 7*B/2 + C;range=0-103;higher values=worse outcome. FAS analysed till Week 16. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4, 8 12 and 16

Notes:

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

Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	129	237	225	241
Units: units on a scale				
least squares mean (confidence interval 95%)				
Itch: Change at Week 2	-1.5 (-1.9 to -1.2)	-2.9 (-3.2 to -2.7)	-3.7 (-4.0 to -3.4)	-2.4 (-2.7 to -2.1)
Itch: Change at Week 4	-2.2 (-2.6 to -1.8)	-3.7 (-4.0 to -3.4)	-4.6 (-4.9 to -4.3)	-3.7 (-4.0 to -3.4)
Itch: Change at Week 8	-2.3 (-2.7 to -1.9)	-3.9 (-4.2 to -3.6)	-4.9 (-5.2 to -4.6)	-4.2 (-4.5 to -3.9)
Itch: Change at Week 12	-2.4 (-2.9 to -2.0)	-3.9 (-4.3 to -3.6)	-5.0 (-5.3 to -4.7)	-4.4 (-4.7 to -4.1)
Itch: Change at Week 16	-2.7 (-3.1 to -2.3)	-3.8 (-4.1 to -3.5)	-4.8 (-5.1 to -4.5)	-4.5 (-4.8 to -4.2)
Sleep loss: Change at Week 2	-1.6 (-2.0 to -1.2)	-2.6 (-2.9 to -2.3)	-3.3 (-3.6 to -3.0)	-2.3 (-2.6 to -1.9)
Sleep loss: Change at Week 4	-2.3 (-2.7 to -1.9)	-3.4 (-3.7 to -3.1)	-4.2 (-4.5 to -3.9)	-3.4 (-3.7 to -3.1)
Sleep loss: Change at Week 8	-2.3 (-2.7 to -1.9)	-3.6 (-3.9 to -3.3)	-4.4 (-4.7 to -4.1)	-3.9 (-4.2 to -3.6)
Sleep loss: Change at Week 12	-2.4 (-2.8 to -2.0)	-3.7 (-4.0 to -3.4)	-4.6 (-4.9 to -4.3)	-4.2 (-4.5 to -3.9)
Sleep loss: Change at Week 16	-2.6 (-3.0 to -2.2)	-3.7 (-4.0 to -3.4)	-4.8 (-5.1 to -4.5)	-4.3 (-4.6 to -4.0)

Statistical analyses

No statistical analyses for this end point

Secondary: SCORAD VAS of Itch and Sleep Loss at Week 18 and 20

End point title	SCORAD VAS of Itch and Sleep Loss at Week 18 and 20

End point description:

SCORAD:scoring index for AD combining extent (A), severity (B), subjective symptoms (C). A: rule of 9 was used to calculate BSA affected by AD as a % of whole BSA for each body region-head and neck 9%, upper limbs 9% each, lower limbs 18% each, anterior trunk 18%, back 18%, 1% for genitals; score for each region was added to give A(0-100). B: severity of each sign (erythema; edema; oozing; excoriation; skin thickening; dryness) was assessed as none=0, mild=1, moderate=2, severe=3; scores were summed to give B(0-18). C: pruritus and sleep, each of these 2 were scored by subject/caregiver using VAS where "0"=no itch/no sleeplessness; "10"=the worst imaginable itch/sleeplessness, higher scores=worse symptoms. Scores for itch and sleeplessness were added to give C (0-20). The SCORAD was calculated: A/5 + 7*B/2 + C;range=0-103;higher values=worse outcome. FAS analysed post Week 16. Here, "n" signifies the number of subjects evaluable for the specified time points.

End point type	Secondary

End point timeframe:

Week 18 and 20

End point values	Placebo up to Wk 16 then PF-04965842 100 mg Wk 16 to 20	Placebo up to Wk 16 then PF-04965842 200 mg Wk 16 to 20	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	57	217	208
Units: units on a scale				
arithmetic mean (standard deviation)				
Itch: Week 18 (n=56, 52, 204, 201, 206)	3.2 (± 2.6)	2.7 (± 2.2)	3.0 (± 2.5)	2.3 (± 2.2)
Itch: Week 20 (n=58, 57, 212, 199, 218)	2.9 (± 2.4)	2.6 (± 2.4)	3.2 (± 2.6)	2.3 (± 2.3)
Sleep loss: Week 18 (n=56, 52, 204, 201, 206)	2.2 (± 2.3)	2.3 (± 2.3)	2.1 (± 2.3)	1.6 (± 2.1)
Sleep loss: Week 20 (n=58, 57, 212, 199, 218)	2.1 (± 2.2)	2.0 (± 2.3)	2.4 (± 2.6)	1.5 (± 2.1)

End point values	Dupilumab 300mg+Oral Placebo up to Wk>Oral Placebo Wk 16-20			
Subject group type	Reporting group			
Number of subjects analysed	223			
Units: units on a scale				
arithmetic mean (standard deviation)				
Itch: Week 18 (n=56, 52, 204, 201, 206)	2.7 (± 2.2)			
Itch: Week 20 (n=58, 57, 212, 199, 218)	2.8 (± 2.2)			
Sleep loss: Week 18 (n=56, 52, 204, 201, 206)	1.8 (± 2.0)			
Sleep loss: Week 20 (n=58, 57, 212, 199, 218)	1.7 (± 2.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Least Square Mean of Number of Steroid-free Days From Baseline up to Week 16

End point title	Least Square Mean of Number of Steroid-free Days From Baseline up to Week 16[22]

End point description:

Number of days when a corticosteroid as a concomitant medication was not used up to Week 16 is

reported as Least square mean in this outcome measure. FAS analysed till Week 16.

End point type	Secondary

End point timeframe:

Baseline up to Week 16

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data have been for reported for those arms which were applicable till Week 16.

End point values	Placebo up to Week (Wk)16	PF-04965842 100 mg + Placebo Injection up to Week 16	PF-04965842 200 mg + Placebo Injection up to Week 16	Dupilumab 300 mg + Oral Placebo up to Week 16
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	131	238	226	242
Units: Days				
least squares mean (confidence interval 95%)	21.8 (14.9 to 28.8)	30.2 (25.1 to 35.4)	33.6 (28.3 to 38.9)	28.1 (23.0 to 33.2)

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

For reporting arms till Week 16 analysis: Baseline up to Week 16; For reporting arms post Week 16 analysis: Week 16 to Week 24 (28 days after last dose of study drug)

Adverse event reporting additional description:

Same event may appear as AE and serious AE, what is presented are distinct events. Event may be categorized as serious in 1 subject and as non-serious in another subject or 1 subject may have experienced both serious and non-serious event during study. Safety analysis set analysed.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1, 23.0

Reporting groups

Reporting group title	Placebo up to Wk 16

Reporting group description:

Subjects were randomised to receive oral placebo matched to PF-04965842 once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 till Week 16.

Reporting group title	PF-04965842 100 mg + Placebo Injection up to Wk 16

Reporting group description:

Subjects were randomised to receive PF-04965842 100 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16.

Reporting group title	PF-04965842 200 mg + Placebo Injection up to Week 16

Reporting group description:

Subjects were randomised to receive PF-04965842 200 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16.

Reporting group title	Dupilumab 300 mg + Oral Placebo up to Week 16

Reporting group description:

Subjects were randomised to receive dupilumab 300 mg subcutaneous injection every other week with oral placebo matched to PF-04965842 once daily from Day 1 to Wk 16.

Reporting group title	Placebo up to Week 16 then PF-04965842 100 mg Week 16 to 20

Reporting group description:

Subjects who were randomised to receive oral placebo matched to PF-04965842 with subcutaneous injectable placebo matched to dupilumab till Week 16, received PF-04965842 100 mg tablet orally once daily post Week 16 up to Week 20.

Reporting group title	Placebo up to Week 16 then PF-04965842 200 mg Week 16 to 20

Reporting group description:

Subjects who were randomised to receive oral placebo matched to PF-04965842 with subcutaneous injectable placebo matched to dupilumab till Week 16, received PF-04965842 200 mg tablet orally once daily post Week 16 up to Week 20.

Reporting group title	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20

Reporting group description:

Subjects who were randomised to receive PF-04965842 100 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, received PF-04965842 100 mg tablet orally once daily post Week 16 up to Week 20.

Reporting group title	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20

Reporting group description:

Subjects who were randomised to receive PF-04965842 200 mg tablet orally once daily with subcutaneous injectable placebo matched to dupilumab every other week from Day 1 to Week 16, received PF-04965842 200 mg tablet orally once daily post Week 16 up to Week 20.

Reporting group title	Dupilumab 300mg+Oral Placebo up to Wk16>Oral Placebo Wk

	16-20

Reporting group description:

Subjects who were randomised to receive dupilumab 300 mg subcutaneous injection every other week with oral placebo matched to PF-04965842 once daily from Day 1 to Week 16, received oral placebo matched to PF-04965842 once daily post Week 16 up to Week 20.

Serious adverse events	Placebo up to Wk 16	PF-04965842 100 mg + Placebo Injection up to Wk 16	PF-04965842 200 mg + Placebo Injection up to Week 16
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 131 (3.82%)	6 / 238 (2.52%)	2 / 226 (0.88%)
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)			
Invasive ductal breast carcinoma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (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
Pyrexia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (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			
Breast mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine haemorrhage	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
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			
Dyspnoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (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
Investigations			
Aspartate aminotransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (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
Meniscus injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (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
Tendon injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (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
Blood and lymphatic system disorders			
Pancytopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (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
Hepatobiliary disorders			
Drug-induced liver injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (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			
Dermatitis atopic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Night sweats	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (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
Renal and urinary disorders			
Hydronephrosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
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	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
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			
Diarrhoea infectious	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (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
Oral herpes	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (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
Enteritis infectious	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
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	Dupilumab 300 mg + Oral Placebo up to Week 16	Placebo up to Week 16 then PF-04965842 100 mg Week 16 to 20	Placebo up to Week 16 then PF-04965842 200 mg Week 16 to 20
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	0 / 57 (0.00%)
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)			
Invasive ductal breast carcinoma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Breast mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine haemorrhage	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (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

