



Clinical trial results:

A Randomized, Double-Blind, Parallel Group study of ADVAIR™ DISKUS™ 100/50 and FLOVENT™DISKUS™ 100, both twice daily, in a Pediatric Population during the Fall Viral Season.

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2015-004887-13 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 16 December 2010 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 25 January 2017 |
| First version publication date | 25 January 2017 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 113872 |
|-----------------------|--------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | GlaxoSmithKline |
| Sponsor organisation address | 980 Great West Road, Brentford, Middlesex, United Kingdom, |
| Public contact | GSK Response Center, GlaxoSmithKline, 1 866-435-7343, |
| Scientific contact | GSK Response Center, GlaxoSmithKline, 1 866-435-7343, |

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 | 13 April 2011 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 16 December 2010 |
| Global end of trial reached? | Yes |
| Global end of trial date | 16 December 2010 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

TBD

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

| | |
|---|----------------|
| Actual start date of recruitment | 02 August 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 | United States: 339 |
| Worldwide total number of subjects | 339 |
| 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) | 339 |
| 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: -

Pre-assignment

Screening details:

A total of 339 participants were treated. Two hundred and ninety-two participants completed the 16-week study and 47 withdrew.

Period 1

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

Arms

| | |
|------------------------------|---------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | FSC DISKUS 100/50 mcg BID |

Arm description:

Fluticasone Propionate/Salmeterol DISKUS Combination Product (FSC) at a dose of 100/50 micrograms (mcg) administered as one inhalation twice daily (BID) for 16 weeks

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Fluticasone propionate + salmeterol combination (FSC) 100/50 mcg DISKUS |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Inhalation powder |
| Routes of administration | Inhalation use |

Dosage and administration details:

FSC was administered at a dose of 100/50 mcg as one inhalation twice daily (BID) for 16 weeks

| | |
|------------------|-----------------------|
| Arm title | FP DISKUS 100 mcg BID |
|------------------|-----------------------|

Arm description:

Fluticasone Propionate (FP) DISKUS 100 mcg administered as one inhalation BID for 16 weeks

| | |
|--|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Fluticasone propionate (FP) 100mcg DISKUS |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Inhalation powder |
| Routes of administration | Inhalation use |

Dosage and administration details:

FP 100 mcg was administered as one inhalation BID for 16 weeks

| Number of subjects in period 1 | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID |
|---------------------------------------|--------------------------------------|----------------------------------|
| Started | 171 | 168 |
| Completed | 147 | 145 |
| Not completed | 24 | 23 |
| Consent withdrawn by subject | 6 | 10 |
| Physician decision | 2 | 4 |
| Adverse event, non-fatal | 2 | 1 |
| Lost to follow-up | 3 | 3 |
| Protocol deviation | 10 | 3 |
| Lack of efficacy | 1 | 2 |

Baseline characteristics

Reporting groups

| | |
|---|---------------------------|
| Reporting group title | FSC DISKUS 100/50 mcg BID |
| Reporting group description: Fluticasone Propionate/Salmeterol DISKUS Combination Product (FSC) at a dose of 100/50 micrograms (mcg) administered as one inhalation twice daily (BID) for 16 weeks | |
| Reporting group title | FP DISKUS 100 mcg BID |
| Reporting group description: Fluticasone Propionate (FP) DISKUS 100 mcg administered as one inhalation BID for 16 weeks | |

| Reporting group values | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID | Total |
|------------------------|---------------------------|-----------------------|-------|
| Number of subjects | 171 | 168 | 339 |
| Age categorical | | | |
| Units: Subjects | | | |

| | | | |
|---|--------|--------|-----|
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 7.5 | 7.4 | |
| standard deviation | ± 2.11 | ± 2.08 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 63 | 56 | 119 |
| Male | 108 | 112 | 220 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| African American/African Heritage | 27 | 33 | 60 |
| American Indian or Alaska Native | 2 | 0 | 2 |
| Asian | 8 | 6 | 14 |
| American Indian or Alaska Native and White | 1 | 0 | 1 |
| White | 129 | 127 | 256 |
| African American/African Heritage and White | 1 | 1 | 2 |
| Asian & Native Hawaiian or Other Pacific Islander | 1 | 0 | 1 |
| Asian and White | 2 | 0 | 2 |
| Native Hawaiian or Other Pacific Islander & White | 0 | 1 | 1 |

End points

End points reporting groups

| | |
|---|---------------------------|
| Reporting group title | FSC DISKUS 100/50 mcg BID |
| Reporting group description: Fluticasone Propionate/Salmeterol DISKUS Combination Product (FSC) at a dose of 100/50 micrograms (mcg) administered as one inhalation twice daily (BID) for 16 weeks | |
| Reporting group title | FP DISKUS 100 mcg BID |
| Reporting group description: Fluticasone Propionate (FP) DISKUS 100 mcg administered as one inhalation BID for 16 weeks | |

Primary: Total number of asthma exacerbations reported during the treatment period

| | |
|--|---|
| End point title | Total number of asthma exacerbations reported during the treatment period |
| End point description: An asthma exacerbation was defined as deterioration of asthma that required the use of outpatient oral/parenteral corticosteroids (tablets, suspensions, or injection) or an urgent care, hospitalization, or emergency room (ER) visit due to asthma that required oral/parenteral corticosteroids. Two exacerbations (out of a total of 51) were excluded: (1) one exacerbation occurred within 7 days of the resolution of an earlier one, and, per protocol, was combined with the previous exacerbation; and (2) one exacerbation occurred post treatment. Intent-to-Treat (ITT) Population: all participants randomized to treatment. Only those participants who reported ≥ 1 exacerbation were analyzed. | |
| End point type | Primary |
| End point timeframe: From Baseline (Week 1) until the end of treatment (up to Week 16) | |

| End point values | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID | | |
|---------------------------------------|---------------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 21 ^[1] | 20 ^[2] | | |
| Units: Number of asthma exacerbations | 24 | 25 | | |

Notes:

[1] - ITT Population

[2] - ITT Population

Statistical analyses

| | |
|--|---|
| Statistical analysis title | Statistical analysis 1 |
| Statistical analysis description: The risk of having an asthma exacerbation during the treatment period was analyzed. | |
| Comparison groups | FP DISKUS 100 mcg BID v FSC DISKUS 100/50 mcg BID |

| | |
|---|------------------------|
| Number of subjects included in analysis | 41 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.928 ^[3] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.971 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.519 |
| upper limit | 1.819 |

Notes:

[3] - Cox Proportional Hazards model adjusted for investigative center

Secondary: Mean asthma symptom scores, as an indicator of severity, associated with the presence of moderate or severe upper respiratory tract symptoms (URTS) or a confirmed rhinovirus (RV) infection at Baseline and during the Peak Viral Period

| | |
|-----------------|---|
| End point title | Mean asthma symptom scores, as an indicator of severity, associated with the presence of moderate or severe upper respiratory tract symptoms (URTS) or a confirmed rhinovirus (RV) infection at Baseline and during the Peak Viral Period |
|-----------------|---|

End point description:

Participants recorded their asthma symptom score over the previous 24 hours (during the day and the previous night) using the following 6-point scale: 0=No symptoms; 1=Symptoms for 1 short period; 2=Symptoms for ≥ 2 short periods; 3=Symptoms for most of the day/previous night that did not affect normal daily activities; 4=Symptoms for most of the day/previous night that affected normal daily activities; 5=Symptoms so severe that participant could not perform normal daily activities. The Baseline mean asthma symptom score was calculated as the average score over 7 days prior to Week 1, Visit 2.

ITT Population. Only those participants with moderate or severe URTS or a confirmed RV infection were analyzed.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline (Week 1) and Peak Viral Period ([period during which the greatest number of viral infections is expected] from 30 August 2010 through the end of the treatment period [up to Week 16])

| End point values | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID | | |
|--------------------------------------|---------------------------------|--------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 106 ^[4] | 104 ^[5] | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline, n=105, 104 | 0.2 (\pm 0.41) | 0.2 (\pm 0.39) | | |
| Peak Viral Period, n=106, 104 | 0.5 (\pm 0.84) | 0.4 (\pm 0.7) | | |

Notes:

[4] - ITT Population

[5] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean duration of worsening asthma symptoms associated with the presence of moderate or severe URTS or a confirmed RV infection

| | |
|-----------------|--|
| End point title | Mean duration of worsening asthma symptoms associated with the presence of moderate or severe URTS or a confirmed RV infection |
|-----------------|--|

End point description:

A worsening asthma day is one on which any of the following occurred: rescue albuterol use above baseline, use of oral/parenteral corticosteroids for asthma, use of asthma medication other than study medication, asthma symptom scores ≥ 3 , nighttime awakenings, unscheduled health care visits, or missed school due to asthma. The duration of worsening asthma is the number of consecutive worsening asthma days after the date of a URTS score of 2 (moderate) or 3 (severe) or collection of a mucus sample containing RV (whichever occurred first). Each span of consecutive days is a participant interval.

ITT Population. Only those participants with relevant data defining a worsening asthma day during the peak viral period and with moderate or severe URTS or a confirmed RV infection were analyzed.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Peak Viral Period (from 30 August 2010 through the end of treatment [up to Week 16])

| End point values | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID | | |
|--------------------------------------|---------------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 121 ^[6] | 145 ^[7] | | |
| Units: Days per participant interval | | | | |
| arithmetic mean (standard error) | 4.1 (\pm 0.18) | 4 (\pm 0.17) | | |

Notes:

[6] - ITT Population

[7] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of asthma exacerbations associated with the presence of moderate or severe URTS or a confirmed RV infection during the Peak Viral Period

| | |
|-----------------|---|
| End point title | Number of asthma exacerbations associated with the presence of moderate or severe URTS or a confirmed RV infection during the Peak Viral Period |
|-----------------|---|

End point description:

Each participant (with assistance from the parent/legal guardian as needed) was instructed to keep an electronic diary (eDiary) with record of daily URTS symptoms that included: runny nose, sneezing, nasal congestion, and sore throat. Based on the best-described aggregate URTS during the previous 24 hours, participants rated symptoms as: 0 = Not present; 1 = Mild, clearly present; 2 = Moderately severe, uncomfortable; and 3 = Severe, interfering with sleep or activity. Mucus samples were collected and analyzed for RV when the eDiary alerted for moderate/severe URTS.

ITT Population. Only those participants who reported ≥ 1 exacerbation were analyzed. Only those participants with moderate or severe URTS or a confirmed RV infection were analyzed.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Peak Viral Period (from 30 August 2010 through the end of treatment [up to Week 16])

| End point values | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID | | |
|---------------------------------------|---------------------------------|--------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 5 ^[8] | 7 ^[9] | | |
| Units: Number of asthma exacerbations | 5 | 7 | | |

Notes:

[8] - ITT Population

[9] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage of asthma-control days

| | |
|-----------------|--|
| End point title | Mean percentage of asthma-control days |
|-----------------|--|

End point description:

An asthma-control day was defined as a day without any of the following: rescue albuterol use, use of oral/parenteral corticosteroids for asthma, use of asthma medication other than double-blind study treatment, asthma symptom score >0, nighttime awakenings due to asthma, unscheduled health care visits (defined as home visits, office visits, or urgent care visits), ER visits, hospitalizations for asthma, or school absenteeism due to asthma. The percentage of asthma-control days = the number (No.) of asthma-control days divided by the No. of days of treatment exposure, multiplied by 100.

ITT Population. Only those participants who recorded data during the Peak Viral Period, had a treatment stop date with a defined Peak Viral Period, and had available data on all days on which data were recorded were analyzed.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Peak Viral Period (from 30 August 2010 through the end of treatment [up to Week 16])

| End point values | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID | | |
|----------------------------------|---------------------------------|--------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 161 ^[10] | 156 ^[11] | | |
| Units: Percentage of days | | | | |
| arithmetic mean (standard error) | 48.3 (± 1.51) | 49.7 (± 1.54) | | |

Notes:

[10] - ITT Population

[11] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage of episode-free (EF) days

| | |
|-----------------|---|
| End point title | Mean percentage of episode-free (EF) days |
|-----------------|---|

End point description:

An EF day was defined as a day without any of the following: rescue albuterol use, use of oral/parenteral corticosteroids for asthma, use of asthma medication other than study treatment, asthma symptom score >0, nighttime awakenings due to asthma, unscheduled health care visits (defined as home visits, office visits, or urgent care visits), ER visits, hospitalizations for asthma, school absenteeism due to asthma, or morning peak expiratory flow (measure of maximum airflow) <80% of baseline. Percentage of EF days=No. of EF days divided by No. of days of treatment exposure, multiplied by 100.

ITT Population. Only those participants who recorded data during the Peak Viral Period, had a treatment stop date with a defined Peak Viral Period, and had available data on all days on which data were recorded were analyzed.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Peak Viral Period (from 30 August 2010 through the end of treatment [up to Week 16])

| End point values | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID | | |
|----------------------------------|---------------------------------|--------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 161 ^[12] | 155 ^[13] | | |
| Units: Percentage of days | | | | |
| arithmetic mean (standard error) | 42.4 (± 1.55) | 44.5 (± 1.61) | | |

Notes:

[12] - ITT Population

[13] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage of symptom-free days

| | |
|-----------------|--------------------------------------|
| End point title | Mean percentage of symptom-free days |
|-----------------|--------------------------------------|

End point description:

A symptom-free day was defined as a day during the Peak Viral Period on which the asthma symptom score was zero. The daily asthma symptom score (measured during the day and the previous night) was reported on a 6-point scale (ranging from 0=no symptoms to 5=severe symptoms). Percentage of symptom-free days was defined as the number of days during the Peak Viral Period on which the asthma symptom score=0, divided by the number of days in that same period on which non-missing values were recorded, multiplied by 100.

ITT Population. Only those participants who recorded data during the Peak Viral Period and had a treatment stop date with a defined Peak Viral Period were analyzed.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Peak Viral Period (from 30 August 2010 through the end of treatment [up to Week 16])

| End point values | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID | | |
|--------------------------------------|---------------------------------|--------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 161 ^[14] | 157 ^[15] | | |
| Units: Percentage of days | | | | |
| arithmetic mean (standard deviation) | 90.1 (± 15.89) | 91.1 (± 13.18) | | |

Notes:

[14] - ITT Population

[15] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage of rescue-free days

| | |
|-----------------|-------------------------------------|
| End point title | Mean percentage of rescue-free days |
|-----------------|-------------------------------------|

End point description:

A rescue-free day was defined as a day during the Peak Viral Period on which no puffs of rescue medication were recorded. Percentage of rescue-free days was defined as the number of days during the Peak Viral Period on which no puffs of rescue medication were recorded, divided by the number of days in that same period on which non-missing values were recorded, multiplied by 100.

ITT Population. Only those participants who recorded data during the Peak Viral Period and had a treatment stop date with a defined Peak Viral Period were analyzed.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Peak Viral Period (from 30 August 2010 through the end of treatment [up to Week 16])

| End point values | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID | | |
|--------------------------------------|---------------------------------|--------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 161 ^[16] | 157 ^[17] | | |
| Units: Percentage of days | | | | |
| arithmetic mean (standard deviation) | 92.1 (± 16.6) | 91.7 (± 14.68) | | |

Notes:

[16] - ITT Population

[17] - ITT Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Participants attended a total of 6 clinic visits (Baseline/Randomization, Weeks 1, 4, 8, 12, and 16) and received one follow-up phone call 7 days after the last clinic visit to assess for adverse events (AEs).

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 13.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------------------------|
| Reporting group title | FSC DISKUS 100/50 mcg BID |
|-----------------------|---------------------------|

Reporting group description:

FSC at a dose of 100/50 mcg administered as one inhalation BID for 16 weeks

| | |
|-----------------------|-----------------------|
| Reporting group title | FP DISKUS 100 mcg BID |
|-----------------------|-----------------------|

Reporting group description:

FP DISKUS 100 mcg administered as one inhalation BID for 16 weeks

| Serious adverse events | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID | |
|---|---------------------------|-----------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 171 (1.17%) | 1 / 168 (0.60%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Nervous system disorders | | | |
| Syncope | | | |
| subjects affected / exposed | 0 / 171 (0.00%) | 1 / 168 (0.60%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Respiratory distress | | | |
| subjects affected / exposed | 1 / 171 (0.58%) | 0 / 168 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status asthmaticus | | | |
| subjects affected / exposed | 1 / 171 (0.58%) | 0 / 168 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |

| | | | |
|---|-----------------|-----------------|--|
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 171 (0.58%) | 0 / 168 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia respiratory syncytialviral | | | |
| subjects affected / exposed | 1 / 171 (0.58%) | 0 / 168 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | FSC DISKUS 100/50 mcg BID | FP DISKUS 100 mcg BID | |
|---|---------------------------|-----------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 93 / 171 (54.39%) | 94 / 168 (55.95%) | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 25 / 171 (14.62%) | 28 / 168 (16.67%) | |
| occurrences (all) | 36 | 50 | |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 20 / 171 (11.70%) | 16 / 168 (9.52%) | |
| occurrences (all) | 25 | 22 | |
| Gastrointestinal disorders | | | |
| Vomiting | | | |
| subjects affected / exposed | 9 / 171 (5.26%) | 6 / 168 (3.57%) | |
| occurrences (all) | 10 | 6 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 26 / 171 (15.20%) | 21 / 168 (12.50%) | |
| occurrences (all) | 35 | 25 | |
| Nasal congestion | | | |
| subjects affected / exposed | 15 / 171 (8.77%) | 13 / 168 (7.74%) | |
| occurrences (all) | 17 | 15 | |
| Oropharyngeal pain | | | |

| | | | |
|--|------------------------|------------------------|--|
| subjects affected / exposed occurrences (all) | 14 / 171 (8.19%) 15 | 12 / 168 (7.14%) 15 | |
| Infections and infestations | | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 29 / 171 (16.96%) | 31 / 168 (18.45%) | |
| occurrences (all) | 35 | 41 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 15 / 171 (8.77%) | 20 / 168 (11.90%) | |
| occurrences (all) | 18 | 29 | |
| Sinusitis | | | |
| subjects affected / exposed | 11 / 171 (6.43%) | 3 / 168 (1.79%) | |
| occurrences (all) | 12 | 3 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 7 / 171 (4.09%) | 9 / 168 (5.36%) | |
| occurrences (all) | 8 | 17 | |
| Otitis media | | | |
| subjects affected / exposed | 3 / 171 (1.75%) | 9 / 168 (5.36%) | |
| occurrences (all) | 5 | 11 | |

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