



Clinical trial results:

A Phase III, Multi-Center, Randomized, Parallel-Group, Placebo-Controlled and Double-Blind Trial to Study the Efficacy and Safety of MK-4117 in Japanese Subjects with Perennial Allergic Rhinitis.

Summary

EudraCT number	2017-000186-76
Trial protocol	Outside EU/EEA
Global end of trial date	26 January 2014

Results information

Result version number	v1 (current)
This version publication date	09 March 2017
First version publication date	09 March 2017

Trial information

Trial identification

Sponsor protocol code	MK-4117-200
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01918033
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.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	26 January 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 January 2014
Global end of trial reached?	Yes
Global end of trial date	26 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a study to evaluate the efficacy and safety of desloratadine (MK-4117) in Japanese participants with perennial allergic rhinitis. The primary hypothesis is that desloratadine is superior to placebo after 2 weeks of treatment with regard to change from baseline in Total Nasal Symptom Score (TNSS) among Japanese participants with perennial allergic rhinitis.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 August 2013
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	Japan: 608
Worldwide total number of subjects	608
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)	82
Adults (18-64 years)	521
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Male and female participants who were at least 12 years of age and had perennial allergic rhinitis were enrolled in this study.

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, Data analyst, Assessor

Blinding implementation details:

Participants were blinded to study treatment.

Arms

Are arms mutually exclusive?	Yes
Arm title	Desloratadine 5 mg

Arm description:

Participants received one desloratadine 5 mg tablet and one placebo tablet orally once daily for up to 2 weeks

Arm type	Experimental
Investigational medicinal product name	Desloratadine
Investigational medicinal product code	MK-4117
Other name	CLARINEX®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One desloratadine 5 mg tablet and one placebo tablet once daily for up to 2 weeks

Arm title	Desloratadine 10 mg
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Arm description:

Participants received two desloratadine 5 mg tablets orally once daily for up to 2 weeks

Arm type	Experimental
Investigational medicinal product name	Desloratadine
Investigational medicinal product code	MK-4117
Other name	CLARINEX®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Two desloratadine 5 mg tablets once daily for up to 2 weeks

Arm title	Placebo
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Arm description:

Participants received two placebo tablets orally once daily for up to 2 weeks

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

Dosage and administration details:

Two placebo tablets once daily for up to 2 weeks

Number of subjects in period 1	Desloratadine 5 mg	Desloratadine 10 mg	Placebo
Started	203	203	202
Treated	202	203	201
Completed	198	201	199
Not completed	5	2	3
Consent withdrawn by subject	2	1	-
Adverse event, non-fatal	1	-	2
Lost to follow-up	-	1	-
Protocol deviation	2	-	1

Baseline characteristics

Reporting groups

Reporting group title	Desloratadine 5 mg
Reporting group description:	
Participants received one desloratadine 5 mg tablet and one placebo tablet orally once daily for up to 2 weeks	
Reporting group title	Desloratadine 10 mg
Reporting group description:	
Participants received two desloratadine 5 mg tablets orally once daily for up to 2 weeks	
Reporting group title	Placebo
Reporting group description:	
Participants received two placebo tablets orally once daily for up to 2 weeks	

Reporting group values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo
Number of subjects	203	203	202
Age categorical			
Units: Subjects			
Adolescents (12-17 years)	30	28	24
Adults (18-64 years)	170	175	176
From 65-84 years	3	0	2
Age Continuous			
Units: Years			
arithmetic mean	34.3	33.7	34.7
standard deviation	± 13.1	± 11.9	± 12.6
Gender, Male/Female			
Units: Subjects			
Female	116	105	121
Male	87	98	81

Reporting group values	Total		
Number of subjects	608		
Age categorical			
Units: Subjects			
Adolescents (12-17 years)	82		
Adults (18-64 years)	521		
From 65-84 years	5		
Age Continuous			
Units: Years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female			
Units: Subjects			
Female	342		
Male	266		

End points

End points reporting groups

Reporting group title	Desloratadine 5 mg
Reporting group description: Participants received one desloratadine 5 mg tablet and one placebo tablet orally once daily for up to 2 weeks	
Reporting group title	Desloratadine 10 mg
Reporting group description: Participants received two desloratadine 5 mg tablets orally once daily for up to 2 weeks	
Reporting group title	Placebo
Reporting group description: Participants received two placebo tablets orally once daily for up to 2 weeks	

