Clinical trial results:
An Open-Label, Uncontrolled 4-Week Study to Assess the Safety, Efficacy and Pharmacokinetics of Allegra® (Dry Syrup Formulation) 15 mg or 30 mg Twice Daily in Pediatric Patients With Atopic Dermatitis

Summary

EudraCT number	2017-000251-74
Trial protocol	Outside EU/EEA
Global end of trial date	08 August 2011

Results information

Result version number	v1 (current)
This version publication date	19 July 2017
First version publication date	19 July 2017

Trial information

Trial identification

Sponsor protocol code	SFY10718

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01244230
WHO universal trial number (UTN)	U1111-1115-4048

Notes:

Sponsors

Sponsor organisation name	Sanofi aventis recherche & développement
Sponsor organisation address	1 avenue Pierre Brossolette, Chilly-Mazarin, France, 91380
Public contact	Trial Transparency Team, Sanofi Aventis Recherche & Developpement, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi Aventis Recherche & Developpement, Contact-US@sanofi.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	02 September 2011
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 August 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety of fexofenadine hydrochloride (HCl) (dry syrup formulation) when administered for 4 weeks at doses of 15 mg or 30 mg twice daily to pediatric subjects 6 months through 11 years of age with atopic dermatitis (AD).

Protection of trial subjects:

The study was conducted by investigators experienced in the treatment of pediatric subjects. The parent(s) or guardian(s) as well as the children were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time. In addition to the consent form for the parent(s)/guardian(s), an assent form in child-appropriate language was provided and explained to the child. Repeated invasive procedures were minimized. The number of blood samples as well as the amount of blood drawn were adjusted according to age and weight. A topical anesthesia may have been used to minimize distress and discomfort.

Background therapy:

Standard topical treatment of 0.1% hydrocortisone butyrate ointment was applied to the tested sites (except for the face and scalp) by simple application method up to 4 weeks during main treatment period (not specified in extension phase).

Evidence for comparator: -

Actual start date of recruitment	09 November 2010
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: 103
Worldwide total number of subjects	103
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)	49
Children (2-11 years)	54

Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 13 centers in Japan from 09 November 2010 to 19 May 2011.

Pre-assignment

Screening details:

Out of 115 subjects screened, 12 were screen failures, 103 subjects were enrolled and treated in this study. The study had two treatment periods: 4-weeks main treatment period and an 8-weeks extension treatment period. Subjects who completed 4-weeks main treatment period and required continuous treatment, entered the extension treatment period.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Age 6 Months to <2 Years

Arm description:

Subjects aged 6 months to <2 years, received one sachet of 15 mg fexofenadine HCl with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Fexofenadine HCl
Investigational medicinal product code	M016455
Other name	Allegra®
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

One sachet of 15 mg fexofenadine HCl with water or suspended in water or lukewarm water twice daily (in the morning and evening).

Arm title	Age 2 to <7 Years

Arm description:

Subjects aged 2 to <7 years, received one sachet of 30 mg fexofenadine HCl (if body weight >10.5 kg) or 15 mg fexofenadine HCl (if body weight <=10.5 kg) with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Fexofenadine HCl
Investigational medicinal product code	M016455
Other name	Allegra®
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

One sachet of 30 mg fexofenadine HCl or 15 mg fexofenadine HCl with water or suspended in water or lukewarm water twice daily (in the morning and evening).

Arm title	Age 7 to 11 Years

Arm description:

Subjects aged 7 to 11 years, received one sachet of 30 mg fexofenadine HCl (if body weight >10.5 kg) or 15 mg fexofenadine HCl (if body weight <=10.5 kg) with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.

Arm type	Experimental

Investigational medicinal product name	Fexofenadine HCl
Investigational medicinal product code	M016455
Other name	Allegra®
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

One sachet of 30 mg fexofenadine HCl or 15 mg fexofenadine HCl with water or suspended in water or lukewarm water twice daily (in the morning and evening).

Number of subjects in period 1	Age 6 Months to <2 Years	Age 2 to <7 Years	Age 7 to 11 Years
Started	49	31	23
Completed 4-Week Main Treatment Period	49	31	23
Entered 8-Week Extension Period	37	21	20
Completed	36	21	20
Not completed	13	10	3
Consent withdrawn by subject	1	-	-
Did not enter 8-week extension phase	12	10	3

Baseline characteristics

Reporting groups	
Reporting group title	Age 6 Months to <2 Years
Reporting group description:	
Subjects aged 6 months to <2 years, received one sachet of 15 mg fexofenadine HCl with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.	
Reporting group title	Age 2 to <7 Years
Reporting group description:	
Subjects aged 2 to <7 years, received one sachet of 30 mg fexofenadine HCl (if body weight >10.5 kg) or 15 mg fexofenadine HCl (if body weight <=10.5 kg) with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.	
Reporting group title	Age 7 to 11 Years
Reporting group description:	
Subjects aged 7 to 11 years, received one sachet of 30 mg fexofenadine HCl (if body weight >10.5 kg) or 15 mg fexofenadine HCl (if body weight <=10.5 kg) with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.	

