Clinical trial results:
A Multi-Center Randomized Double Blind Verhicle-Controlled, Phase 2 Study of the safety and efficacy of Benzoyl Peroxide/Clindamycin Gel and Tazarotene Cream when used in combination in the treatment of Acne Vulgaris

Summary

EudraCT number	2015-004900-44
Trial protocol	Outside EU/EEA
Global end of trial date	02 March 2009

Results information

Result version number	v2 (current)
This version publication date	23 March 2017
First version publication date	22 January 2017
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	114570

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,

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	02 July 2009
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 March 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and efficacy of Duac and Tazorac when applied simultaneously to subjects with facial acne vulgaris.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 June 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 587
Worldwide total number of subjects	587
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	301
Adults (18-64 years)	286
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

In this multi-center, double-blind, vehicle controlled study, participants were assigned to one of the six treatment groups in a 2:2:2:2:2:1 ratio for 12 weeks.

Pre-assignment

Screening details:

Participants with facial acne vulgaris, 12 to 45 years of age were enrolled in this study. A total of 596 participants were randomized and 587 participants received study product.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Benzoyl peroxide/Clindamycin + Tazarotene

Arm description:

Participants applied the study product (Benzoyl peroxide/Clindamycin + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 grams [g] of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Arm type	Experimental
Investigational medicinal product name	Benzoyl peroxide/Clindamycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Benzoyl peroxide/Clindamycin contained 1% clindamycin phosphate and 5% BPO in a gel vehicle. It was applied once daily in the evening.

Investigational medicinal product name	Tazarotene
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Tazarotene, which contained 0.1 % tazarotene in a cream vehicle. It was applied once daily in the evening.

Arm title	Benzoyl peroxide/Clindamycin + vehicle cream

Arm description:

Participants applied the study product (Benzoyl peroxide/Clindamycin + vehicle cream with identical ingredients as Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Arm type	Active comparator

Investigational medicinal product name	Benzoyl peroxide/Clindamycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Benzoyl peroxide/Clindamycin contained 1% clindamycin phosphate and 5% BPO in a gel vehicle. It was applied once daily in the evening.

Investigational medicinal product name	Vehicle cream
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Vehicle cream contained identical ingredients as Tazarotene but without the active ingredient. It was applied once daily in the evening.

Arm title	Benzoyl peroxide gel + Tazarotene

Arm description:

Participants applied the study product (Benzoyl peroxide gel + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant’s palm and mixed. A thin film was then applied to the entire face.

Arm type	Active comparator
Investigational medicinal product name	Benzoyl Peroxide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Benzoyl Peroxide gel contained identical ingredients as Benzoyl peroxide/Clindamycin but without the clindamycin. It was applied once daily in the evening.

Investigational medicinal product name	Tazarotene
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Tazarotene, which contained 0.1 % tazarotene in a cream vehicle. It was applied once daily in the evening.

Arm title	Clindamycin gel + Tazarotene

Arm description:

Participants applied the study product (Clindamycin gel + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant’s palm and mixed. A thin film was then applied to the entire face.

Arm type	Active comparator
Investigational medicinal product name	Clindamycin gel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Clindamycin gel contained identical ingredients as Benzoyl peroxide/Clindamycin but without the Benzoyl Peroxide. It was applied once daily in the evening.

Investigational medicinal product name	Tazarotene
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Tazarotene, which contained 0.1 % tazarotene in a cream vehicle. It was applied once daily in the evening.

Arm title	Vehicle gel + Tazarotene

Arm description:

Participants applied the study product (Vehicle gel with identical ingredients as Benzoyl peroxide/Clindamycin + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Arm type	Active comparator
Investigational medicinal product name	Vehicle gel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Vehicle gel contained identical ingredients as Benzoyl peroxide/Clindamycin but without the active ingredients. It was applied once daily in the evening.

Investigational medicinal product name	Tazarotene
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Tazarotene, which contained 0.1 % tazarotene in a cream vehicle. It was applied once daily in the evening.

Arm title	Vehicle gel + vehicle cream

Arm description:

Participants applied the study product (Vehicle gel with identical ingredients as Benzoyl peroxide/Clindamycin+ vehicle cream with identical ingredients as Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

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

Dosage and administration details:

Vehicle gel contained identical ingredients as Benzoyl peroxide/Clindamycin but without the active ingredients. It was applied once daily in the evening.

Investigational medicinal product name	Vehicle cream
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Vehicle cream contained identical ingredients as Tazarotene but without the active ingredient. It was applied once daily in the evening.

Number of subjects in period 1	Benzoyl peroxide/Clindamycin + Tazarotene	Benzoyl peroxide/Clindamycin + vehicle cream	Benzoyl peroxide gel + Tazarotene
Started	106	105	107
Completed	85	90	92
Not completed	21	15	15
Consent withdrawn by subject	6	1	5
Adverse event, non-fatal	2	-	2
Non-compliance with Study Treatment	1	1	2
Lost to follow-up	5	7	5
Lack of efficacy	1	3	-
Protocol deviation	6	3	1

Number of subjects in period 1	Clindamycin gel + Tazarotene	Vehicle gel + Tazarotene	Vehicle gel + vehicle cream
Started	108	106	55
Completed	99	87	47
Not completed	9	19	8
Consent withdrawn by subject	1	5	7
Adverse event, non-fatal	2	3	1
Non-compliance with Study Treatment	-	1	-
Lost to follow-up	5	7	-
Lack of efficacy	-	1	-
Protocol deviation	1	2	-

Baseline characteristics

Reporting groups	
Reporting group title	Benzoyl peroxide/Clindamycin + Tazarotene
Reporting group description:	
Participants applied the study product (Benzoyl peroxide/Clindamycin + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 grams [g] of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.	
Reporting group title	Benzoyl peroxide/Clindamycin + vehicle cream
Reporting group description:	
Participants applied the study product (Benzoyl peroxide/Clindamycin + vehicle cream with identical ingredients as Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.	
Reporting group title	Benzoyl peroxide gel + Tazarotene
Reporting group description:	
Participants applied the study product (Benzoyl peroxide gel + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.	
Reporting group title	Clindamycin gel + Tazarotene
Reporting group description:	
Participants applied the study product (Clindamycin gel + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.	
Reporting group title	Vehicle gel + Tazarotene
Reporting group description:	
Participants applied the study product (Vehicle gel with identical ingredients as Benzoyl peroxide/Clindamycin + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.	
Reporting group title	Vehicle gel + vehicle cream
Reporting group description:	
Participants applied the study product (Vehicle gel with identical ingredients as Benzoyl peroxide/Clindamycin+ vehicle cream with identical ingredients as Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.	

Reporting group values	Benzoyl peroxide/Clindamycin + Tazarotene	Benzoyl peroxide/Clindamycin + vehicle cream	Benzoyl peroxide gel + Tazarotene
Number of subjects	106	105	107
Age categorical Units: Subjects			

Age continuous			
Age continuous description			
Units: years			
arithmetic mean	19.7	19.7	20.2
standard deviation	± 6.2	± 6.9	± 7.3

Gender categorical			
Gender categorical description			
Units: Subjects			
Female	58	56	60
Male	48	49	47
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	8	14	5
Black	23	16	24
Multiracial	10	11	9
Native Hawaiian or Other Pacific Islander	1	1	1
White	63	63	68

Reporting group values	Clindamycin gel + Tazarotene	Vehicle gel + Tazarotene	Vehicle gel + vehicle cream
Number of subjects	108	106	55
Age categorical Units: Subjects			
Age continuous			
Age continuous description			
Units: years			
arithmetic mean	19.2	21.7	19.8
standard deviation	± 6.2	± 8.4	± 6.6
Gender categorical			
Gender categorical description			
Units: Subjects			
Female	60	65	35
Male	48	41	20
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	6	9	5
Black	15	14	8
Multiracial	8	8	5
Native Hawaiian or Other Pacific Islander	0	1	0
White	79	74	37

Reporting group values	Total		
Number of subjects	587		
Age categorical Units: Subjects			
Age continuous			
Age continuous description			
Units: years			
arithmetic mean			

standard deviation	-		

Gender categorical			
Gender categorical description			
Units: Subjects			
Female	334		
Male	253		
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	1		
Asian	47		
Black	100		
Multiracial	51		
Native Hawaiian or Other Pacific Islander	4		
White	384		

End points

End points reporting groups

Reporting group title	Benzoyl peroxide/Clindamycin + Tazarotene

Reporting group description:

Participants applied the study product (Benzoyl peroxide/Clindamycin + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 grams [g] of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Reporting group title	Benzoyl peroxide/Clindamycin + vehicle cream

Reporting group description:

Participants applied the study product (Benzoyl peroxide/Clindamycin + vehicle cream with identical ingredients as Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Reporting group title	Benzoyl peroxide gel + Tazarotene

Reporting group description:

Participants applied the study product (Benzoyl peroxide gel + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Reporting group title	Clindamycin gel + Tazarotene

Reporting group description:

Participants applied the study product (Clindamycin gel + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Reporting group title	Vehicle gel + Tazarotene

Reporting group description:

Participants applied the study product (Vehicle gel with identical ingredients as Benzoyl peroxide/Clindamycin + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Reporting group title	Vehicle gel + vehicle cream

Reporting group description:

Participants applied the study product (Vehicle gel with identical ingredients as Benzoyl peroxide/Clindamycin+ vehicle cream with identical ingredients as Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Subject analysis set title	Benzoyl peroxide/Clindamycin + Tazarotene
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants applied the study product (Benzoyl peroxide/Clindamycin + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 grams [g] of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Subject analysis set title	Benzoyl peroxide/Clindamycin + vehicle cream
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants applied the study product (Benzoyl peroxide/Clindamycin + vehicle cream with identical ingredients as Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Subject analysis set title	Benzoyl peroxide gel + Tazarotene.
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants applied the study product (Benzoyl peroxide gel + Tazarotene) to the face once daily in the

evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Subject analysis set title	Clindamycin gel + Tazarotene.
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants applied the study product (Clindamycin gel + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Subject analysis set title	Vehicle gel + Tazarotene.
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants applied the study product (Vehicle gel with identical ingredients as Benzoyl peroxide/Clindamycin + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Subject analysis set title	Vehicle gel + vehicle cream.
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants applied the study product (Vehicle gel with identical ingredients as Benzoyl peroxide/Clindamycin+ vehicle cream with identical ingredients as Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant's palm and mixed. A thin film was then applied to the entire face.

Primary: Absolute change in lesion counts (total, inflammatory, and non-inflammatory) from Baseline to Week 12

End point title	Absolute change in lesion counts (total, inflammatory, and non-inflammatory) from Baseline to Week 12

End point description:

The investigator or designee took count of inflammatory lesions (papules, pustules, nodules and cysts [only post-Baseline]) (ILC), noninflammatory lesions (open and closed comedones) (NILC) and total lesions (TLC) at Baseline, Weeks 2, 4, 8, and 12. Lesion counts were confined to the face. Each of 3 lesion counts (total, inflammatory and non-inflammatory) was analyzed using an analysis of covariance (ANCOVA) model with terms for treatment, center, Baseline value and treatment-by-center interaction. If the interaction was not significant at 0.1 level, this interaction was excluded in ANCOVA model. Day 1 (Visit 1) was defined as Baseline. Only participants available at specified timepoints were analyzed (represented by n=X in the category titles).

End point type	Primary

End point timeframe:

Baseline and up to Week 12

End point values	Benzoyl peroxide/Clindamycin + Tazarotene	Benzoyl peroxide/Clindamycin + vehicle cream	Benzoyl peroxide gel + Tazarotene	Clindamycin gel + Tazarotene
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106[1]	105[2]	107[3]	107[4]
Units: Lesion count				
arithmetic mean (standard deviation)				
ILC, n=101, 103, 105, 105, 104, 52	-16.8 (± 14.35)	-18.1 (± 14.45)	-18.9 (± 12.84)	-18.8 (± 11.49)
NILC, n=101, 103, 105, 105, 104, 52	-33 (± 23.94)	-24.9 (± 33.41)	-37.1 (± 29.7)	-37.5 (± 29.51)

TLC, n=101, 103, 105, 105, 104, 52	-49.8 (± 31.78)	-43 (± 42.24)	-56 (± 34.99)	-56.3 (± 35.42)

Notes:

[1] - Intent-to-treat (ITT) Analysis Set: all randomized participants who received study product and reach

[2] - Intent-to-treat (ITT) Analysis Set: all randomized participants who received study product and reach

[3] - Intent-to-treat (ITT) Analysis Set: all randomized participants who received study product and reach

[4] - Intent-to-treat (ITT) Analysis Set: all randomized participants who received study product and reach

End point values	Vehicle gel + Tazarotene	Vehicle gel + vehicle cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	106[5]	55[6]		
Units: Lesion count				
arithmetic mean (standard deviation)				
ILC, n=101, 103, 105, 105, 104, 52	-14.5 (± 12.76)	-8.96 (± 12.63)		
NILC, n=101, 103, 105, 105, 104, 52	-33 (± 25.89)	-18.9 (± 28.41)		
TLC, n=101, 103, 105, 105, 104, 52	-47.6 (± 33.32)	-27.8 (± 35.06)		

Notes:

[5] - Intent-to-treat (ITT) Analysis Set: all randomized participants who received study product and reach

[6] - Intent-to-treat (ITT) Analysis Set: all randomized participants who received study product and reach

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide gel + Tazarotene
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.692 [7]
Method	ANCOVA

Notes:

[7] - For ILC

Statistical analysis title	Statistical analysis 2
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide gel + Tazarotene
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.467 [8]
Method	ANCOVA

Notes:

[8] - For ILC

Statistical analysis title	Statistical analysis 3
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Clindamycin gel

	+ Tazarotene
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.281 [9]
Method	ANCOVA

Notes:

[9] - For ILC

Statistical analysis title	Statistical analysis 4
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + Tazarotene
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.075 [10]
Method	ANCOVA

Notes:

[10] - For ILC

Statistical analysis title	Statistical analysis 5
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + vehicle cream
Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [11]
Method	ANCOVA

Notes:

[11] - For ILC

Statistical analysis title	Statistical analysis 6
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide/Clindamycin + vehicle cream
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [12]
Method	ANCOVA

Notes:

[12] - For NILC

Statistical analysis title	Statistical analysis 7
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide gel + Tazarotene

Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.803 [13]
Method	ANCOVA

Notes:

[13] - For NILC

Statistical analysis title	Statistical analysis 8
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Clindamycin gel + Tazarotene
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.175 [14]
Method	ANCOVA

Notes:

[14] - For NILC

Statistical analysis title	Statistical analysis 9
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + Tazarotene
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.552 [15]
Method	ANCOVA

Notes:

[15] - For NILC

Statistical analysis title	Statistical analysis 10
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + vehicle cream
Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [16]
Method	ANCOVA

Notes:

[16] - For NILC

Statistical analysis title	Statistical analysis 11
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide/Clindamycin + vehicle cream

Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [17]
Method	ANCOVA

Notes:

[17] - For TC

Statistical analysis title	Statistical analysis 12
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide gel + Tazarotene
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.618 [18]
Method	ANCOVA

Notes:

[18] - For TC

Statistical analysis title	Statistical analysis 13
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Clindamycin gel + Tazarotene
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.149 [19]
Method	ANCOVA

Notes:

[19] - For TC

Statistical analysis title	Statistical analysis 14
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + Tazarotene
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.255 [20]
Method	ANCOVA

Notes:

[20] - For TC

Statistical analysis title	Statistical analysis 15
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + vehicle cream

Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [21]
Method	ANCOVA

Notes:

[21] - For TC

Primary: Proportion of participants with a minimum 2-grade improvement in the Investigator's Static Global Assessment (ISGA) score from Baseline to Week 12

End point title	Proportion of participants with a minimum 2-grade improvement in the Investigator's Static Global Assessment (ISGA) score from Baseline to Week 12

End point description:

An ISGA was obtained at Baseline and at Weeks 2, 4, 8, and 12. The scores range from 0-5 (0=clear skin with no inflammatory or non-inflammatory lesions; 5=very severe with many non-inflammatory and inflammatory lesions and more than a few nodular lesions (may have cystic lesions). The higher score indicates more severe. The area considered for the ISGA was confined to the face. When possible, the same efficacy assessor performed all ISGA assessments on the same participant at all visits. Day 1 (Visit 1) was defined as Baseline. Only participants available at specified time points were analyzed.

End point type	Primary

End point timeframe:

Baseline and up to Week 12

End point values	Benzoyl peroxide/Clindamycin + Tazarotene	Benzoyl peroxide/Clindamycin + vehicle cream	Benzoyl peroxide gel + Tazarotene	Clindamycin gel + Tazarotene
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106[22]	105[23]	107[24]	108[25]
Units: Percentage of participants	22	22	31	36

Notes:

[22] - ITT Analysis Set

[23] - ITT Analysis Set

[24] - ITT Analysis Set

[25] - ITT Analysis Set

End point values	Vehicle gel + Tazarotene	Vehicle gel + vehicle cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	106[26]	55[27]		
Units: Percentage of participants	20	5		

Notes:

[26] - ITT Analysis Set

[27] - ITT Analysis Set

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide/Clindamycin + vehicle cream

Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.922
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 2
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide gel + Tazarotene
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.132
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 3
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Clindamycin gel + Tazarotene
Number of subjects included in analysis	214
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.02
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 4
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + Tazarotene
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.706
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 5
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + vehicle cream

Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Cochran-Mantel-Haenszel

Secondary: Percent change from Baseline to Week 12 in each of 3 lesion counts (total, inflammatory, and non-inflammatory)

End point title	Percent change from Baseline to Week 12 in each of 3 lesion counts (total, inflammatory, and non-inflammatory)

End point description:

The investigator or designee took count of inflammatory lesions (papules, pustules, nodules and cysts) (ILC), noninflammatory lesions (open and closed comedones) (NILC) and total lesions (TLC) at Baseline, Weeks 2, 4, 8, and 12. Lesion counts were confined to the face. Each of 3 lesion counts (total, inflammatory and non-inflammatory) was analyzed using an analysis of covariance (ANCOVA) model with terms for treatment, center, Baseline value and treatment-by-center interaction. If the interaction was not significant at 0.1 level, this interaction was excluded in ANCOVA model. Day 1 (Visit 1) was defined as Baseline. Only participants available at specified timepoints were analyzed (represented by n=X in the category titles).

End point type	Secondary

End point timeframe:

Baseline and up to Week 12

End point values	Benzoyl peroxide/Clindamycin + Tazarotene	Benzoyl peroxide/Clindamycin + vehicle cream	Benzoyl peroxide gel + Tazarotene	Clindamycin gel + Tazarotene
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106[28]	105[29]	107[30]	108[31]
Units: Percent change				
arithmetic mean (standard deviation)				
ILC, n=101, 103, 105, 105, 104, 52	-58.3 (± 45.57)	-62.4 (± 39.33)	-62.4 (± 34.83)	-65.7 (± 33.38)
NILC, n=101, 103, 105, 105, 104, 52	-58 (± 29.97)	-39.2 (± 51.29)	-60.6 (± 35)	-61.2 (± 31.6)
TLC, n=101, 103, 105, 105, 104, 52	-59.1 (± 29.96)	-47.9 (± 38.89)	-62 (± 29.42)	-63.4 (± 28.75)

Notes:

[28] - ITT Analysis Set

[29] - ITT Analysis Set

[30] - ITT Analysis Set

[31] - ITT Analysis Set

End point values	Vehicle gel + Tazarotene	Vehicle gel + vehicle cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	106[32]	55[33]		
Units: Percent change				
arithmetic mean (standard deviation)				
ILC, n=101, 103, 105, 105, 104, 52	-49 (± 40.9)	-33.5 (± 41.1)		

NILC, n=101, 103, 105, 105, 104, 52	-53.1 (± 30.56)	-29.5 (± 44.05)		
TLC, n=101, 103, 105, 105, 104, 52	-51.8 (± 29.18)	-31.5 (± 37.59)		

Notes:

[32] - ITT Analysis Set

[33] - ITT Analysis Set

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide/Clindamycin + vehicle cream
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.504 [34]
Method	ANCOVA

Notes:

[34] - For ILC

Statistical analysis title	Statistical analysis 2
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide gel + Tazarotene
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.504 [35]
Method	ANCOVA

Notes:

[35] - For ILC

Statistical analysis title	Statistical analysis 3
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Clindamycin gel + Tazarotene
Number of subjects included in analysis	214
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.177 [36]
Method	ANCOVA

Notes:

[36] - For ILC

Statistical analysis title	Statistical analysis 4
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + Tazarotene

Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.084 [37]
Method	ANCOVA

Notes:

[37] - For ILC

Statistical analysis title	Statistical analysis 5
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + vehicle cream
Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [38]
Method	ANCOVA

Notes:

[38] - For ILC

Statistical analysis title	Statistical analysis 6
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide/Clindamycin + vehicle cream
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [39]
Method	ANCOVA

Notes:

[39] - For NILC

Statistical analysis title	Statistical analysis 7
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide gel + Tazarotene
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.776 [40]
Method	ANCOVA

Notes:

[40] - For NILC

Statistical analysis title	Statistical analysis 8
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Clindamycin gel + Tazarotene

Number of subjects included in analysis	214
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.465 [41]
Method	ANCOVA

Notes:

[41] - For NILC

Statistical analysis title	Statistical analysis 9
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + Tazarotene
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.288 [42]
Method	ANCOVA

Notes:

[42] - For NILC

Statistical analysis title	Statistical analysis 10
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + vehicle cream
Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [43]
Method	ANCOVA

Notes:

[43] - For NILC

Statistical analysis title	Statistical analysis 11
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide/Clindamycin + vehicle cream
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [44]
Method	ANCOVA

Notes:

[44] - For TC

Statistical analysis title	Statistical analysis 12
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide gel + Tazarotene

Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.62 [45]
Method	ANCOVA

Notes:

[45] - For TC

Statistical analysis title	Statistical analysis 13
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Clindamycin gel + Tazarotene
Number of subjects included in analysis	214
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.291 [46]
Method	ANCOVA

Notes:

[46] - For TC

Statistical analysis title	Statistical analysis 14
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + Tazarotene
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.085 [47]
Method	ANCOVA

Notes:

[47] - For TC

Statistical analysis title	Statistical analysis 15
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + vehicle cream
Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [48]
Method	ANCOVA

Notes:

[48] - For TC

Secondary: Proportion of Participants with an ISGA score of 0 or 1 at Week 12

End point title	Proportion of Participants with an ISGA score of 0 or 1 at Week 12

End point description:

An ISGA was obtained at Baseline and at Weeks 2, 4, 8, and 12. The scores range from 0-5 (0=clear skin with no inflammatory or non-inflammatory lesions; 5=very severe with many non-inflammatory and inflammatory lesions and more than a few nodular lesions (may have cystic lesions). The higher score indicates more severe. The area considered for the ISGA was confined to the face. When possible, the same efficacy assessor performed all ISGA assessments on the same participant at all visits. Day 1 (Visit 1) was defined as Baseline. Only participants available at specified time points were analyzed.

End point type	Secondary

End point timeframe:
Week 12

End point values	Benzoyl peroxide/Clindamycin + Tazarotene	Benzoyl peroxide/Clindamycin + vehicle cream	Benzoyl peroxide gel + Tazarotene	Clindamycin gel + Tazarotene
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106[49]	105[50]	107[51]	108[52]
Units: Percentage of participants	33	31	27	39

Notes:
[49] - ITT Analysis Set
[50] - ITT Analysis Set
[51] - ITT Analysis Set
[52] - ITT Analysis Set

End point values	Vehicle gel + Tazarotene	Vehicle gel + vehicle cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	106[53]	55[54]		
Units: Percentage of participants	22	13		

Notes:
[53] - ITT Analysis Set
[54] - ITT Analysis Set

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide/Clindamycin + vehicle cream
Number of subjects included in analysis	211
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.652
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 2
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Benzoyl peroxide gel + Tazarotene
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.279
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 3

Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Clindamycin gel + Tazarotene
Number of subjects included in analysis	214
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.312
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 4
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + Tazarotene
Number of subjects included in analysis	212
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.063
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Statistical analysis 5
Comparison groups	Benzoyl peroxide/Clindamycin + Tazarotene v Vehicle gel + vehicle cream
Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Cochran-Mantel-Haenszel

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs) and non-serious adverse events (AEs) were collected from Day 1 up to Day 89.

Adverse event reporting additional description:

SAEs and non-serious AEs were assessed in the ITT Analysis Set.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.1

Reporting groups

Reporting group title	Benzoyl peroxide/Clindamycin + Tazarotene

Reporting group description:

Participants applied the study product (Benzoyl peroxide/Clindamycin + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 grams [g] of the combined product in an approximate 1:1 ratio) were dispensed into the participant’s palm and mixed. A thin film was then applied to the entire face.

Reporting group title	Benzoyl peroxide/Clindamycin + vehicle cream

Reporting group description:

Participants applied the study product (Benzoyl peroxide/Clindamycin + vehicle cream with identical ingredients as Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant’s palm and mixed. A thin film was then applied to the entire face.

Reporting group title	Benzoyl peroxide gel + Tazarotene

Reporting group description:

Participants applied the study product (Benzoyl peroxide gel + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant’s palm and mixed. A thin film was then applied to the entire face.

Reporting group title	Clindamycin gel + Tazarotene

Reporting group description:

Participants applied the study product (Clindamycin gel + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant’s palm and mixed. A thin film was then applied to the entire face.

Reporting group title	Vehicle gel + Tazarotene

Reporting group description:

Participants applied the study product (Vehicle gel with identical ingredients as Benzoyl peroxide/Clindamycin + Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant’s palm and mixed. A thin film was then applied to the entire face.

Reporting group title	Vehicle gel + vehicle cream

Reporting group description:

Participants applied the study product (Vehicle gel with identical ingredients as Benzoyl peroxide/Clindamycin+ vehicle cream with identical ingredients as Tazarotene) to the face once daily in the evening up to 12 weeks. Two actuations of test product (approximately 0.6 g of the combined product in an approximate 1:1 ratio) were dispensed into the participant’s palm and mixed. A thin film was then applied to the entire face.

Serious adverse events	Benzoyl peroxide/Clindamycin + Tazarotene	Benzoyl peroxide/Clindamycin + vehicle cream	Benzoyl peroxide gel + Tazarotene
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Clindamycin gel + Tazarotene	Vehicle gel + Tazarotene	Vehicle gel + vehicle cream
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

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

Non-serious adverse events	Benzoyl peroxide/Clindamycin + Tazarotene	Benzoyl peroxide/Clindamycin + vehicle cream	Benzoyl peroxide gel + Tazarotene
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 106 (23.58%)	22 / 105 (20.95%)	24 / 107 (22.43%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibromatosis			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	1 / 107 (0.93%)
occurrences (all)	0	1	1
Surgical and medical procedures			
Wisdom teeth removal			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Application site burn			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Application site dermatitis			

subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Application site discolouration			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Application site dryness			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
Application site erythema			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	2 / 107 (1.87%)
occurrences (all)	1	0	2
Application site exfoliation			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Application site irritation			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	3 / 107 (2.80%)
occurrences (all)	1	0	3
Application site pain			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
Application site pruritus			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Condition aggravated			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Cyst			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Local swelling			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	2 / 106 (1.89%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	2	0	0
Allergy to metals			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Food allergy			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Multiple allergies			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Ovarian cyst			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchitis			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	3 / 107 (2.80%)
occurrences (all)	0	0	3
Nasal congestion			

subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Investigations			
Smear cervix abnormal			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	1 / 107 (0.93%)
occurrences (all)	0	1	1
Facial bones fracture			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Joint injury			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Joint sprain			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Muscle strain			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Procedural pain			

subjects affected / exposed	1 / 106 (0.94%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
Sunburn			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Eye disorders			
Conjunctivitis			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Tooth impacted			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			

Dermatitis			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
Dermatitis atopic			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Rash generalised			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Furuncle			

subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	1 / 106 (0.94%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
Herpes simplex			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	1 / 107 (0.93%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Localised infection			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Lyme disease			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	3 / 106 (2.83%)	3 / 105 (2.86%)	3 / 107 (2.80%)
occurrences (all)	3	3	3
Oral herpes			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Pharyngitis streptococcal			

subjects affected / exposed	1 / 106 (0.94%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
Sinusitis			
subjects affected / exposed	1 / 106 (0.94%)	1 / 105 (0.95%)	2 / 107 (1.87%)
occurrences (all)	1	1	2
Tinea pedis			
subjects affected / exposed	0 / 106 (0.00%)	1 / 105 (0.95%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	5 / 106 (4.72%)	4 / 105 (3.81%)	5 / 107 (4.67%)
occurrences (all)	5	4	5
Urinary tract infection			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
Vaginitis bacterial			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 106 (0.00%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 106 (0.94%)	0 / 105 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Clindamycin gel + Tazarotene	Vehicle gel + Tazarotene	Vehicle gel + vehicle cream
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 108 (16.67%)	29 / 106 (27.36%)	12 / 55 (21.82%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Fibromatosis			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Wisdom teeth removal			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application site burn			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	1 / 55 (1.82%)
occurrences (all)	0	1	1
Application site dermatitis			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Application site discolouration			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Application site dryness			
subjects affected / exposed	1 / 108 (0.93%)	1 / 106 (0.94%)	1 / 55 (1.82%)
occurrences (all)	1	1	1
Application site erythema			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	1 / 55 (1.82%)
occurrences (all)	1	0	1
Application site exfoliation			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Application site irritation			
subjects affected / exposed	4 / 108 (3.70%)	2 / 106 (1.89%)	0 / 55 (0.00%)
occurrences (all)	4	2	0
Application site pain			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	2 / 55 (3.64%)
occurrences (all)	0	0	2

Application site pruritus			
subjects affected / exposed	0 / 108 (0.00%)	2 / 106 (1.89%)	1 / 55 (1.82%)
occurrences (all)	0	2	1
Condition aggravated			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Cyst			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Local swelling			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	1 / 108 (0.93%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Allergy to metals			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Food allergy			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Multiple allergies			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Menorrhagia			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchitis			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Investigations			
Smear cervix abnormal			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0

Excoriation			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Facial bones fracture			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Joint sprain			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Sunburn			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 108 (0.00%)	2 / 106 (1.89%)	0 / 55 (0.00%)
occurrences (all)	0	2	0
Insomnia			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous stomatitis			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			

subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Lip blister			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Tooth impacted			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 108 (0.00%)	2 / 106 (1.89%)	0 / 55 (0.00%)
occurrences (all)	0	2	0
Dermatitis atopic			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Rash generalised			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Skin irritation			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	1 / 55 (1.82%)
occurrences (all)	0	1	1
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	1 / 55 (1.82%)
occurrences (all)	1	0	1
Herpes simplex			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 108 (0.00%)	2 / 106 (1.89%)	0 / 55 (0.00%)
occurrences (all)	0	2	0
Localised infection			

subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Lyme disease			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	5 / 108 (4.63%)	4 / 106 (3.77%)	3 / 55 (5.45%)
occurrences (all)	5	4	3
Oral herpes			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 108 (0.00%)	1 / 106 (0.94%)	2 / 55 (3.64%)
occurrences (all)	0	1	2
Tinea pedis			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 108 (1.85%)	4 / 106 (3.77%)	1 / 55 (1.82%)
occurrences (all)	2	4	1
Urinary tract infection			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Vaginitis bacterial			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Viral infection			

subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 108 (0.00%)	0 / 106 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 August 2008	21 Aug 2008 In Section 7.2, Inclusion criterion #3, was updated " To Allow up to 80 inflammatory lesions (increased from 60), and up to 3 nodules of no more than 5 millimeter (mm) each (increased from none)." In Section 7.2, Inclusion criterion #7 was removed. In Section 7.3, Exclusion criterion #3, was updated "To Allow subjects with seborrheic dermatitis if it has been inactive for at least a year and/or does not affect the face." In Section 12.1.3, "Additional endpoints were revised to include a 2-grade drop in ISGA from Baseline to weeks 2, 4, and 8." In Section 12.4.5.3, "Definition of statistical analysis to be used for the additional endpoint of the proportion of subjects with an ISGA score of 0 or 1 at weeks 2, 4, and 8 was added."

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported