



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 occurrences (all) | 0 / 49 (0.00%) 0 | 0 / 31 (0.00%) 0 | 1 / 23 (4.35%) 1 |
| Injury, poisoning and procedural complications Arthropod Sting subjects affected / exposed occurrences (all) Contusion subjects affected / exposed occurrences (all) Face Injury subjects affected / exposed occurrences (all) Thermal Burn subjects affected / exposed occurrences (all) | 3 / 49 (6.12%) 3 1 / 49 (2.04%) 1 1 / 49 (2.04%) 1 1 / 49 (2.04%) 1 | 0 / 31 (0.00%) 0 1 / 31 (3.23%) 2 0 / 31 (0.00%) 0 0 / 31 (0.00%) 0 | 0 / 23 (0.00%) 0 0 / 23 (0.00%) 0 0 / 23 (0.00%) 0 0 / 23 (0.00%) 0 |
| General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all) | 2 / 49 (4.08%) 2 | 2 / 31 (6.45%) 2 | 1 / 23 (4.35%) 1 |
| Immune system disorders Food Allergy subjects affected / exposed occurrences (all) | 1 / 49 (2.04%) 1 | 0 / 31 (0.00%) 0 | 0 / 23 (0.00%) 0 |
| Eye disorders Conjunctivitis subjects affected / exposed occurrences (all) Conjunctivitis Allergic subjects affected / exposed occurrences (all) | 3 / 49 (6.12%) 4 0 / 49 (0.00%) 0 | 0 / 31 (0.00%) 0 1 / 31 (3.23%) 1 | 0 / 23 (0.00%) 0 1 / 23 (4.35%) 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