Reporting group values	Age 6 Months to <2 Years	Age 2 to <7 Years	Age 7 to 11 Years
Number of subjects	49	31	23
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 0.5 ± 0.5	 4 ± 1.4	 8.6 ± 1.2
Gender categorical Units: Subjects			
Female	23	10	10
Male	26	21	13

Reporting group values	Total		
Number of subjects	103		
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 -	 	
Gender categorical Units: Subjects			
Female	43		
Male	60		

End points

End points reporting groups

Reporting group title	Age 6 Months to <2 Years
Reporting group description:	
Subjects aged 6 months to <2 years, received one sachet of 15 mg fexofenadine HCl with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.	
Reporting group title	Age 2 to <7 Years
Reporting group description:	
Subjects aged 2 to <7 years, received one sachet of 30 mg fexofenadine HCl (if body weight >10.5 kg) or 15 mg fexofenadine HCl (if body weight <=10.5 kg) with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.	
Reporting group title	Age 7 to 11 Years
Reporting group description:	
Subjects aged 7 to 11 years, received one sachet of 30 mg fexofenadine HCl (if body weight >10.5 kg) or 15 mg fexofenadine HCl (if body weight <=10.5 kg) with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.	

Primary: Number of Subjects With Adverse Events (AEs) up to 4 Weeks

End point title	Number of Subjects With Adverse Events (AEs) up to 4
End point description:	
AEs were any unfavorable and unintended sign, symptom, syndrome, or illness observed by the investigator or reported by the subject during the study. Analysis was performed on safety population defined as all treated subjects.	
End point type	Primary
End point timeframe:	
From first dose of study drug up to 4 weeks	

Notes:

[1] - 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	Age 6 Months to <2 Years	Age 2 to <7 Years	Age 7 to 11 Years	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	31	23	
Units: subjects	30	22	6	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities up to 4 Weeks: Safety Population

End point title	Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities up to 4 Weeks: Safety Population[2]
End point description:	
Laboratory parameters used were related to renal functions (creatinine) and liver functions (alanine transaminase, aspartate aminotransferase, bilirubin). Subjects with potentially clinically significant	

laboratory abnormalities were as determined by sponsor. Analysis was performed on safety population defined as all treated subjects.

End point type	Primary

End point timeframe:

Baseline up to 4 weeks

Notes:

[2] - 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	Age 6 Months to <2 Years	Age 2 to <7 Years	Age 7 to 11 Years	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	31	23	
Units: subjects				
Creatinine	5	0	1	
Alanine Transaminase	0	1	0	
Aspartate Aminotransferase	0	1	0	
Bilirubin	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities

End point title	Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities up to 4 Weeks: For Subjects Aged 2 to 11 Years[3][4]

End point description:

Laboratory parameters used were related to hematology (hemoglobin, hematocrit, red blood cell count, platelets count, white blood cell count), renal functions (blood urea nitrogen) and liver functions (alkaline phosphatase). Subjects with potentially clinically significant laboratory abnormalities were as determined by sponsor. Analysis was performed on a subset of safety population (defined as all treated subjects) consisted of subjects aged 2 to 11 years.

End point type	Primary

End point timeframe:

Baseline up to 4 weeks

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: As the endpoint is descriptive in nature, no statistical analysis is provided.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: For this endpoint, data was reported only for the subjects above 2 years of age.

End point values	Age 2 to <7 Years	Age 7 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	23		
Units: subjects				
Hemoglobin	1	0		
Hematocrit	10	3		

Red Blood Cell Count	0	0		
Platelets	0	0		
White Blood Cell Count	0	1		
Blood Urea Nitrogen	0	0		
Alkaline Phosphatase	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Adverse Events (AEs) up to 12 Weeks

End point title	Number of Subjects With Adverse Events (AEs) up to 12 Weeks

End point description:

AEs were any unfavorable and unintended sign, symptom, syndrome, or illness observed by the investigator or reported by the subject during the study. Analysis was performed on safety population defined as all treated subjects.

End point type	Secondary

End point timeframe:

From first dose of study drug up to 12 weeks

End point values	Age 6 Months to <2 Years	Age 2 to <7 Years	Age 7 to 11 Years	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	31	23	
Units: subjects	38	28	10	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities

End point title	Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities up to 12 Weeks: Safety Population

End point description:

Laboratory parameters used were related to renal functions (creatinine) and liver functions (alanine transaminase, aspartate aminotransferase, bilirubin). Subjects with potentially clinically significant laboratory abnormalities were as determined by sponsor. Analysis was performed on safety population defined as all treated subjects.

End point type	Secondary

End point timeframe:

Baseline up to 12 weeks

End point values	Age 6 Months to <2 Years	Age 2 to <7 Years	Age 7 to 11 Years	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	31	23	
Units: subjects				
Creatinine	9	0	1	
Alanine Transaminase	0	1	0	
Aspartate Aminotransferase	0	1	0	
Bilirubin	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities up to 12 Weeks: For Subjects Aged 2 to 11 Years

End point title	Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities up to 12 Weeks: For Subjects Aged 2 to 11 Years[5]

End point description:

Laboratory parameters used were related to hematology (hemoglobin, hematocrit, red blood cell count, platelets count, white blood cell count), renal functions (blood urea nitrogen) and liver functions (alkaline phosphatase). Subjects with potentially clinically significant laboratory abnormalities were as determined by sponsor. Analysis was performed on a subset of safety population (defined as all treated subjects) consisted of subjects aged 2 to 11 years.

End point type	Secondary

End point timeframe:

Baseline up to 12 weeks

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: For this endpoint, data was reported only for the subjects above 2 years of age.

End point values	Age 2 to <7 Years	Age 7 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	23		
Units: subjects				
Hemoglobin	1	0		
Hematocrit	10	5		
Red Blood Cell Count	0	0		
Platelets	0	0		
White Blood Cell Count	0	1		
Blood Urea Nitrogen	0	0		
Alkaline Phosphatase	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Main Itching Scores Through Week 4

End point title	Change From Baseline in Main Itching Scores Through Week 4

End point description:

The intensity of itching was assessed using itching scores on a 5-point scale ranging from 0 (hardly feels itchy) to 4 (unbearable itchiness/can hardly sleep due to itchiness). A higher score indicated worse disease status, and a negative change from baseline indicated improvement. Analysis was performed on modified intention-to-treat (mITT) population defined as all registered subjects whose main itching scores, both baseline and post treatment, were available.

End point type	Secondary

End point timeframe:

Baseline through Week 4

End point values	Age 6 Months to <2 Years	Age 2 to <7 Years	Age 7 to 11 Years	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	31	23	
Units: scores on a scale				
arithmetic mean (standard deviation)	-0.46 (± 0.55)	-0.51 (± 0.54)	-0.39 (± 0.47)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Pruritus Intensity Scores at Week 2 and Week 4

End point title	Change From Baseline in Pruritus Intensity Scores at Week 2 and Week 4

End point description:

The pruritus intensity score were assessed by the investigator or sub-investigator. The intensity of pruritus was evaluated using pruritus intensity scores on a 5-point scale, ranging from 0 (no pruritus) to 4 (severe). A higher score indicated worse disease status, and a negative change from baseline indicated improvement. Analysis was performed on mITT population defined as all registered subjects whose pruritus intensity scores both baseline and post treatment were available.

End point type	Secondary

End point timeframe:

Baseline, Week 2 and Week 4

End point values	Age 6 Months to <2 Years	Age 2 to <7 Years	Age 7 to 11 Years	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	31	23	
Units: scores on a scale				
arithmetic mean (standard deviation)				
Week 2	-0.5 (± 0.7)	-0.4 (± 0.9)	-0.5 (± 0.6)	
Week 4	-0.7 (± 0.9)	-0.8 (± 1.1)	-0.9 (± 1)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All AEs were collected from signature of the informed consent form up to the final visit (Day 89) regardless of seriousness or relationship to investigational product.

Adverse event reporting additional description:

Reported AEs are treatment-emergent adverse events that is AEs that developed/worsened during the 'on treatment period' (time from first dose of study drug up to 5 days after the last dose of study drug).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.0

Reporting groups

Reporting group title	Age 6 Months to <2 Years

Reporting group description:

Subjects aged 6 months to <2 years, received one sachet of 15 mg fexofenadine HCl with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.

Reporting group title	Age 2 to <7 Years

Reporting group description:

Subjects aged 2 to <7 years received one sachet of 30 mg fexofenadine HCl (if body weight >10.5 kg) or 15 mg fexofenadine HCl (if body weight <=10.5 kg) with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.

Reporting group title	Age 7 to 11 Years

Reporting group description:

Subjects aged 7 to 11 years received one sachet of 30 mg fexofenadine HCl (if body weight >10.5 kg) or 15 mg fexofenadine HCl (if body weight <=10.5 kg) with water or suspended in water or lukewarm water twice daily (in the morning and evening) up to 12 weeks.

Serious adverse events	Age 6 Months to <2 Years	Age 2 to <7 Years	Age 7 to 11 Years
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (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	Age 6 Months to <2 Years	Age 2 to <7 Years	Age 7 to 11 Years
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 49 (77.55%)	28 / 31 (90.32%)	10 / 23 (43.48%)
Investigations			
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 49 (0.00%)	0 / 31 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Arthropod Sting			
subjects affected / exposed	3 / 49 (6.12%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	3	0	0
Contusion			
subjects affected / exposed	1 / 49 (2.04%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	1	2	0
Face Injury			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Thermal Burn			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 49 (4.08%)	2 / 31 (6.45%)	1 / 23 (4.35%)
occurrences (all)	2	2	1
Immune system disorders			
Food Allergy			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	3 / 49 (6.12%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	4	0	0
Conjunctivitis Allergic			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
Gastrointestinal disorders			

Vomiting			
subjects affected / exposed	0 / 49 (0.00%)	4 / 31 (12.90%)	0 / 23 (0.00%)
occurrences (all)	0	4	0
Constipation			
subjects affected / exposed	2 / 49 (4.08%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	2	1	0
Diarrhoea			
subjects affected / exposed	2 / 49 (4.08%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	2	1	0
Colitis			
subjects affected / exposed	0 / 49 (0.00%)	2 / 31 (6.45%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
Aphthous Stomatitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 31 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Dental Caries			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Enterocolitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Upper Respiratory Tract Inflammation			
subjects affected / exposed	12 / 49 (24.49%)	8 / 31 (25.81%)	2 / 23 (8.70%)
occurrences (all)	15	9	2
Cough			
subjects affected / exposed	0 / 49 (0.00%)	2 / 31 (6.45%)	1 / 23 (4.35%)
occurrences (all)	0	2	1
Oropharyngeal Pain			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			

Urticaria			
subjects affected / exposed	2 / 49 (4.08%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	2	1	0
Heat Rash			
subjects affected / exposed	2 / 49 (4.08%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Dermatitis Allergic			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Dermatitis Atopic			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Dermatitis Diaper			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 49 (0.00%)	0 / 31 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Skin Exfoliation			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	18 / 49 (36.73%)	5 / 31 (16.13%)	4 / 23 (17.39%)
occurrences (all)	27	8	4
Gastroenteritis			
subjects affected / exposed	4 / 49 (8.16%)	2 / 31 (6.45%)	3 / 23 (13.04%)
occurrences (all)	4	2	3
Bronchitis			
subjects affected / exposed	5 / 49 (10.20%)	1 / 31 (3.23%)	1 / 23 (4.35%)
occurrences (all)	5	1	1
Influenza			

subjects affected / exposed	2 / 49 (4.08%)	2 / 31 (6.45%)	0 / 23 (0.00%)
occurrences (all)	2	3	0
Impetigo			
subjects affected / exposed	2 / 49 (4.08%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	3	1	0
Otitis Media			
subjects affected / exposed	2 / 49 (4.08%)	0 / 31 (0.00%)	1 / 23 (4.35%)
occurrences (all)	2	0	1
Exanthema Subitum			
subjects affected / exposed	2 / 49 (4.08%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	2 / 49 (4.08%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Herpangina			
subjects affected / exposed	2 / 49 (4.08%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Tonsillitis			
subjects affected / exposed	0 / 49 (0.00%)	2 / 31 (6.45%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
Varicella			
subjects affected / exposed	2 / 49 (4.08%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Adenoviral Conjunctivitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Erythema Infectiosum			
subjects affected / exposed	0 / 49 (0.00%)	0 / 31 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Gastroenteritis Viral			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Genital Candidiasis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Hordeolum			

subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Lice Infestation			
subjects affected / exposed	0 / 49 (0.00%)	0 / 31 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Mumps			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Oral Herpes			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Respiratory Syncytial Virus Bronchitis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 31 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Streptococcal Infection			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Vulvovaginitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 31 (3.23%)	0 / 23 (0.00%)
occurrences (all)	0	1	0

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