Primary: Change From Baseline in Total Nasal Symptom Score (TNSS) Assessed by the Investigator at Week 2

End point title	Change From Baseline in Total Nasal Symptom Score (TNSS) Assessed by the Investigator at Week 2
End point description: The investigator interviewed and examined participants to evaluate for nasal symptoms of: sneezing (daily frequency of attacks; score of 0=less than 1 time to 3=11+ times), rhinorrhea (daily frequency of blowing nose; score of 0=less than 1 time to 3=11+ times), nasal congestion (score of 0=less than nasal blockage without oral breathing to 3=severe nasal blockage causing prolonged oral breathing in a day), and nasal itching (score of 0=none to 3=nose is itchy, requiring frequent rubbing or blowing nose). The TNSS is the sum of the 4 nasal symptom sub-scores. TNSS scores could range from 0 to 12, with a higher score indicating more frequent/severe nasal symptoms. The Full Analysis Set (FAS) population consisted of all participants who took at least one dose of study drug and had a baseline or at least one post-baseline assessment for TNSS.	
End point type	Primary
End point timeframe: Baseline and Week 2	

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	203	201	
Units: Score on a Scale				
least squares mean (confidence interval 95%)	-1.96 (-2.25 to -1.67)	-1.94 (-2.23 to -1.65)	-1.87 (-2.16 to -1.58)	

Statistical analyses

Statistical analysis title	TNSS: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo

Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.661 ^[1]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares (LS) Means
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.49
upper limit	0.31

Notes:

[1] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	TNSS: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.707 ^[2]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	0.32

Notes:

[2] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Primary: Number of Participants Experiencing an Adverse Event (AE)

End point title	Number of Participants Experiencing an Adverse Event (AE) ^[3]
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End point description:

An AE is defined as any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of the study drug or protocol-specified procedure, whether or not considered related to the study drug or protocol-specified procedure. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a pre-existing condition that is temporally associated with the use of the study drug, is also an AE. The number of participants who experienced an AE, regardless of causality or severity, was summarized. The All-Subjects-as-Treated (ASaT) population consisted of all participants who received at least one dose of study drug.

End point type	Primary
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End point timeframe:

Up to Week 4

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for or performed for this end point.

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	203	201	
Units: Participants	27	29	20	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Discontinuing Study Drug Due to an AE

End point title	Number of Participants Discontinuing Study Drug Due to an
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End point description:

An AE is defined as any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of the study drug or protocol-specified procedure, whether or not considered related to the study drug or protocol-specified procedure. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a pre-existing condition that is temporally associated with the use of the study drug, is also an AE. The number of participants who discontinued study drug, whether permanently or temporarily, due to an AE was summarized. The ASaT population consisted of all participants who received at least one dose of study drug.

End point type	Primary
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End point timeframe:

Up to Week 2

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for or performed for this end point.

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	203	201	
Units: Participants	1	0	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in TNSS Assessed by the Investigator at Day 3 and Week 1

End point title	Change From Baseline in TNSS Assessed by the Investigator at Day 3 and Week 1
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End point description:

The investigator interviewed and examined participants to evaluate for nasal symptoms of: sneezing (daily frequency of attacks; score of 0=less than 1 time to 3=11+ times), rhinorrhea (daily frequency of blowing nose; score of 0=less than 1 time to 3=11+ times), nasal congestion (score of 0=less than nasal blockage without oral breathing to 3=severe nasal blockage causing prolonged oral breathing in a day), and nasal itching (score of 0=none to 3=nose is itchy, requiring frequent rubbing or blowing nose). The TNSS is the sum of the 4 nasal symptom sub-scores. TNSS scores could range from 0 to 12, with a higher score indicating more frequent/severe nasal symptoms. The FAS population consisted of

all participants who took at least one dose of study drug and had a baseline or at least one post-baseline assessment for TNSS.

End point type	Secondary
End point timeframe:	
Baseline and Day 3, Week 1	

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	203	201	
Units: Score on a Scale				
least squares mean (confidence interval 95%)				
Change from Baseline (BL) at Day 3	-1.12 (-1.38 to -0.86)	-1.11 (-1.37 to -0.85)	-0.63 (-0.89 to -0.37)	
Change from BL at Week 1	-1.39 (-1.68 to -1.09)	-1.39 (-1.69 to -1.1)	-1.48 (-1.78 to -1.18)	

Statistical analyses

Statistical analysis title	TNSS Day 3: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01 ^[5]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.84
upper limit	-0.11

Notes:

[5] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	TNSS Day 3: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013 ^[6]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.46

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.82
upper limit	-0.1

Notes:

[6] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	TNSS Week 1: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.569 ^[7]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.29
upper limit	0.53

Notes:

[7] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	TNSS Week 1: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.685 ^[8]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	0.5

Notes:

[8] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Secondary: Change From Baseline in Nasal Symptom Sub-Scores Assessed by the Investigator at Day 3, Week 1 and Week 2

End point title	Change From Baseline in Nasal Symptom Sub-Scores Assessed by the Investigator at Day 3, Week 1 and Week 2
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End point description:

The investigator interviewed and examined participants to evaluate for nasal symptoms of: sneezing (daily frequency of attacks; score of 0=less than 1 time to 3=11+ times), rhinorrhea (daily frequency of blowing nose; score of 0=less than 1 time to 3=11+ times), nasal congestion (score of 0=less than nasal blockage without oral breathing to 3=severe nasal blockage causing prolonged oral breathing in a

day), and nasal itching (score of 0=none to 3=nose is itchy, requiring frequent rubbing or blowing nose). Nasal symptom sub-scores could range from 0 to 3, with a higher nasal symptom sub-score indicating more frequent/severe nasal symptoms. The FAS population consisted of all participants who took at least one dose of study drug and had a baseline or at least one post-baseline assessment for nasal symptom sub-scores as assessed by the investigator.

End point type	Secondary
End point timeframe:	
Baseline and Day 3, Week 1, Week 2	

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	203	201	
Units: Score on a Scale				
least squares mean (confidence interval 95%)				
Sneezing: Change from BL at Day 3	-0.21 (-0.3 to -0.13)	-0.29 (-0.38 to -0.2)	-0.13 (-0.21 to -0.04)	
Sneezing: Change from BL at Week 1	-0.27 (-0.36 to -0.17)	-0.36 (-0.45 to -0.27)	-0.38 (-0.47 to -0.29)	
Sneezing: Change from BL at Week 2	-0.44 (-0.52 to -0.35)	-0.51 (-0.59 to -0.42)	-0.4 (-0.49 to -0.32)	
Rhinorrhea: Change from BL at Day 3	-0.37 (-0.47 to -0.28)	-0.32 (-0.41 to -0.22)	-0.24 (-0.33 to -0.15)	
Rhinorrhea: Change from BL at Week 1	-0.39 (-0.49 to -0.29)	-0.38 (-0.48 to -0.28)	-0.44 (-0.54 to -0.34)	
Rhinorrhea: Change from BL at Week 2	-0.57 (-0.67 to -0.47)	-0.53 (-0.63 to -0.43)	-0.56 (-0.66 to -0.46)	
Nasal Congestion: Change from BL at Day 3	-0.22 (-0.3 to -0.13)	-0.17 (-0.26 to -0.09)	-0.13 (-0.22 to -0.04)	
Nasal Congestion: Change from BL at Week 1	-0.28 (-0.38 to -0.18)	-0.22 (-0.32 to -0.13)	-0.32 (-0.42 to -0.23)	
Nasal Congestion: Change from BL at Week 2	-0.33 (-0.43 to -0.23)	-0.33 (-0.43 to -0.23)	-0.37 (-0.47 to -0.27)	
Nasal Itching: Change from BL at Day 3	-0.32 (-0.42 to -0.22)	-0.33 (-0.43 to -0.23)	-0.15 (-0.25 to -0.05)	
Nasal Itching: Change from BL at Week 1	-0.44 (-0.55 to -0.33)	-0.44 (-0.55 to -0.34)	-0.35 (-0.45 to -0.24)	
Nasal Itching: Change from BL at Week 2	-0.63 (-0.74 to -0.53)	-0.58 (-0.68 to -0.48)	-0.52 (-0.62 to -0.42)	

Statistical analyses

Statistical analysis title	Sneezing Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.547 ^[9]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.08

Notes:

[9] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	Sneezing Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.067 ^[10]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	0.01

Notes:

[10] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	Rhinorrhea Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.895 ^[11]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.13

Notes:

[11] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	Rhinorrhea Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo

Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.627 ^[12]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.17

Notes:

[12] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	Congestion Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.535 ^[13]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	0.18

Notes:

[13] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	Congestion Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.557 ^[14]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.18

Notes:

[14] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	Itching Week 2: Desloratadine 5 mg v. Placebo
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Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.119 ^[15]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	0.03

Notes:

[15] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	Itching Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.403 ^[16]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.08

Notes:

[16] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Secondary: Change From Baseline in Nasal Finding Score Assessed by the Investigator at Day 3, Week 1 and Week 2

End point title	Change From Baseline in Nasal Finding Score Assessed by the Investigator at Day 3, Week 1 and Week 2
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End point description:

The investigator conducted rhinoscopic examinations on participants to evaluate: swelling of inferior nasal concha mucosa (INCM) (score of 0=none to 3=middle nasal concha is not visible), coloring of inferior nasal concha mucosa (INCM) (score of 0=normal to 3=pale), and nasal discharge production (NDP) (score of 0=none to 3=congesting). The score for each nasal finding component could range from 0 to 3, with a higher score indicating more severe symptoms. The FAS population consisted of all participants who took at least one dose of study drug and had a baseline or at least one post-baseline assessment for nasal finding score.

End point type	Secondary
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End point timeframe:

Baseline and Day 3, Week 1, Week 2

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	203	201	
Units: Score on a Scale				
least squares mean (confidence interval 95%)				
Swelling of INCM: Change from BL at Day 3	-0.23 (-0.32 to -0.14)	-0.17 (-0.26 to -0.08)	-0.13 (-0.22 to -0.05)	
Swelling of INCM: Change from BL at Week 1	-0.35 (-0.44 to -0.25)	-0.31 (-0.4 to 0.21)	-0.34 (-0.43 to -0.24)	
Swelling of INCM: Change from BL at Week 2	-0.38 (-0.48 to -0.28)	-0.34 (-0.44 to -0.24)	-0.32 (-0.41 to -0.22)	
Coloring of INCM: Change from BL at Day 3	-0.27 (-0.37 to -0.16)	-0.26 (-0.36 to -0.15)	-0.26 (-0.36 to -0.15)	
Coloring of INCM: Change from BL at Week 1	-0.35 (-0.47 to -0.24)	-0.38 (-0.49 to -0.27)	-0.4 (-0.51 to 0.28)	
Coloring of INCM: Change from BL at Week 2	-0.48 (-0.6 to 0.36)	-0.48 (-0.6 to 0.37)	-0.45 (-0.57 to -0.33)	
NDP: Change from BL at Day 3	-0.23 (-0.32 to -0.14)	-0.24 (-0.32 to -0.15)	-0.18 (-0.27 to -0.09)	
NDP: Change from BL at Week 1	-0.33 (-0.42 to -0.24)	-0.36 (-0.45 to -0.26)	-0.41 (-0.5 to 0.31)	
NDP: Change from BL at Week 2	-0.41 (-0.51 to -0.32)	-0.38 (-0.48 to -0.29)	-0.44 (-0.54 to -0.35)	

Statistical analyses

Statistical analysis title	Swelling Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.376 ^[17]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.07

Notes:

[17] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	Swelling Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo

Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.714 ^[18]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.11

Notes:

[18] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	Coloring Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.725 ^[19]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.13

Notes:

[19] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	Coloring Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.708 ^[20]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.13

Notes:

[20] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	NDP Week 2: Desloratadine 5 mg v. Placebo
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Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.68 ^[21]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.16

Notes:

[21] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	NDP Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.373 ^[22]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.07
upper limit	0.19

Notes:

[22] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Secondary: Change From Baseline in Eye Symptom Score Assessed by the Investigator at Day 3, Week 1 and Week 2

End point title	Change From Baseline in Eye Symptom Score Assessed by the Investigator at Day 3, Week 1 and Week 2
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End point description:

The investigator interviewed and examined participants for eye (itching) symptoms (score of 0=none to 3=eye is itchy, requiring frequent rubbing of eye). Eye symptom scores could range from 0 to 3, with a higher score indicating greater eye itchiness. The FAS population consisted of all participants who took at least one dose of study drug and had a baseline or at least one post-baseline assessment for eye symptom score as assessed by the investigator.

End point type	Secondary
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End point timeframe:

Baseline and Day 3, Week 1, Week 2

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	203	201	
Units: Score on a Scale				
least squares mean (confidence interval 95%)				
Change from BL at Day 3	-0.17 (-0.27 to -0.08)	-0.24 (-0.34 to -0.15)	-0.13 (-0.22 to -0.04)	
Change from BL at Week 1	-0.28 (-0.38 to -0.18)	-0.35 (-0.44 to -0.25)	-0.26 (-0.36 to -0.16)	
Change from BL at Week 2	-0.38 (-0.48 to -0.28)	-0.44 (-0.54 to -0.34)	-0.37 (-0.46 to -0.27)	

Statistical analyses

Statistical analysis title	Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.849 ^[23]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.14
upper limit	0.12

Notes:

[23] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Statistical analysis title	Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.26 ^[24]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.06

Notes:

[24] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as categorical variable.

Secondary: Number of Participants With Moderate-to-Remarkable Improvement in Global Improvement Assessed by the Investigator at Day 3, Week 1 and Week 2

End point title	Number of Participants With Moderate-to-Remarkable Improvement in Global Improvement Assessed by the Investigator at Day 3, Week 1 and Week 2
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End point description:

The investigator comprehensively evaluated participants on global improvement according to 5 grades: 1=remarkably improved, 2=moderately improved, 3=slightly improved, 4=unchanged, and 5=aggravated. The number of participants who were evaluated as remarkably improved and moderately improved was calculated. The FAS population consisted of all participants who took at least one dose of study drug and had a baseline or at least one post-baseline assessment for global improvement. The FAS population consisted of all participants who took at least one dose of study drug and had a baseline or at least one post-baseline assessment for global improvement.

End point type	Secondary
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End point timeframe:

Day 3, Week 1, Week 2

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	200	203	201	
Units: Participants				
Day 3 (n=199, 201, 200)	67	61	53	
Week 1 (n=200, 203, 201)	72	83	91	
Week 2 (n=200, 203, 201)	96	93	106	

Statistical analyses

Statistical analysis title	Week 2: Desloratadine 5 mg v. Placebo
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Statistical analysis description:

Difference in the number of participants with moderate or remarkable improvement at Week 2. An odds ratio >1 is in favor of the first group of the pairwise comparison.

Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	401
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.34 ^[25]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.826
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.558
upper limit	1.223

Notes:

[25] - Logistic model with global improvement rate as response variable and treatment, age strata and severity as factors

Statistical analysis title	Week 2: Desloratadine 10 mg v. Placebo
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Statistical analysis description:

Difference in the number of participants with moderate or remarkable improvement at Week 2. An odds ratio >1 is in favor of the first group of the pairwise comparison.

Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.159 ^[26]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.755
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.116

Notes:

[26] - Logistic model with global improvement rate as response variable and treatment, age strata and severity as factors

Secondary: Change From Baseline in Score on Interference With Daily Activities Assessed by the Investigator at Day 3, Week 1 and Week 2

End point title	Change From Baseline in Score on Interference With Daily Activities Assessed by the Investigator at Day 3, Week 1 and Week 2
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End point description:

The investigator interviewed participants at Baseline, Day 3, Week 1 and Week 2 to evaluate interference with daily activities according to the following scale: 0=none, 1=nasal symptom interferes with daily activities from time to time (+), 2=between 1 and 3 (++), and 3=nasal symptom interferes with daily activity often (+++). Interference with daily activities scores could range from 0 to 3, with a higher score indicating greater interference with daily activities. The FAS population consisted of all participants who took at least one dose of study drug and had a baseline or at least one post-baseline assessment for interference with daily activities.

End point type	Secondary
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End point timeframe:

Baseline and Day 3, Week 1, Week 2

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	203	201	
Units: Score on a Scale				
least squares mean (confidence interval 95%)				
Change from BL at Day 3	-0.18 (-0.26 to -0.1)	-0.19 (-0.27 to -0.12)	-0.07 (-0.15 to 0)	
Change from BL at Week 1	-0.22 (-0.3 to -0.13)	-0.21 (-0.29 to -0.12)	-0.2 (-0.28 to -0.11)	
Change from BL at Week 2	-0.25 (-0.34 to -0.16)	-0.29 (-0.38 to -0.2)	-0.27 (-0.36 to -0.19)	

Statistical analyses

Statistical analysis title	Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.705 ^[27]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	0.14

Notes:

[27] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Statistical analysis title	Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.782 ^[28]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	0.1

Notes:

[28] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Secondary: Change From Baseline in Nasal Symptom Sub-Scores Reported in Participant Diaries at Day 3, Week 1 and Week 2

End point title	Change From Baseline in Nasal Symptom Sub-Scores Reported in Participant Diaries at Day 3, Week 1 and Week 2
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End point description:

Participants evaluated themselves in their daily allergy diaries for nasal symptoms of: sneezing (daily frequency of attacks; score of 0=less than 1 time to 3=11+ times), rhinorrhea (daily frequency of blowing nose; score of 0=less than 1 time to 3=11+ times), nasal congestion (score of 0=less than nasal blockage without oral breathing to 3=severe nasal blockage causing prolonged oral breathing in a day), and nasal itching (score of 0=none to 3=nose is itchy, requiring frequent rubbing or blowing nose). Each nasal symptom sub-score could range from 0 to 3, with a higher sub-score indicating more frequent/severe nasal symptoms. The FAS population consisted of all participants who took at least one dose of study drug and had a baseline or at least one post-baseline assessment for participant-rated nasal symptom score.

End point type	Secondary
End point timeframe:	
Baseline and Day 3, Week 1, Week 2	

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	203	201	
Units: Score on a Scale				
least squares mean (confidence interval 95%)				
Sneezing: Change from BL at Day 3	-0.27 (-0.36 to -0.18)	-0.32 (-0.41 to -0.23)	-0.23 (-0.32 to -0.13)	
Sneezing: Change from BL at Week 1	-0.38 (-0.48 to -0.29)	-0.4 (-0.49 to 0.3)	-0.3 (-0.39 to 0.2)	
Sneezing: Change from BL at Week 2	-0.43 (-0.54 to -0.32)	-0.45 (-0.55 to -0.35)	-0.33 (-0.44 to -0.23)	
Rhinorrhea: Change from BL at Day 3	-0.2 (-0.3 to 0.11)	-0.29 (-0.39 to -0.19)	-0.17 (-0.27 to -0.08)	
Rhinorrhea: Change from BL at Week 1	-0.29 (-0.39 to -0.18)	-0.36 (-0.46 to -0.26)	-0.34 (-0.44 to -0.23)	
Rhinorrhea: Change from BL at Week 2	-0.33 (-0.45 to -0.22)	-0.38 (-0.5 to 0.27)	-0.45 (-0.57 to -0.34)	
Nasal Congestion: Change from BL at Day 3	-0.18 (-0.28 to -0.09)	-0.17 (-0.27 to -0.08)	-0.18 (-0.28 to -0.09)	
Nasal Congestion: Change from BL at Week 1	-0.23 (-0.33 to -0.13)	-0.24 (-0.34 to -0.14)	-0.25 (-0.35 to -0.15)	
Nasal Congestion: Change from BL at Week 2	-0.23 (-0.34 to 0.12)	-0.26 (-0.37 to -0.15)	-0.32 (-0.43 to -0.2)	
Nasal Itching: Change from BL at Day 3	-0.29 (-0.39 to -0.19)	-0.35 (-0.45 to -0.25)	-0.22 (-0.33 to -0.12)	
Nasal Itching: Change from BL at Week 1	-0.4 (-0.51 to 0.3)	-0.42 (-0.53 to -0.32)	-0.39 (-0.5 to 0.29)	
Nasal Itching: Change from BL at Week 2	-0.52 (-0.64 to -0.4)	-0.47 (-0.59 to -0.36)	-0.44 (-0.56 to -0.33)	

Statistical analyses

Statistical analysis title	Sneezing Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.175 ^[29]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.24
upper limit	0.04

Notes:

[29] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Statistical analysis title	Sneezing Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.098 ^[30]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	0.02

Notes:

[30] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Statistical analysis title	Rhinorrhea Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.13 ^[31]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.04
upper limit	0.27

Notes:

[31] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Statistical analysis title	Rhinorrhea Week 2: Desloratadine 10 mg. v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.375 ^[32]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.07

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.08
upper limit	0.22

Notes:

[32] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Statistical analysis title	Congestion Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.285 ^[33]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.07
upper limit	0.24

Notes:

[33] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Statistical analysis title	Congestion Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.49 ^[34]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.21

Notes:

[34] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Statistical analysis title	Itching Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo

Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.345 ^[35]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.23
upper limit	0.08

Notes:

[35] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Statistical analysis title	Itching Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.699 ^[36]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.13

Notes:

[36] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Secondary: Change From Baseline in Eye Symptom Score Reported in Participant Diaries at Day 3, Week 1 and Week 2

End point title	Change From Baseline in Eye Symptom Score Reported in Participant Diaries at Day 3, Week 1 and Week 2
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End point description:

Participants evaluated themselves in their daily allergy diaries for eye (itching) symptoms (score of 0=none to 3=eye is itchy, requiring frequent rubbing of eye). Eye symptom scores could range from 0 to 3, with a higher score indicating greater eye itchiness. The FAS population consisted of all participants who took at least one dose of study drug and had a baseline or at least one post-baseline assessment for participant-rated eye symptom score.

End point type	Secondary
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End point timeframe:

Baseline and Day 3, Week 1, Week 2

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	203	201	
Units: Score on a Scale				
least squares mean (confidence interval 95%)				
Change from BL at Day 3	-0.28 (-0.38 to -0.19)	-0.25 (-0.34 to -0.15)	-0.2 (-0.3 to -0.11)	
Change from BL at Week 1	-0.31 (-0.4 to -0.21)	-0.33 (-0.43 to -0.24)	-0.26 (-0.35 to -0.16)	
Change from BL at Week 2	-0.33 (-0.44 to -0.22)	-0.35 (-0.45 to -0.24)	-0.27 (-0.38 to -0.17)	

Statistical analyses

Statistical analysis title	Week 2: Desloratadine 5 mg v. Placebo
Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.414 ^[37]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.08

Notes:

[37] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Statistical analysis title	Week 2: Desloratadine 10 mg v. Placebo
Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.281 ^[38]
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS Means
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	0.06

Notes:

[38] - Model with terms for visit, visit-by-treatment, visit-by-age strata, visit-by-severity interactions; visit treated as a categorical variable

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 2 weeks after last dose of study drug (up to 4 weeks)

Adverse event reporting additional description:

The population consisted of all participants who received at least one dose of study drug.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.1
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Reporting groups

Reporting group title	Desloratadine 5 mg
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Reporting group description:

Participants receive one desloratadine 5 mg tablet and one placebo tablet orally once daily for up to 2 weeks

Reporting group title	Desloratadine 10 mg
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Reporting group description:

Participants receive two desloratadine 5 mg tablets orally once daily for up to 2 weeks

Reporting group title	Placebo
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Reporting group description:

Participants receive two placebo tablets orally once daily for up to 2 weeks

Serious adverse events	Desloratadine 5 mg	Desloratadine 10 mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 202 (0.50%)	0 / 203 (0.00%)	0 / 201 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	1 / 202 (0.50%)	0 / 203 (0.00%)	0 / 201 (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: 5 %

Non-serious adverse events	Desloratadine 5 mg	Desloratadine 10 mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 202 (5.45%)	17 / 203 (8.37%)	9 / 201 (4.48%)
Infections and infestations			

Nasopharyngitis subjects affected / exposed occurrences (all)	11 / 202 (5.45%) 12	17 / 203 (8.37%) 17	9 / 201 (4.48%) 10
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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