Clinical trial results:
Safety and Efficacy Evaluation of Topical Moxidex Otic Solution in the Treatment of Acute Otitis Externa

Summary

EudraCT number	2018-000615-25
Trial protocol	Outside EU/EEA
Global end of trial date	05 January 2009

Results information

Result version number	v1 (current)
This version publication date	05 August 2018
First version publication date	05 August 2018

Trial information

Trial identification

Sponsor protocol code	C-07-13

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00750633
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Alcon Research Ltd
Sponsor organisation address	6201 S. Freeway, Fort Worth, TX, United States, 76134
Public contact	Ophthalmology Unit, Novartis Pharmaceuticals, +44 0127666733385, Linda.masson@novartis.com
Scientific contact	Ophthalmology Unit, Novartis Pharmaceuticals, +44 0127666733385, Linda.masson@novartis.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 January 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 January 2009
Global end of trial reached?	Yes
Global end of trial date	05 January 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study was to evaluate the efficacy and safety of topical Moxidex for the treatment of acute otitis externa (AOE).

Protection of trial subjects:

Prior to the start of the study, the study protocol, the informed consent and assent documents, patient instruction sheets, the Investigator's Brochure, as well as any advertising materials used to recruit patients were submitted to institutional review boards (IRBs) and independent ethics committees (IECs). The IRB/IECs reviewed all documents and approved required documents; copies of the approval letters were provided to Alcon. Consistent with both the IRB/IEC's requirements and all applicable regulations, the Investigators periodically provided study updates to the IRB/IEC. A patient or parent/legal guardian (if necessary, a legally authorized representative) provided informed consent, and children signed an approved assent form when appropriate. This study was conducted in accordance with Good Clinical Practices (GCP) and the ethical principles that have their origins in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 June 2008
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	United States: 990
Worldwide total number of subjects	990
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)	11
Children (2-11 years)	381
Adolescents (12-17 years)	189

Adults (18-64 years)	379
From 65 to 84 years	30
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 76 study centers located in the United States.

Pre-assignment

Screening details:

This reporting group includes all randomized and treated subjects (Intent to Treat (ITT) Analysis Set).

Period 1

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

Blinding implementation details:

The Investigator, study site personnel, sponsor, and the subject (or parent/guardian) were masked from the identity of each subject's randomized test article.

Arms

Are arms mutually exclusive?	Yes
Arm title	Moxidex

Arm description:

Moxidex solution, 4 drops in the infected ear(s) BID for 7 days

Arm type	Experimental
Investigational medicinal product name	Moxifloxacin 0.5%/dexamethasone phosphate 0.1% solution
Investigational medicinal product code	
Other name	Moxidex
Pharmaceutical forms	Ear drops
Routes of administration	Auricular use

Dosage and administration details:

4 drops in the infected ear(s) twice daily (BID) for 7 days

Arm title	Moxifloxacin

Arm description:

Moxifloxacin solution, 4 drops in the infected ear(s) BID for 7 days

Arm type	Active comparator
Investigational medicinal product name	Moxifloxacin 0.5% solution
Investigational medicinal product code	
Other name	Moxifloxacin
Pharmaceutical forms	Ear drops
Routes of administration	Auricular use

Dosage and administration details:

4 drops in the infected ear(s) BID for 7 days

Arm title	Dexamethasone

Arm description:

Dexamethasone solution, 4 drops in the infected ear(s) BID for 7 days

Arm type	Active comparator

Investigational medicinal product name	Dexamethasone phosphate 0.1% solution
Investigational medicinal product code	
Other name	Dexamethasone
Pharmaceutical forms	Ear drops
Routes of administration	Auricular use

Dosage and administration details:

4 drops in the infected ear(s) BID for 7 days

Number of subjects in period 1	Moxidex	Moxifloxacin	Dexamethasone
Started	330	333	327
Completed	292	284	241
Not completed	38	49	86
Treatment failure	19	30	48
Baseline culture positive-Group A Strep	2	-	2
Adverse event, non-fatal	10	11	21
Inclusion/exclusion violation	-	-	2
Baseline culture results positive - yeast	-	-	4
Subject decision unrelated to an AE	2	4	4
Lost to follow-up	2	2	2
Other - Reason not given	3	2	2
Noncompliance	-	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Moxidex
Reporting group description:	
Moxidex solution, 4 drops in the infected ear(s) BID for 7 days	
Reporting group title	Moxifloxacin
Reporting group description:	
Moxifloxacin solution, 4 drops in the infected ear(s) BID for 7 days	
Reporting group title	Dexamethasone
Reporting group description:	
Dexamethasone solution, 4 drops in the infected ear(s) BID for 7 days	

Reporting group values	Moxidex	Moxifloxacin	Dexamethasone
Number of subjects	330	333	327
Age categorical			
ITT Analysis Set			
Units: Subjects			
Infants and toddlers (28 days-23 months)	2	5	4
Children (2-11 years)	130	128	123
Adolescents (12-17 years)	63	67	59
Adults (18-64 years)	125	121	133
From 65-84 years	10	12	8
Gender categorical			
ITT Analysis Set			
Units: Subjects			
Female	173	185	177
Male	157	148	150

Reporting group values	Total		
Number of subjects	990		
Age categorical			
ITT Analysis Set			
Units: Subjects			
Infants and toddlers (28 days-23 months)	11		
Children (2-11 years)	381		
Adolescents (12-17 years)	189		
Adults (18-64 years)	379		
From 65-84 years	30		
Gender categorical			
ITT Analysis Set			
Units: Subjects			
Female	535		
Male	455		

End points

End points reporting groups

Reporting group title	Moxidex
Reporting group description:	
Moxidex solution, 4 drops in the infected ear(s) BID for 7 days	
Reporting group title	Moxifloxacin
Reporting group description:	
Moxifloxacin solution, 4 drops in the infected ear(s) BID for 7 days	
Reporting group title	Dexamethasone
Reporting group description:	
Dexamethasone solution, 4 drops in the infected ear(s) BID for 7 days	

Primary: Percentage of subjects with Clinical Cure - Moxidex vs Moxifloxacin

End point title	Percentage of subjects with Clinical Cure - Moxidex vs Moxifloxacin[1]
End point description:	
Clinical cure was attained if the sum of the 3 signs and symptoms of acute otitis externa (AOE) (erythema, edema and tenderness) was zero (i.e. none) and remained zero for the remainder of the study. Pre-specified for Moxidex and Moxifloxacin. This analysis population includes all subjects who received drug and were culture positive for bacteria on Day 1 (Modified intent-to-treat (MITT) Analysis Set).	
End point type	Primary
End point timeframe:	
Day 3	

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: This endpoint was pre-specified for Moxidex and Moxifloxacin only.

End point values	Moxidex	Moxifloxacin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	330	333		
Units: percentage of subjects				
number (not applicable)	13.0	15.5		

Statistical analyses

Statistical analysis title	Clinical Cure
Comparison groups	Moxidex v Moxifloxacin
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.382 [2]
Method	Chi-squared

Notes:

[2] - Demonstration of efficacy (p<0.05) is required for both primary end point comparisons to control family wise error (FWE) rate at α=0.05. If only one end point is significant at p<0.05, the primary objective is not met.

Primary: Percentage of subjects with Clinical Cure - Moxidex vs Dexamethasone

End point title	Percentage of subjects with Clinical Cure - Moxidex vs Dexamethasone[3]

End point description:

Clinical cure was attained if the sum of the 3 signs and symptoms of acute otitis externa (AOE) (erythema, edema and tenderness) was zero (i.e. none) and remained zero for the remainder of the study. Prespecified for Moxidex and Dexamethasone. MITT Analysis Set.

End point type	Primary

End point timeframe:

Day 12

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: This endpoint was pre-specified for Moxidex and Dexamethasone only.

End point values	Moxidex	Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	301	295		
Units: percentage of subjects				
number (not applicable)	79.4	57.6		

Statistical analyses

Statistical analysis title	Clinical Cure
Comparison groups	Moxidex v Dexamethasone
Number of subjects included in analysis	596
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [4]
Method	Chi-squared

Notes:

[4] - Demonstration of efficacy (p<0.05) is required for both primary end point comparisons to control family wise error (FWE) rate at α=0.05. If only one end point is significant at p<0.05, the primary objective is not met.

Secondary: Percentage of subjects with Microbiological Success

End point title	Percentage of subjects with Microbiological Success[5]

End point description:

Microbiological success was defined as the eradication of pre-therapy pathogens at subsequent visits. This end point was pre-specified for Moxidex and Dexamethasone. MITT Analysis Set.

End point type	Secondary

End point timeframe:

Day 8, Day 12

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: This endpoint was pre-specified for Moxidex and Dexamethasone only.

End point values	Moxidex	Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	301	295		
Units: percentage of subjects				
number (not applicable)				
Day 8	74.4	26.4		
Day 12	79.1	40.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with Clinical Cure - Moxidex vs Moxifloxacin

End point title	Percentage of subjects with Clinical Cure - Moxidex vs Moxifloxacin[6]

End point description:

Clinical cure was attained if the sum of the 3 signs and symptoms of AOE (erythema, edema and tenderness) was zero (i.e. none) and remained zero for remainder of the study. Pre-specified for Moxidex and Moxifloxacin. MITT Analysis Set.

End point type	Secondary

End point timeframe:

Day 8, Day 12

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: This endpoint was pre-specified for Moxidex and Moxifloxacin only.

End point values	Moxidex	Moxifloxacin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	301	291		
Units: percentage of subjects				
number (not applicable)				
Day 8	63.1	56.0		
Day 12	79.4	73.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with Clinical Cure - Moxidex vs Dexamethasone

End point title	Percentage of subjects with Clinical Cure - Moxidex vs Dexamethasone[7]

End point description:

Clinical cure was attained if the sum of the 3 signs and symptoms of AOE (erythema, edema and tenderness) was zero (i.e. none) and remained zero for remainder of the study. Pre-specified for Moxidex and Dexamethasone. MITT Analysis Set.

End point type	Secondary

End point timeframe:

Day 3, Day 8

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: This endpoint was pre-specified for Moxidex and Dexamethasone only.

End point values	Moxidex	Dexamethason e		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	301	295		
Units: percentage of subjects				
number (not applicable)				
Day 3	13.0	11.2		
Day 8	63.1	41.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Treatment Failure

End point title	Percentage of Subjects with Treatment Failure

End point description:

Treatment failure was defined as a subject who discontinued the study due to treatment failure prior to or at the Day 3 or Day 8 visit, or were not considered to be a clinical cure at the Day 12 visit. MITT Analysis Set.

End point type	Secondary

End point timeframe:

Day 3, Day 8, Day 12

End point values	Moxidex	Moxifloxacin	Dexamethason e	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	301	291	295	
Units: percentage of subjects				
number (not applicable)				
Day 3	5.6	9.6	15.9	
Day 8	5.6	9.6	15.9	
Day 12	20.6	26.1	42.4	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs) are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All
AEs reported in this record are from date of First Patient First Treatment until Last Patient Last Visit.

Adverse event reporting additional description:

This analysis population includes all subjects who received drug (Safety Analysis Set).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Moxidex - Otic
Reporting group description:	
Subjects treated with Moxidex solution	
Reporting group title	Moxifloxacin - Otic
Reporting group description:	
Subjects treated with Moxifloxacin solution	
Reporting group title	Dexamethasone - Otic
Reporting group description:	
Subjects treated with Dexamethasone solution	
Reporting group title	Moxidex - Non-Otic
Reporting group description:	
Subjects treated with Moxidex solution	
Reporting group title	Moxifloxacin - Non-Otic
Reporting group description:	
Subjects treated with Moxifloxacin solution	
Reporting group title	Dexamethasone - Non-Otic
Reporting group description:	
Subjects treated with Dexamethasone solution	

Serious adverse events	Moxidex - Otic	Moxifloxacin - Otic	Dexamethasone - Otic
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Anaesthetic complication			

subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
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	Moxidex - Non-Otic	Moxifloxacin - Non-Otic	Dexamethasone - Non-Otic
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Anaesthetic complication			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (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	Moxidex - Otic	Moxifloxacin - Otic	Dexamethasone - Otic
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 330 (4.55%)	19 / 333 (5.71%)	30 / 327 (9.17%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Acrochordon excision			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Anxiety			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Foreign body			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Arthropod sting			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Excoriation			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Procedural complication			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Injury			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Epilepsy			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	1	0	1

Ear and labyrinth disorders			
Ear pruritus			
subjects affected / exposed	1 / 330 (0.30%)	2 / 333 (0.60%)	1 / 327 (0.31%)
occurrences (all)	1	2	1
Tympanic membrane perforation			
subjects affected / exposed	1 / 330 (0.30%)	1 / 333 (0.30%)	0 / 327 (0.00%)
occurrences (all)	1	1	0
Ear pain			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	5 / 327 (1.53%)
occurrences (all)	1	0	5
Ear discomfort			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	1	0	1
Eustachian tube dysfunction			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Hypoacusis			
subjects affected / exposed	0 / 330 (0.00%)	1 / 333 (0.30%)	1 / 327 (0.31%)
occurrences (all)	0	1	1
Ear haemorrhage			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Excessive cerumen production			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Eye disorders			
Eye irritation			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			

subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	0 / 330 (0.00%)	1 / 333 (0.30%)	0 / 327 (0.00%)
occurrences (all)	0	1	0
Intertrigo			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			

subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Otitis media			
subjects affected / exposed	4 / 330 (1.21%)	8 / 333 (2.40%)	9 / 327 (2.75%)
occurrences (all)	4	8	9
Otitis externa			
subjects affected / exposed	2 / 330 (0.61%)	6 / 333 (1.80%)	9 / 327 (2.75%)
occurrences (all)	2	6	9
Mastoiditis			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Otitis externa fungal			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Bronchitis viral			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Moxidex - Non-Otic	Moxifloxacin - Non-Otic	Dexamethasone - Non-Otic
Total subjects affected by non-serious adverse events			
subjects affected / exposed	35 / 330 (10.61%)	27 / 333 (8.11%)	28 / 327 (8.56%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 330 (0.00%)	1 / 333 (0.30%)	0 / 327 (0.00%)
occurrences (all)	0	1	0
Orthostatic hypotension			

subjects affected / exposed	0 / 330 (0.00%)	1 / 333 (0.30%)	0 / 327 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			
Acrochordon excision			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 330 (0.61%)	0 / 333 (0.00%)	3 / 327 (0.92%)
occurrences (all)	2	0	3
Fatigue			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 330 (0.00%)	1 / 333 (0.30%)	0 / 327 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	1 / 330 (0.30%)	2 / 333 (0.60%)	1 / 327 (0.31%)
occurrences (all)	1	2	1
Oropharyngeal pain			
subjects affected / exposed	1 / 330 (0.30%)	1 / 333 (0.30%)	1 / 327 (0.31%)
occurrences (all)	1	1	1
Cough			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract congestion			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0

Epistaxis			
subjects affected / exposed	0 / 330 (0.00%)	1 / 333 (0.30%)	1 / 327 (0.31%)
occurrences (all)	0	1	1
Rhinitis allergic			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Foreign body			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Excoriation			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Procedural complication			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Injury			
subjects affected / exposed	0 / 330 (0.00%)	2 / 333 (0.60%)	0 / 327 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
Headache			
subjects affected / exposed	9 / 330 (2.73%)	7 / 333 (2.10%)	6 / 327 (1.83%)
occurrences (all)	9	7	7
Dizziness			
subjects affected / exposed	3 / 330 (0.91%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	3	0	0

Epilepsy			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Tension headache			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pruritus			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Eustachian tube dysfunction			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Eye irritation			
subjects affected / exposed	0 / 330 (0.00%)	1 / 333 (0.30%)	0 / 327 (0.00%)
occurrences (all)	0	1	0
Eye pruritus			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	3 / 330 (0.91%)	2 / 333 (0.60%)	0 / 327 (0.00%)
occurrences (all)	3	2	0
Diarrhoea			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 330 (0.00%)	1 / 333 (0.30%)	0 / 327 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact			

subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Rotator cuff syndrome			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Infections and infestations			
Otitis media			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Mastoiditis			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Otitis externa fungal			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 330 (0.91%)	7 / 333 (2.10%)	3 / 327 (0.92%)
occurrences (all)	3	7	3
Pharyngitis streptococcal			
subjects affected / exposed	3 / 330 (0.91%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	3	0	0
Urinary tract infection			
subjects affected / exposed	2 / 330 (0.61%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	2	0	0
Sinusitis			

subjects affected / exposed	1 / 330 (0.30%)	1 / 333 (0.30%)	0 / 327 (0.00%)
occurrences (all)	1	1	0
Tonsillitis			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	1	0	1
Body tinea			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Bronchitis viral			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	1 / 330 (0.30%)	0 / 333 (0.00%)	0 / 327 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 330 (0.00%)	1 / 333 (0.30%)	4 / 327 (1.22%)
occurrences (all)	0	1	4
Conjunctivitis			
subjects affected / exposed	0 / 330 (0.00%)	1 / 333 (0.30%)	0 / 327 (0.00%)
occurrences (all)	0	1	0
Subcutaneous abscess			
subjects affected / exposed	0 / 330 (0.00%)	1 / 333 (0.30%)	0 / 327 (0.00%)
occurrences (all)	0	1	0
Impetigo			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Localised infection			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 330 (0.00%)	0 / 333 (0.00%)	1 / 327 (0.31%)
occurrences (all)	0	0	1
Varicella			

subjects affected / exposed occurrences (all)	0 / 330 (0.00%) 0	0 / 333 (0.00%) 0	1 / 327 (0.31%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported