



Clinical trial results:

A Phase III, Open-Label Clinical Trial to Study the Safety and Pharmacokinetics of MK-0476 in Japanese Pediatric Subjects Aged 1 to 15 Years Old with Perennial Allergic Rhinitis

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2014-004871-22 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 24 December 2013 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 (current) |
| This version publication date | 13 April 2016 |
| First version publication date | 15 July 2015 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | 0476-520 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|------------------------------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01852812 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | MK-0476-520: Merck protocol number |

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 | 24 December 2013 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 24 December 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 24 December 2013 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

This study will evaluate the safety and pharmacokinetics of montelukast (MK-0476) in the treatment of Japanese pediatric participants with perennial allergic rhinitis (PAR). The primary hypothesis of this study is that montelukast oral granules (OG) and chewable tablets (CT) provide appropriate exposure to montelukast in Japanese pediatric participants with PAR.

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 | 07 June 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: 87 |
| Worldwide total number of subjects | 87 |
| 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) | 81 |
| Adolescents (12-17 years) | 6 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Japanese participants aged 1 to 15 years who had perennial allergic rhinitis (PAR) were screened for this study.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Blinding implementation details:

No blinding was used in this open-label study.

Arms

| | |
|------------------------------|-----------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Montelukast 4 mg OG/1-5 year olds |

Arm description:

Participants receive montelukast 4 mg oral granules (OG) in one sachet orally (PO) once daily (QD) at bed time for 4 weeks with an option to continue for an additional 8 weeks (12 weeks total)

| | |
|----------------------------------------|---------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Montelukast Oral Granules |
| Investigational medicinal product code | |
| Other name | MK-0475 |
| Pharmaceutical forms | Granules in sachet |
| Routes of administration | Oral use |

Dosage and administration details:

Montelukast 4 mg oral granules in one sachet once daily at bedtime for up to 12 weeks

| | |
|------------------|-----------------------------------|
| Arm title | Montelukast 5 mg CT/6-9 year olds |
|------------------|-----------------------------------|

Arm description:

Participants receive montelukast 5 mg chewable tablets (CT) in one tablet PO QD at bed time for 12 weeks

| | |
|----------------------------------------|------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Montelukast Chewable Tablets |
| Investigational medicinal product code | |
| Other name | MK-0476 |
| Pharmaceutical forms | Chewable tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Montelukast 5 mg chewable tablets once daily at bedtime for up to 12 weeks

| | |
|------------------|-------------------------------------|
| Arm title | Montelukast 5 mg CT/10-15 year olds |
|------------------|-------------------------------------|

Arm description:

Participants receive montelukast 5 mg CT in one tablet PO QD at bed time for 12 weeks

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|----------------------------------------|------------------------------|
| Investigational medicinal product name | Montelukast Chewable Tablets |
| Investigational medicinal product code | |
| Other name | MK-0476 |
| Pharmaceutical forms | Chewable tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Montelukast 5 mg chewable tablets once daily at bedtime for up to 12 weeks

| Number of subjects in period 1 | Montelukast 4 mg OG/1-5 year olds | Montelukast 5 mg CT/6-9 year olds | Montelukast 5 mg CT/10-15 year olds |
|---------------------------------------|--------------------------------------|--------------------------------------|----------------------------------------|
| Started | 51 | 18 | 18 |
| Completed | 51 | 17 | 17 |
| Not completed | 0 | 1 | 1 |
| Adverse event, non-fatal | - | - | 1 |
| Non-compliance with study drug | - | 1 | - |

Baseline characteristics

Reporting groups

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Reporting group title | Montelukast 4 mg OG/1-5 year olds |
| Reporting group description: Participants receive montelukast 4 mg oral granules (OG) in one sachet orally (PO) once daily (QD) at bed time for 4 weeks with an option to continue for an additional 8 weeks (12 weeks total) | |
| Reporting group title | Montelukast 5 mg CT/6-9 year olds |
| Reporting group description: Participants receive montelukast 5 mg chewable tablets (CT) in one tablet PO QD at bed time for 12 weeks | |
| Reporting group title | Montelukast 5 mg CT/10-15 year olds |
| Reporting group description: Participants receive montelukast 5 mg CT in one tablet PO QD at bed time for 12 weeks | |

| Reporting group values | Montelukast 4 mg OG/1-5 year olds | Montelukast 5 mg CT/6-9 year olds | Montelukast 5 mg CT/10-15 year olds |
|----------------------------------------------------|-----------------------------------|-----------------------------------|-------------------------------------|
| Number of subjects | 51 | 18 | 18 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 51 | 18 | 12 |
| Adolescents (12-17 years) | 0 | 0 | 6 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous Units: Years | | | |
| arithmetic mean | 3.6 | 7.8 | 11.3 |
| standard deviation | ± 1.4 | ± 1.3 | ± 1 |
| Gender, Male/Female Units: Participants | | | |
| Female | 24 | 8 | 5 |
| Male | 27 | 10 | 13 |

| Reporting group values | Total | | |
|----------------------------------------------------|-------|--|--|
| Number of subjects | 87 | | |
| Age categorical Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | | |
| Newborns (0-27 days) | 0 | | |
| Infants and toddlers (28 days-23 months) | 0 | | |
| Children (2-11 years) | 81 | | |

| | | | |
|-------------------------------------------------------------------------|----|--|--|
| Adolescents (12-17 years) | 6 | | |
| Adults (18-64 years) | 0 | | |
| From 65-84 years | 0 | | |
| 85 years and over | 0 | | |
| Age Continuous Units: Years arithmetic mean standard deviation | - | | |
| Gender, Male/Female Units: Participants | | | |
| Female | 37 | | |
| Male | 50 | | |

Subject analysis sets

| | |
|----------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Subject analysis set title | Montelukast 5 mg CT/6-15 year olds |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Participants receive montelukast 5 mg CT in one tablet PO QD at bed time for 12 weeks | |

| Reporting group values | Montelukast 5 mg CT/6-15 year olds | | |
|-------------------------------------------------------------------------|------------------------------------|--|--|
| Number of subjects | 36 | | |
| Age categorical Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | | |
| Newborns (0-27 days) | 0 | | |
| Infants and toddlers (28 days-23 months) | 0 | | |
| Children (2-11 years) | 30 | | |
| Adolescents (12-17 years) | 6 | | |
| Adults (18-64 years) | 0 | | |
| From 65-84 years | 0 | | |
| 85 years and over | 0 | | |
| Age Continuous Units: Years arithmetic mean standard deviation | ± | | |
| Gender, Male/Female Units: Participants | | | |
| Female | | | |
| Male | | | |

End points

End points reporting groups

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Reporting group title | Montelukast 4 mg OG/1-5 year olds |
| Reporting group description: Participants receive montelukast 4 mg oral granules (OG) in one sachet orally (PO) once daily (QD) at bed time for 4 weeks with an option to continue for an additional 8 weeks (12 weeks total) | |
| Reporting group title | Montelukast 5 mg CT/6-9 year olds |
| Reporting group description: Participants receive montelukast 5 mg chewable tablets (CT) in one tablet PO QD at bed time for 12 weeks | |
| Reporting group title | Montelukast 5 mg CT/10-15 year olds |
| Reporting group description: Participants receive montelukast 5 mg CT in one tablet PO QD at bed time for 12 weeks | |
| Subject analysis set title | Montelukast 5 mg CT/6-15 year olds |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Participants receive montelukast 5 mg CT in one tablet PO QD at bed time for 12 weeks | |

Primary: Percentage of Participants Who Experience at Least One Adverse Event (AE)

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants Who Experience at Least One Adverse Event (AE) ^{[1][2]} |
| End point description: An AE is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of study drug or protocol-specified procedure, whether or not considered related to the study drug or protocol-specified procedure. Any worsening of a pre-existing condition that is temporally associated with the use of study drug is also an AE. Participants were monitored for the occurrence of AEs for up to 14 days after last dose of study drug (up to a total of 14 weeks). AEs were reported based on the dose of study drug participants received. | |
| End point type | Primary |
| End point timeframe: Up to 14 days after last dose of study drug (Up to 14 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: No statistical analyses were planned for this end point.

[2] - 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: Safety data from the two montelukast 5 mg CT groups (6-9 year olds and 10-15 year olds) were pooled for safety analyses.

| End point values | Montelukast 4 mg OG/1-5 year olds | Montelukast 5 mg CT/6-15 year olds | | |
|-----------------------------------|-----------------------------------|------------------------------------|--|--|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 51 ^[3] | 36 ^[4] | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 74.5 | 55.6 | | |

Notes:

[3] - All randomized participants who received ≥ 1 dose of study drug.

[4] - All randomized participants who received ≥ 1 dose of study drug.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Who Discontinue Study Drug Due to an AE

| | |
|-----------------|--------------------------------------------------------------------------------------|
| End point title | Percentage of Participants Who Discontinue Study Drug Due to an AE ^{[5][6]} |
|-----------------|--------------------------------------------------------------------------------------|

End point description:

An AE is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of study drug or protocol-specified procedure, whether or not considered related to the study drug or protocol-specified procedure. Any worsening of a pre-existing condition that is temporally associated with the use of study drug is also an AE. Discontinuations due to an AE were reported based on the dose of study drug participants received.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to 12 weeks

Notes:

[5] - 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 analyses were planned for this end point.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Safety data from the two montelukast 5 mg CT groups (6-9 year olds and 10-15 year olds) were pooled for safety analyses.

| End point values | Montelukast 4 mg OG/1-5 year olds | Montelukast 5 mg CT/6-15 year olds | | |
|-----------------------------------|-----------------------------------|------------------------------------|--|--|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 51 ^[7] | 36 ^[8] | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 0 | 2.8 | | |

Notes:

[7] - All randomized participants who received ≥ 1 dose of study drug.

[8] - All randomized participants who received ≥ 1 dose of study drug.

Statistical analyses

No statistical analyses for this end point

Primary: Area Under the Time-Concentration Curve (AUC 0- ∞) of Montelukast CT and Montelukast OG

| | |
|-----------------|----------------------------------------------------------------------------------------------------------------|
| End point title | Area Under the Time-Concentration Curve (AUC 0- ∞) of Montelukast CT and Montelukast OG ^[9] |
|-----------------|----------------------------------------------------------------------------------------------------------------|

End point description:

Blood samples for pharmacokinetic (PK) assessments were collected at either 1 hour (h) or 3 h post-dose on Day 1 and at either 14 h or 22 h post-dose on Day 28.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to Day 28 after first dose of study drug

Notes:

[9] - 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 analyses were planned for this end point.

| End point values | Montelukast 4 mg OG/1-5 year olds | Montelukast 5 mg CT/6-9 year olds | Montelukast 5 mg CT/10-15 year olds | |
|--------------------------------------|-----------------------------------|-----------------------------------|-------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 51 ^[10] | 18 ^[11] | 18 ^[12] | |
| Units: h*ng/mL | | | | |
| arithmetic mean (standard deviation) | 4300 (± 890) | 4350 (± 760) | 3500 (± 620) | |

Notes:

[10] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol violations.

[11] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol violations.

[12] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol violations.

Statistical analyses

No statistical analyses for this end point

Primary: Maximum Plasma Concentration (Cmax) of Montelukast CT and Montelukast OG

| | |
|-----------------|------------------------------------------------------------------------------------------|
| End point title | Maximum Plasma Concentration (Cmax) of Montelukast CT and Montelukast OG ^[13] |
|-----------------|------------------------------------------------------------------------------------------|

End point description:

Blood samples for PK assessments were collected at either 1 h or 3 h post-dose on Day 1 and at either 14 h or 22 h post-dose on Day 28.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to Day 28 after first dose of study drug

Notes:

[13] - 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 analyses were planned for this end point.

| End point values | Montelukast 4 mg OG/1-5 year olds | Montelukast 5 mg CT/6-9 year olds | Montelukast 5 mg CT/10-15 year olds | |
|--------------------------------------|-----------------------------------|-----------------------------------|-------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 51 ^[14] | 18 ^[15] | 18 ^[16] | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 510 (± 84) | 438 (± 82) | 344 (± 61) | |

Notes:

[14] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol violations.

[15] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol violations.

[16] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol violations.

Statistical analyses

No statistical analyses for this end point

Primary: Time to Cmax (Tmax) of Montelukast CT and Montelukast OG

| | |
|-----------------|-------------------------------------------------------|
| End point title | Time to Cmax (Tmax) of Montelukast CT and Montelukast |
|-----------------|-------------------------------------------------------|

End point description:

Blood samples for PK assessments were collected at either 1 h or 3 h post-dose on Day 1 and at either

14 h or 22 h post-dose on Day 28.

| | |
|---------------------------------------------|---------|
| End point type | Primary |
| End point timeframe: | |
| Up to Day 28 after first dose of study drug | |

Notes:

[17] - 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 analyses were planned for this end point.

| End point values | Montelukast 4 mg OG/1-5 year olds | Montelukast 5 mg CT/6-9 year olds | Montelukast 5 mg CT/10-15 year olds | |
|--------------------------------------|-----------------------------------|-----------------------------------|-------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 51 ^[18] | 18 ^[19] | 18 ^[20] | |
| Units: Hours | | | | |
| arithmetic mean (standard deviation) | 2.74 (± 0.6) | 3.55 (± 0.71) | 3.65 (± 0.6) | |

Notes:

[18] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol violations.

[19] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol violations.

[20] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol violations.

Statistical analyses

No statistical analyses for this end point

Primary: Apparent Elimination Half-life (t_{1/2}) of Montelukast CT and Montelukast OG

| | |
|-----------------|---------------------------------------------------------------------------------------------------------|
| End point title | Apparent Elimination Half-life (t _{1/2}) of Montelukast CT and Montelukast OG ^[21] |
|-----------------|---------------------------------------------------------------------------------------------------------|

End point description:

Blood samples for PK assessments were collected at either 1 h or 3 h post-dose on Day 1 and at either 14 h or 22 h post-dose on Day 28.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to Day 28 after first dose of study drug

Notes:

[21] - 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 analyses were planned for this end point.

| End point values | Montelukast 4 mg OG/1-5 year olds | Montelukast 5 mg CT/6-9 year olds | Montelukast 5 mg CT/10-15 year olds | |
|--------------------------------------|-----------------------------------|-----------------------------------|-------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 51 ^[22] | 18 ^[23] | 18 ^[24] | |
| Units: Hours | | | | |
| arithmetic mean (standard deviation) | 1.27 (± 0.56) | 2.01 (± 0.75) | 2.08 (± 0.66) | |

Notes:

[22] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol violations.

[23] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol violations.

[24] - All participants who received ≥1 dose of study drug, had ≥1 PK assessment & no protocol

violations.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 14 days after last dose of study drug (Up to 14 weeks)

Adverse event reporting additional description:

The safety population consisted of all participants who received at least one dose of study drug. AEs were reported based on the dose of study drug participants received. Data from the two montelukast 5 mg CT groups (6-9 year olds and 10-15 year olds) were pooled for safety analyses.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 16.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------------------------------|
| Reporting group title | Montelukast 5 mg CT/6-15 year olds |
|-----------------------|------------------------------------|

Reporting group description:

Participants receive montelukast 5 mg CT in one tablet PO QD at bed time for 12 weeks

| | |
|-----------------------|-----------------------------------|
| Reporting group title | Montelukast 4 mg OG/1-5 year olds |
|-----------------------|-----------------------------------|

Reporting group description:

Participants receive montelukast 4 mg OG in one sachet PO QD at bed time for 4 weeks with an option to continue for an additional 8 weeks (12 weeks total)

| Serious adverse events | Montelukast 5 mg CT/6-15 year olds | Montelukast 4 mg OG/1-5 year olds | |
|---------------------------------------------------|------------------------------------|-----------------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 36 (0.00%) | 0 / 51 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | Montelukast 5 mg CT/6-15 year olds | Montelukast 4 mg OG/1-5 year olds | |
|-------------------------------------------------------|------------------------------------|-----------------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 18 / 36 (50.00%) | 37 / 51 (72.55%) | |
| Injury, poisoning and procedural complications | | | |
| Arthropod sting | | | |
| subjects affected / exposed | 2 / 36 (5.56%) | 2 / 51 (3.92%) | |
| occurrences (all) | 4 | 2 | |
| Gastrointestinal disorders | | | |

| | | | |
|------------------------------------------------------------------------------------------------------------------|------------------------|------------------------|--|
| Diarrhoea subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 4 / 51 (7.84%) 4 | |
| Respiratory, thoracic and mediastinal disorders Epistaxis subjects affected / exposed occurrences (all) | 2 / 36 (5.56%) 2 | 0 / 51 (0.00%) 0 | |
| Skin and subcutaneous tissue disorders Miliaria subjects affected / exposed occurrences (all) | 2 / 36 (5.56%) 2 | 0 / 51 (0.00%) 0 | |
| Infections and infestations Acute sinusitis subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 6 / 51 (11.76%) 8 | |
| Bronchitis subjects affected / exposed occurrences (all) | 3 / 36 (8.33%) 3 | 3 / 51 (5.88%) 4 | |
| Gastroenteritis subjects affected / exposed occurrences (all) | 1 / 36 (2.78%) 1 | 3 / 51 (5.88%) 3 | |
| Hand-foot-and-mouth disease subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 3 / 51 (5.88%) 3 | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 12 / 36 (33.33%) 15 | 22 / 51 (43.14%) 32 | |
| Otitis media subjects affected / exposed occurrences (all) | 1 / 36 (2.78%) 1 | 4 / 51 (7.84%) 4 | |
| Otitis media acute subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 3 / 51 (5.88%) 4 | |
| Pharyngitis subjects affected / exposed occurrences (all) | 3 / 36 (8.33%) 4 | 9 / 51 (17.65%) 14 | |

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