Muscle injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Pancytopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Drug-induced liver injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Night sweats	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Hydronephrosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Diarrhoea infectious	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20	Dupilumab 300mg+Oral Placebo up to Wk16>Oral Placebo Wk 16-20
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	1 / 223 (0.45%)
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)			
Invasive ductal breast carcinoma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
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			
Breast mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine haemorrhage	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
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			
Dyspnoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury	Additional description: MedDRA v22.1 was used for coding events till Week 16		

	and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Pancytopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
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			
Drug-induced liver injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Night sweats	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Hydronephrosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
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			
Diarrhoea infectious	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
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	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (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

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

Non-serious adverse events	Placebo up to Wk 16	PF-04965842 100 mg + Placebo Injection up to Wk 16	PF-04965842 200 mg + Placebo Injection up to Week 16
Total subjects affected by non-serious adverse events			
subjects affected / exposed	68 / 131 (51.91%)	121 / 238 (50.84%)	140 / 226 (61.95%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Skin papilloma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Aortic stenosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Essential hypertension	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Hot flush	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Hypertension	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 238 (0.84%)	3 / 226 (1.33%)
occurrences (all)	0	2	3
Surgical and medical procedures			
Rotator cuff repair	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Tooth extraction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Pregnancy, puerperium and perinatal conditions			
Pregnancy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 238 (0.84%)	2 / 226 (0.88%)
occurrences (all)	0	2	2
Chest pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	2 / 238 (0.84%)	0 / 226 (0.00%)
occurrences (all)	1	2	0
Chills	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	2 / 238 (0.84%)	3 / 226 (1.33%)
occurrences (all)	1	3	4
Feeling abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Feeling cold	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Feeling hot	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Influenza like illness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Injection site erythema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Injection site oedema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Injection site pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	2 / 226 (0.88%)
occurrences (all)	0	1	2
Injection site swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Malaise	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Medical device site rash	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	2 / 226 (0.88%)
occurrences (all)	0	1	2
Pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Pyrexia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 238 (0.84%)	0 / 226 (0.00%)
occurrences (all)	0	2	0
Swelling face	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 238 (0.84%)	0 / 226 (0.00%)
occurrences (all)	0	2	0
Therapeutic response unexpected	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	0	0	2
Xerosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 238 (0.84%)	0 / 226 (0.00%)
occurrences (all)	0	4	0
Immune system disorders			
Allergy to chemicals	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Food allergy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0

Hypersensitivity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	0	0	2
Seasonal allergy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Social circumstances			
Victim of crime	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Dysmenorrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	3	0
Erectile dysfunction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Hypomenorrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Menorrhagia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Metrorrhagia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Ovarian cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	0	0	2
Ovarian disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Balanoposthitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Prostatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	2 / 238 (0.84%)	0 / 226 (0.00%)
occurrences (all)	1	2	0
Cough	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	3 / 238 (1.26%)	4 / 226 (1.77%)
occurrences (all)	2	3	5
Dyspnoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Epistaxis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Nasal crusting	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Nasal dryness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Oropharyngeal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	2	1	0
Pulmonary mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	2	0	2
Sinus congestion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Snoring	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Throat irritation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Sleep apnoea syndrome	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 238 (0.84%)	0 / 226 (0.00%)
occurrences (all)	0	2	0
Apathy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Depression	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	0	1	1
Depression suicidal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1

Insomnia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	2	0	1
Irritability	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Libido decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Mood swings	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Schizophrenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Gallbladder polyp	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Biliary colic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Hepatic function abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Hepatic lesion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Hyperbilirubinaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Liver disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Investigations			
Activated partial thromboplastin time prolonged	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	2 / 238 (0.84%)	1 / 226 (0.44%)
occurrences (all)	1	2	1
Aspartate aminotransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	2 / 238 (0.84%)	1 / 226 (0.44%)
occurrences (all)	1	2	1
Biopsy endometrium	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Blood cholesterol increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	3 / 131 (2.29%)	7 / 238 (2.94%)	6 / 226 (2.65%)
occurrences (all)	3	7	7
Blood creatinine increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Body temperature increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
C-reactive protein increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Cardiac murmur	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Ejection fraction decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram QT prolonged	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave amplitude increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	2	0
Haematocrit decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Haemoglobin decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	3 / 226 (1.33%)
occurrences (all)	0	0	3
Lipids increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Liver function test increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Natural killer cell count decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 238 (0.84%)	4 / 226 (1.77%)
occurrences (all)	0	2	4
Red blood cell count decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16		

	and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	0	0	2
T-lymphocyte count decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Transaminases increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Weight increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Blood pressure increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Blood urea increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Liver function test abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Eosinophil percentage increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Animal bite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Clavicle fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	0	1	1
Eye injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Fall	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Foot fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Head injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Joint injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Ligament sprain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	2	0	0
Limb injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Medication error	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Muscle strain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Procedural pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Road traffic accident	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	2	0	0
Scapula fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Skin abrasion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	3 / 226 (1.33%)
occurrences (all)	0	1	3
Skin laceration	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	1	1	0
Soft tissue injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Tooth fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Traumatic haematoma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Wound haemorrhage	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Arthropod bite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Epicondylitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Humerus fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Thermal burn	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Wound	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Dermoid cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Congenital lacrimal passage anomaly	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Atrioventricular block first degree	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Bradycardia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Defect conduction intraventricular	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	2	1	0
Palpitations	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Sinus bradycardia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Ventricular extrasystoles	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	4 / 238 (1.68%)	7 / 226 (3.10%)
occurrences (all)	2	5	8
Dysaesthesia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
External compression headache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Headache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	6 / 131 (4.58%)	10 / 238 (4.20%)	15 / 226 (6.64%)
occurrences (all)	9	12	17
Hypertonia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Hypoaesthesia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Migraine	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	1	1	0
Nerve compression	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0

Neuralgia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Paraesthesia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Parosmia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Presyncope	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Somnolence	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	3 / 238 (1.26%)	2 / 226 (0.88%)
occurrences (all)	0	3	2
Tension headache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Leukopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	3 / 226 (1.33%)
occurrences (all)	0	1	3
Lymphadenitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Lymphadenopathy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	0	1	1
Lymphopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	0	1	1
Microcytic anaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Thrombocytopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	0	0	2
Thrombocytosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 238 (0.84%)	0 / 226 (0.00%)
occurrences (all)	0	2	0
Ear and labyrinth disorders			
External ear inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Vertigo positional	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Asthenopia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Blepharitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Conjunctival irritation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis allergic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	0	1	1
Dry eye	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Eye irritation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Eye pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	0	1	1
Eye pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	1	1	1
Eyelid oedema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	3 / 238 (1.26%)	1 / 226 (0.44%)
occurrences (all)	1	3	1
Eyelid pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Eyelids pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Lacrimation increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Noninfective conjunctivitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Presbyopia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Vision blurred	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Eczema eyelids	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Eyelid cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	3 / 226 (1.33%)
occurrences (all)	0	0	3
Abdominal distension	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	1	0	1
Abdominal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	3 / 226 (1.33%)
occurrences (all)	1	0	5
Abdominal pain upper	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	2 / 226 (0.88%)
occurrences (all)	0	1	2

Anal pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Constipation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Dental caries	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	1	0	2
Diarrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	4 / 131 (3.05%)	4 / 238 (1.68%)	4 / 226 (1.77%)
occurrences (all)	4	5	4
Dyspepsia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 238 (0.84%)	1 / 226 (0.44%)
occurrences (all)	0	2	1
Faeces soft			
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Flatulence	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Food poisoning	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Frequent bowel movements	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Gastritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	2 / 238 (0.84%)	0 / 226 (0.00%)
occurrences (all)	1	2	0

Gingival pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Nausea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	10 / 238 (4.20%)	25 / 226 (11.06%)
occurrences (all)	2	12	29
Noninfective gingivitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Tooth impacted	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Toothache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	1	1	1
Vomiting	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	1 / 238 (0.42%)	3 / 226 (1.33%)
occurrences (all)	1	1	4
Gastritis erosive	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	7 / 238 (2.94%)	15 / 226 (6.64%)
occurrences (all)	0	7	15
Actinic keratosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Alopecia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Alopecia areata	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Angioedema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Blister	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Dermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 238 (0.84%)	1 / 226 (0.44%)
occurrences (all)	0	2	1
Dermatitis allergic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Dermatitis atopic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	4 / 131 (3.05%)	7 / 238 (2.94%)	3 / 226 (1.33%)
occurrences (all)	6	8	3
Drug eruption	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Dyshidrotic eczema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Eczema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	1	0	1
Erythema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Ingrowing nail	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Intertrigo	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Keratosis pilaris	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Nail bed disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Nail fold inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Neurodermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Neutrophilic dermatosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	2
Photosensitivity reaction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	3 / 238 (1.26%)	0 / 226 (0.00%)
occurrences (all)	1	6	0
Pruritus allergic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Rash	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	2 / 238 (0.84%)	2 / 226 (0.88%)
occurrences (all)	1	3	2
Rash erythematous	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Rash papular	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Seborrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	0	1	1
Seborrhoeic dermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Skin discolouration	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Skin disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	2	0	0
Skin fissures	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	0	1	1
Skin lesion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	0	1	2
Urticaria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	3 / 238 (1.26%)	1 / 226 (0.44%)
occurrences (all)	0	3	3
Dermatitis contact	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Dysuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	1	0	1
Pollakiuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Polyuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Calculus urinary	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Leukocyturia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Urinary tract inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	1	0	2
Arthritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Arthropathy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Back pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	5 / 131 (3.82%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	5	0	1
Bursitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	1	0	1
Foot deformity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Mandibular mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Muscle spasms	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Muscle tightness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Musculoskeletal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal stiffness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Osteoarthritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Pain in extremity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Plantar fasciitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Spinal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Synovitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Temporomandibular joint syndrome	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Tendonitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	0	0	2
Bacterial vaginosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	0	1	1

Body tinea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	1	1	0
Bronchitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	1	1	1
Cellulitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	1	0	2
Conjunctivitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	3 / 131 (2.29%)	2 / 238 (0.84%)	3 / 226 (1.33%)
occurrences (all)	4	2	3
Conjunctivitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Cystitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Dermatophytosis of nail	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Ear infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Eczema herpeticum	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Eczema infected	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Epstein-Barr virus infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0

Erysipelas	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Folliculitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	4 / 131 (3.05%)	4 / 238 (1.68%)	4 / 226 (1.77%)
occurrences (all)	4	4	4
Fungal infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Fungal skin infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Furuncle	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	2	1	0
Gastroenteritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	1	0	2
Gastroenteritis viral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Hand-foot-and-mouth disease	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Herpes dermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0

Herpes simplex	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	5 / 238 (2.10%)	8 / 226 (3.54%)
occurrences (all)	1	5	8
Herpes virus infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Herpes zoster	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	4 / 226 (1.77%)
occurrences (all)	0	1	4
Hordeolum	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	2 / 238 (0.84%)	1 / 226 (0.44%)
occurrences (all)	1	2	1
Impetigo	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	5 / 238 (2.10%)	0 / 226 (0.00%)
occurrences (all)	0	5	0
Influenza	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Kaposi's varicelliform eruption	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Laryngitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Malassezia infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Molluscum contagiosum	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0

Nasopharyngitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	9 / 131 (6.87%)	22 / 238 (9.24%)	15 / 226 (6.64%)
occurrences (all)	12	24	16
Ophthalmic herpes simplex	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	1	0	2
Ophthalmic herpes zoster	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Oral herpes	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	3 / 238 (1.26%)	2 / 226 (0.88%)
occurrences (all)	1	3	2
Otitis media	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Paronychia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	1	0	1
Perichondritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Pharyngitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	2 / 238 (0.84%)	1 / 226 (0.44%)
occurrences (all)	1	2	1
Pharyngitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Pharyngotonsillitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1

Pustule	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Rash pustular	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	2 / 238 (0.84%)	0 / 226 (0.00%)
occurrences (all)	2	2	0
Respiratory tract infection viral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Rhinitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	2 / 226 (0.88%)
occurrences (all)	0	0	3
Sinusitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	1	1	0
Sinusitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Skin bacterial infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	1	0	1
Skin candida	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Skin infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	1	1	1
Staphylococcal skin infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0

Subcutaneous abscess	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Tinea pedis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 131 (0.76%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	1	0	0
Tinea versicolour	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Tonsillitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	1 / 226 (0.44%)
occurrences (all)	0	1	1
Tooth abscess	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	6 / 131 (4.58%)	12 / 238 (5.04%)	9 / 226 (3.98%)
occurrences (all)	6	13	10
Ureaplasma infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Urinary tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 131 (1.53%)	4 / 238 (1.68%)	7 / 226 (3.10%)
occurrences (all)	2	5	8
Urinary tract infection bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Viral infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0

Viral upper respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 238 (0.84%)	2 / 226 (0.88%)
occurrences (all)	0	2	2
Vulvovaginal mycotic infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Wound infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Bronchitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Bronchitis viral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Nasal herpes	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Pneumonia bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Decreased appetite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Dyslipidaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Hyperglycaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Increased appetite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Obesity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	1 / 226 (0.44%)
occurrences (all)	0	0	1
Type 2 diabetes mellitus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 238 (0.42%)	0 / 226 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 131 (0.00%)	0 / 238 (0.00%)	0 / 226 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dupilumab 300 mg + Oral Placebo up to Week 16	Placebo up to Week 16 then PF-04965842 100 mg	Placebo up to Week 16 then PF-04965842 200 mg

		Week 16 to 20	Week 16 to 20
Total subjects affected by non-serious adverse events			
subjects affected / exposed	120 / 242 (49.59%)	13 / 60 (21.67%)	16 / 57 (28.07%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin papilloma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Aortic stenosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Essential hypertension	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypertension	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Rotator cuff repair	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Tooth extraction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Pregnancy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0

General disorders and administration site conditions			
Asthenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Chills	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Fatigue	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0
Feeling abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Feeling cold	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Feeling hot	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Injection site erythema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Injection site oedema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Injection site pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Injection site swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Malaise	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Medical device site rash	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0
Swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Swelling face	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Therapeutic response unexpected	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Xerosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to chemicals	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Food allergy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Victim of crime	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypomenorrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Menorrhagia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Ovarian cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Ovarian disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Prostatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Cough	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	3 / 242 (1.24%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	4	0	0
Dyspnoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Epistaxis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nasal crusting	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nasal dryness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Pulmonary mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Sinus congestion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Snoring	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Throat irritation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Wheezing	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Apathy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Depression	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Depression suicidal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Irritability	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Libido decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Schizophrenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
Gallbladder polyp	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Biliary colic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hepatic function abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Hepatic lesion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Liver disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	1	1	0
Aspartate aminotransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Biopsy endometrium	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	3	1	0
Blood creatinine increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Body temperature increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram T wave amplitude increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Haematocrit decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Lipids increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Liver function test increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Natural killer cell count decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
T-lymphocyte count decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Transaminases increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Weight increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Blood urea increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Gamma-glutamyltransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Liver function test abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Urine analysis abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Eosinophil percentage increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Contusion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Eye injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Fall	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Foot fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Head injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Joint injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Ligament sprain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Limb injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Medication error	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Muscle strain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Procedural pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Road traffic accident	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Scapula fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Soft tissue injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Traumatic haematoma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Wound haemorrhage	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Epicondylitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Humerus fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Thermal burn	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Wound	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
Dermoid cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Congenital lacrimal passage anomaly	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block first degree	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Bradycardia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Defect conduction intraventricular	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Palpitations	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	3 / 242 (1.24%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	3	0	0
Ventricular extrasystoles	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
External compression headache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	13 / 242 (5.37%)	1 / 60 (1.67%)	1 / 57 (1.75%)
occurrences (all)	14	1	1
Hypertonia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Migraine	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nerve compression	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Parosmia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0
Tension headache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Leukopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Microcytic anaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
External ear inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Vertigo positional	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Blepharitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Conjunctival irritation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0
Dry eye	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Eye irritation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0
Eye pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Eye pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0

Eyelid oedema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Eyelid pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Eyelids pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Noninfective conjunctivitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Ocular discomfort	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Presbyopia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Swelling of eyelid	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Eczema eyelids	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Eyelid cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Abdominal distension	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Abdominal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	3 / 242 (1.24%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	3	0	0
Abdominal pain upper	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Anal pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dental caries	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Diarrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	3 / 242 (1.24%)	0 / 60 (0.00%)	2 / 57 (3.51%)
occurrences (all)	3	0	2
Dyspepsia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Faeces soft			

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Food poisoning	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Gingival pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	7 / 242 (2.89%)	0 / 60 (0.00%)	5 / 57 (8.77%)
occurrences (all)	8	0	6
Noninfective gingivitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Tooth impacted	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Toothache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Vomiting	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	4 / 242 (1.65%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	4	0	0
Gastritis erosive	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	3 / 242 (1.24%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	3	1	0
Actinic keratosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Alopecia areata	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Angioedema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Blister	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Dermatitis atopic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0
Drug eruption	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dyshidrotic eczema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Eczema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Erythema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Hyperkeratosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Ingrowing nail	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Intertrigo	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Keratosis pilaris	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Nail fold inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Neutrophilic dermatosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Pruritus allergic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Rash	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Rash erythematous	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Seborrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Skin discolouration	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Skin disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Urticaria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dysuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pollakiuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Polyuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Calculus urinary	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Haematuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Leukocyturia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Urinary tract inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0
Arthritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Arthropathy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Back pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	7 / 242 (2.89%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	7	0	0
Bursitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Foot deformity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Mandibular mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Muscle spasms	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Muscle tightness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Pain in extremity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Plantar fasciitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Rotator cuff syndrome	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Synovitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Temporomandibular joint syndrome	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Tendonitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Joint swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Body tinea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Bronchitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Cellulitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	15 / 242 (6.20%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	16	0	0
Conjunctivitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Cystitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Ear infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Eczema herpeticum	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Eczema infected	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Epstein-Barr virus infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Erysipelas	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Folliculitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	1 / 57 (1.75%)
occurrences (all)	2	0	1
Fungal infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Furuncle	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	0	1	0

Gastroenteritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	3 / 242 (1.24%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	3	0	0
Gastroenteritis viral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Herpes dermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Herpes simplex	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0
Herpes virus infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hordeolum	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Impetigo	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Influenza	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	1	1	0
Kaposi's varicelliform eruption	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Laryngitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Malassezia infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Molluscum contagiosum	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	23 / 242 (9.50%)	3 / 60 (5.00%)	2 / 57 (3.51%)
occurrences (all)	24	3	2
Ophthalmic herpes simplex	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Ophthalmic herpes zoster	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Oral herpes	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	5 / 242 (2.07%)	0 / 60 (0.00%)	1 / 57 (1.75%)
occurrences (all)	6	0	1
Otitis media	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Paronychia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Perichondritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	2	1	0
Pharyngitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Pulpitis dental	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Pustule	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Rash pustular	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection viral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	3 / 242 (1.24%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	3	0	0

Sinusitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	1 / 57 (1.75%)
occurrences (all)	1	0	1
Sinusitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin bacterial infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin candida	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Skin infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Staphylococcal skin infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Tinea pedis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Tonsillitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Tooth abscess	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0

Tooth infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	9 / 242 (3.72%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	9	1	0
Ureaplasma infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	4 / 242 (1.65%)	2 / 60 (3.33%)	0 / 57 (0.00%)
occurrences (all)	4	2	0
Urinary tract infection bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 242 (0.83%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	2	0	0
Viral infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1
Vulvovaginal mycotic infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Wound infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Asymptomatic bacteriuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Bronchitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	1 / 57 (1.75%)
occurrences (all)	0	0	1

Bronchitis viral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Genital herpes simplex	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Nasal herpes	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	1 / 60 (1.67%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
Pneumonia bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Dyslipidaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	1 / 242 (0.41%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Increased appetite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Obesity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 242 (0.00%)	0 / 60 (0.00%)	0 / 57 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PF-04965842 100mg+Placebo Inj. Wk 16>PF-04965842 100mg Wk16-20	PF-04965842 200mg+Placebo Inj. Wk 16>PF-04965842 200mg Wk16-20	Dupilumab 300mg+Oral Placebo up to Wk16>Oral Placebo Wk 16-20
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 217 (23.04%)	45 / 208 (21.63%)	31 / 223 (13.90%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Skin papilloma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	0
Vascular disorders			
Aortic stenosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Essential hypertension	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hot flush	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hypertension	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	2 / 208 (0.96%)	1 / 223 (0.45%)
occurrences (all)	0	2	1
Surgical and medical procedures			
Rotator cuff repair	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Tooth extraction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Pregnancy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Chest pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Chills	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Fatigue	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Feeling cold	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Feeling hot	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Influenza like illness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Injection site erythema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Injection site oedema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Injection site pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Injection site swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Malaise	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Medical device site rash	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Swelling face	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Therapeutic response unexpected	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Xerosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to chemicals	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	1
Food allergy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Hypersensitivity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Victim of crime	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hypomenorrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Menorrhagia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Ovarian disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Prostatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Cough	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	3 / 217 (1.38%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	3	0	1
Dyspnoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Epistaxis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Nasal crusting	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Nasal dryness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	1	0	1
Pulmonary mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Sinus congestion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Snoring	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Throat irritation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Wheezing	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Sleep apnoea syndrome	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Apathy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Depression	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Depression suicidal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Insomnia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Irritability	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Libido decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Mood swings	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Schizophrenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Gallbladder polyp	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Biliary colic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Hepatic function abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hepatic lesion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Liver disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	2 / 208 (0.96%)	0 / 223 (0.00%)
occurrences (all)	0	3	0
Aspartate aminotransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Biopsy endometrium	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	1 / 223 (0.45%)
occurrences (all)	0	1	1
Blood creatine phosphokinase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Body temperature increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	1	1	0
C-reactive protein increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave amplitude increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Haematocrit decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	2 / 208 (0.96%)	0 / 223 (0.00%)
occurrences (all)	0	2	0
Lipids increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Liver function test increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Natural killer cell count decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Red blood cell count decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
T-lymphocyte count decreased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Transaminases increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Weight increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Blood urea increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Liver function test abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Eosinophil percentage increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Clavicle fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Contusion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Eye injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Fall	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Foot fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Head injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Joint injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Ligament sprain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Limb injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Medication error	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Muscle strain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Procedural pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Road traffic accident	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Scapula fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Skin abrasion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Skin laceration	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Soft tissue injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Tooth fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Traumatic haematoma	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Wound haemorrhage	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Arthropod bite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Epicondylitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Humerus fracture	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	1
Thermal burn	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Wound	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Dermoid cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Congenital lacrimal passage anomaly	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	1
Cardiac disorders			
Arrhythmia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block first degree	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Bradycardia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Defect conduction intraventricular	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	1	0	1
Palpitations	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 217 (0.92%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	2	0	0
Dysaesthesia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
External compression headache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 217 (0.92%)	0 / 208 (0.00%)	2 / 223 (0.90%)
occurrences (all)	3	0	2
Hypertonia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Hypoaesthesia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Migraine	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Nerve compression	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Neuralgia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Paraesthesia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Parosmia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Presyncope	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Somnolence	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Tension headache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Leukopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Lymphopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Microcytic anaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
External ear inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Vertigo positional	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Blepharitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Conjunctival haemorrhage	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Conjunctival irritation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	1
Dry eye	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	1
Eye irritation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Eye pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Eye pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Eyelid pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Eyelids pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Noninfective conjunctivitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Presbyopia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Vision blurred	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Eczema eyelids	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Eyelid cyst	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Abdominal distension	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	1
Abdominal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Anal pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Dental caries	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Diarrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	3 / 217 (1.38%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	3	1	0
Dyspepsia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Faeces soft			
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Flatulence	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Food poisoning	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Frequent bowel movements	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Gastritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Gingival pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Noninfective gingivitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Tooth impacted	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Toothache	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Vomiting	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 217 (0.92%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	2	0	0
Gastritis erosive	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	1

Skin and subcutaneous tissue disorders			
Acne	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 217 (0.92%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	2	0	0
Actinic keratosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Alopecia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Alopecia areata	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Angioedema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Blister	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Dermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	4 / 208 (1.92%)	2 / 223 (0.90%)
occurrences (all)	1	4	2
Drug eruption	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Dyshidrotic eczema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Eczema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Erythema	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Intertrigo	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Keratosis pilaris	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Nail fold inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Neutrophilic dermatosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Pruritus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 217 (0.92%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	2	0	0
Pruritus allergic	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Rash	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Rash erythematous	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Rash papular	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	2 / 208 (0.96%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Seborrhoea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	2 / 208 (0.96%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Skin discolouration	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Skin disorder	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Skin fissures	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Skin lesion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Urticaria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Dermatitis contact	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Acute kidney injury	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Dysuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Pollakiuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Polyuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Calculus urinary	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Haematuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Leukocyturia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0

Urinary tract inflammation	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Arthritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Arthropathy	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Back pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	1	0	1
Bursitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	0
Foot deformity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Mandibular mass	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Muscle spasms	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Muscle tightness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Pain in extremity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Plantar fasciitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Spinal pain	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Synovitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Temporomandibular joint syndrome	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Tendonitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Joint swelling	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc protrusion	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	1
Infections and infestations			
Abscess limb	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Body tinea	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Bronchitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	2 / 208 (0.96%)	0 / 223 (0.00%)
occurrences (all)	0	2	0
Cellulitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 217 (0.92%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	2	0	0
Conjunctivitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	2 / 223 (0.90%)
occurrences (all)	0	0	2
Conjunctivitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Cystitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Ear infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Eczema herpeticum	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Eczema infected	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Epstein-Barr virus infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Erysipelas	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Folliculitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Fungal infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Furuncle	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	1
Gastrointestinal infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Gingivitis			
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Herpes dermatitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Herpes simplex	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	4 / 208 (1.92%)	1 / 223 (0.45%)
occurrences (all)	1	4	1
Herpes virus infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Herpes zoster	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Hordeolum	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Impetigo	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Influenza	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 217 (0.92%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	2	0	0
Kaposi's varicelliform eruption	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Laryngitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Malassezia infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Molluscum contagiosum	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	3 / 217 (1.38%)	9 / 208 (4.33%)	5 / 223 (2.24%)
occurrences (all)	3	9	5
Ophthalmic herpes simplex	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Ophthalmic herpes zoster	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	0
Oral herpes	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	0	0	1
Otitis media	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Paronychia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Perichondritis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Pharyngitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Pharyngitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Pustule	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Rash pustular	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	1	1	0
Respiratory tract infection viral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 217 (0.92%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	2	0	0
Sinusitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Sinusitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Skin bacterial infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Skin candida	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Skin infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Staphylococcal skin infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Tinea pedis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Tonsillitis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Tooth abscess	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Tooth infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	6 / 217 (2.76%)	5 / 208 (2.40%)	7 / 223 (3.14%)
occurrences (all)	6	5	8
Ureaplasma infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 217 (0.92%)	0 / 208 (0.00%)	1 / 223 (0.45%)
occurrences (all)	2	0	1
Urinary tract infection bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Viral infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	2 / 217 (0.92%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	2	0	0
Vulvovaginal mycotic infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Wound infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Bronchitis bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	1 / 223 (0.45%)
occurrences (all)	0	1	1
Bronchitis viral	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	1 / 208 (0.48%)	0 / 223 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal viral infection	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Genital herpes simplex	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0

Nasal herpes	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Pneumonia bacterial	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal candidiasis	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Dyslipidaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Increased appetite	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Obesity	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		

subjects affected / exposed	1 / 217 (0.46%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	1	0	0
Type 2 diabetes mellitus	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	0 / 208 (0.00%)	0 / 223 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia	Additional description: MedDRA v22.1 was used for coding events till Week 16 and MedDRA v23.0 was used for coding events post Week 16.		
subjects affected / exposed	0 / 217 (0.00%)	2 / 208 (0.96%)	0 / 223 (0.00%)
occurrences (all)	0	2	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 May 2019	A clarification to the criteria for screening ECG findings has been added ,as the intent is that the subject's screening ECG must not have clinically significant adverse findings.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported