



Clinical trial results:

A Multicenter, Randomized, Double-Blind, Parallel Group, 52-Week Comparison of Asthma Control and Measures of Airway Inflammation in Subjects of African Descent Receiving Fluticasone Propionate/Salmeterol 100/50mcg DISKUS® BID or Fluticasone Propionate 100mcg DISKUS® BID Alone

Summary

EudraCT number	2015-004864-12
Trial protocol	Outside EU/EEA
Global end of trial date	12 April 2007

Results information

Result version number	v1 (current)
This version publication date	25 September 2016
First version publication date	25 September 2016

Trial information

Trial identification

Sponsor protocol code	SFA103153
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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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	11 July 2007
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	12 April 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to demonstrate that fluticasone propionate/ salmeterol 100/50mcg DISKUS BID (FSC 100/50) was superior to fluticasone propionate 100mcg DISKUS BID (FP 100) in controlling the asthma exacerbation rate in subjects of African descent with persistent asthma.

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 November 2004
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: 523
Worldwide total number of subjects	523
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	114
Adults (18-64 years)	409
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants with persistent asthma, who were symptomatic while taking an inhaled corticosteroid (ICS) were entered a 2-week screening period. Participants completed the open-label Fluticasone propionate (FP) 250 microgram (mcg) run-in period were eligible to enter the double-blind treatment period.

Pre-assignment

Screening details:

A total of 865 participants were enrolled, of these, 342 were screen failures and 523 entered the Run-in period. Total 48 participants were run-in failures and 475 completed the Run-in period. Total 475 participants who were randomized into the study and received treatment were included in the Intent-to-Treat (ITT) Population.

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	Fluticasone propionate/salmeterol 100/50 mcg

Arm description:

Participants self administered one inhalation of Fluticasone propionate/salmeterol 100/50 mcg via dry powder inhaler (DPI) twice daily, morning and evening 12 hours apart for 52 weeks treatment period. Participants were provided albuterol inhalation aerosol for relief of asthma symptoms.

Arm type	Experimental
Investigational medicinal product name	FSC 100/50 mcg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Inhalation use

Dosage and administration details:

Participants self administered one inhalation twice daily, approximately 12 hours apart, in morning and evening via dry powder inhaler for the treatment duration of 52 weeks.

Arm title	Fluticasone propionate 100 mcg
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Arm description:

Participants self administered one inhalation of Fluticasone propionate (FP) 100 mcg via DPI twice daily, morning and evening 12 hours apart for 52 weeks treatment period. Participants were provided albuterol inhalation aerosol for relief of asthma symptoms.

Arm type	Experimental
Investigational medicinal product name	FP 100 mcg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Inhalation use

Dosage and administration details:

Participants self administered one inhalation twice daily, approximately 12 hours apart, in morning and evening via dry powder inhaler for the treatment duration of 52 weeks.

Number of subjects in period 1[1]	Fluticasone propionate/salmeterol 100/50 mcg	Fluticasone propionate 100 mcg
Started	239	236
Completed	169	151
Not completed	70	85
Lack of Efficacy	1	1
Dropped by GSK	-	1
Consent withdrawn by subject	16	18
Too many days between visits	-	1
Adverse event, non-fatal	5	6
Exacerbation	6	9
No Medicines taken	1	-
Non-compliance	10	19
Moving out of the Area	1	-
Lost to follow-up	19	13
Subject Withdrew Consent Due to Moving	-	1
Elective Surgery	1	-
Pregnancy	6	5
Moved out of the state	1	1
Protocol deviation	3	10

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: A total of 523 participants entered the Run-in period; however, 48 participants were run-in failures so only 475 participants completed the Run-in period and were randomized into the study.

Baseline characteristics

Reporting groups

Reporting group title	Fluticasone propionate/salmeterol 100/50 mcg
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Reporting group description:

Participants self administered one inhalation of Fluticasone propionate/salmeterol 100/50 mcg via dry powder inhaler (DPI) twice daily, morning and evening 12 hours apart for 52 weeks treatment period. Participants were provided albuterol inhalation aerosol for relief of asthma symptoms.

Reporting group title	Fluticasone propionate 100 mcg
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Reporting group description:

Participants self administered one inhalation of Fluticasone propionate (FP) 100 mcg via DPI twice daily, morning and evening 12 hours apart for 52 weeks treatment period. Participants were provided albuterol inhalation aerosol for relief of asthma symptoms.

Reporting group values	Fluticasone propionate/salmeterol 100/50 mcg	Fluticasone propionate 100 mcg	Total
Number of subjects	239	236	475
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	31.5 ± 13.48	32.2 ± 13.57	-
Gender categorical Units: Subjects			
Female	143	150	293
Male	96	86	182
Race, Customized Units: Subjects			
African American/African Heritage	233	231	464
Mixed race	6	5	11

End points

End points reporting groups

Reporting group title	Fluticasone propionate/salmeterol 100/50 mcg
Reporting group description: Participants self administered one inhalation of Fluticasone propionate/salmeterol 100/50 mcg via dry powder inhaler (DPI) twice daily, morning and evening 12 hours apart for 52 weeks treatment period. Participants were provided albuterol inhalation aerosol for relief of asthma symptoms.	
Reporting group title	Fluticasone propionate 100 mcg
Reporting group description: Participants self administered one inhalation of Fluticasone propionate (FP) 100 mcg via DPI twice daily, morning and evening 12 hours apart for 52 weeks treatment period. Participants were provided albuterol inhalation aerosol for relief of asthma symptoms.	

Primary: Asthma exacerbation rate per patient per year

End point title	Asthma exacerbation rate per patient per year
End point description:	
End point type	Primary
End point timeframe: From Baseline (Week 0) up to Week 52	

End point values	Fluticasone propionate/salmeterol 100/50 mcg	Fluticasone propionate 100 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	239 ^[1]	236 ^[2]		
Units: Rate of exacerbations per year				
arithmetic mean (standard error)	0.449 (± 0.0926)	0.529 (± 0.0916)		

Notes:

[1] - ITT Population comprised of all participants randomized to study drug

[2] - ITT Population comprised of all participants randomized to study drug

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Fluticasone propionate/salmeterol 100/50 mcg v Fluticasone propionate 100 mcg
Number of subjects included in analysis	475
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.169
Method	Poisson regression

Secondary: Mean change from baseline morning (AM) peak expiratory flow (PEF)

End point title	Mean change from baseline morning (AM) peak expiratory flow (PEF)
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End point description:

PEF is defined as the maximum airflow during a forced expiration beginning with the lungs fully inflated. PEF was measured by the participants using a hand-held electronic peak flow meter each morning prior to the dose of study medication. The best of three measurements was recorded. Change from Baseline was calculated as the value of the averaged daily AM PEF over the 52-week Treatment Period minus the Baseline value. Baseline values (Week 0) were derived from pre-treatment measurements. Baseline was defined as the mean value over the day of randomization plus the six preceeding days. Statistical analysis was performed using an analysis of covariance (ANCOVA) model. Participants analyzed included those who have PEF data.

End point type	Secondary
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End point timeframe:

From Baseline (Week 0) up to Week 52

End point values	Fluticasone propionate/salmeterol 100/50 mcg	Fluticasone propionate 100 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	221 ^[3]	216 ^[4]		
Units: Liter/minute				
arithmetic mean (standard error)	15.6 (± 3.48)	1.4 (± 3.42)		

Notes:

[3] - ITT Population. Participants analyzed included those who have PEF data.

[4] - ITT Population. Participants analyzed included those who have PEF data.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Fluticasone propionate/salmeterol 100/50 mcg v Fluticasone propionate 100 mcg
Number of subjects included in analysis	437
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	15.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.5
upper limit	24.7
Variability estimate	Standard error of the mean
Dispersion value	4.89

Secondary: Mean change from baseline in morning pre-dose clinic forced expiratory volume in one second (FEV1)

End point title	Mean change from baseline in morning pre-dose clinic forced expiratory volume in one second (FEV1)
End point description:	
FEV1 is defined as the volume of air forcefully expelled from the lungs in 1 second. FEV1 was measured each morning prior to the dose of study medication by spirometry. Change from Baseline was calculated as the value of the averaged daily FEV1 over the 52-week Treatment Period minus the Baseline value. Baseline values (Week 0) were derived from pre-treatment measurements. Statistical analysis was performed using ANCOVA model. Participants analyzed included those who have FEV1 data.	
End point type	Secondary
End point timeframe:	
From Baseline (Week 0) up to Week 52	

End point values	Fluticasone propionate/salmeterol 100/50 mcg	Fluticasone propionate 100 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	233 ^[5]	226 ^[6]		
Units: Liter				
arithmetic mean (standard error)	0.045 (± 0.0234)	-0.061 (± 0.0211)		

Notes:

[5] - ITT Population. Participants analyzed included those who have FEV1 data.

[6] - ITT Population. Participants analyzed included those who have FEV1 data.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Fluticasone propionate 100 mcg v Fluticasone propionate/salmeterol 100/50 mcg
Number of subjects included in analysis	459
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.001
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.103
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.041
upper limit	0.165
Variability estimate	Standard error of the mean
Dispersion value	0.0317

Secondary: Mean change from baseline in symptom-free days

End point title	Mean change from baseline in symptom-free days
End point description:	
Symptom-free days are number of days that a participant goes without asthma symptoms over the 52-week Treatment Period. Percent change from Baseline was calculated as the value of the averaged daily	

Symptom-free days over the 52-week Treatment Period minus the Baseline value multiplied by 100. Baseline values (Week 0) were derived from pre-treatment measurements. Statistical analysis was performed using ANCOVA model. Participants analyzed included those who have Symptom-free days data.

End point type	Secondary
End point timeframe:	
From Baseline (Week 0) up to Week 52	

End point values	Fluticasone propionate/salmeterol 100/50 mcg	Fluticasone propionate 100 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	218 ^[7]	214 ^[8]		
Units: Days				
arithmetic mean (standard error)	10.8 (± 2.46)	8.9 (± 2.21)		

Notes:

[7] - ITT Population. Participants analyzed included those who have Symptom-free days data.

[8] - ITT Population. Participants analyzed included those who have Symptom-free days data.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Fluticasone propionate/salmeterol 100/50 mcg v Fluticasone propionate 100 mcg
Number of subjects included in analysis	432
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.296
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	9.6
Variability estimate	Standard error of the mean
Dispersion value	3.2

Secondary: Mean change from baseline in albuterol-free days

End point title	Mean change from baseline in albuterol-free days
End point description:	
Albuterol-free days were days when Albuterol use was unnecessary based on daily record and symptom free days. Percent change from Baseline was calculated as the value of the averaged daily albuterol-free days over the 52-week Treatment Period minus the Baseline value multiplied by 100. Baseline values (Week 0) were derived from pre-treatment measurements. Statistical analysis was performed using ANCOVA model. Participants analyzed included those who have albuterol-free days data.	
End point type	Secondary

End point timeframe:

From Baseline (Week 0) up to Week 52

End point values	Fluticasone propionate/salmeterol 100/50 mcg	Fluticasone propionate 100 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216 ^[9]	211 ^[10]		
Units: Days				
arithmetic mean (standard error)	10.8 (± 2.5)	5.6 (± 2.54)		

Notes:

[9] - ITT Population. Participants analyzed included those who have albuterol-free days data.

[10] - ITT Population. Participants analyzed included those who have albuterol-free days data.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Fluticasone propionate/salmeterol 100/50 mcg v Fluticasone propionate 100 mcg
Number of subjects included in analysis	427
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.159
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	10.9
Variability estimate	Standard error of the mean
Dispersion value	3.22

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On-treatment serious adverse events (SAEs) and non-serious adverse events (AEs) were collected from start of IP (Week 0) until Week 52 for double blind treatment period.

Adverse event reporting additional description:

On-treatment SAEs and non-serious AEs are reported for ITT Population, comprised of all participants who were randomized to treatment and who received at least one dose of study medication.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10.0
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Reporting groups

Reporting group title	Fluticasone propionate/salmeterol 100/50 mcg
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Reporting group description:

Participants self administered one inhalation of Fluticasone propionate/salmeterol 100/50 mcg via dry powder inhaler (DPI) twice daily, morning and evening 12 hours apart for 52 weeks treatment period. Participants were provided albuterol inhalation aerosol for relief of asthma symptoms.

Reporting group title	Fluticasone propionate 100 mcg
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Reporting group description:

Participants self administered one inhalation of Fluticasone propionate (FP) 100 mcg via DPI twice daily, morning and evening 12 hours apart for 52 weeks treatment period. Participants were provided albuterol inhalation aerosol for relief of asthma symptoms.

Serious adverse events	Fluticasone propionate/salmeterol 100/50 mcg	Fluticasone propionate 100 mcg	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 239 (2.51%)	11 / 236 (4.66%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ligament rupture			
subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	1 / 239 (0.42%)	0 / 236 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Arteriospasm coronary			
subjects affected / exposed	1 / 239 (0.42%)	0 / 236 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			
subjects affected / exposed	1 / 239 (0.42%)	0 / 236 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Migraine			
subjects affected / exposed	1 / 239 (0.42%)	0 / 236 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			

subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Sarcoidosis			
subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
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	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	2 / 239 (0.84%)	2 / 236 (0.85%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Arthritis infective			
subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			

subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	1 / 239 (0.42%)	0 / 236 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetes mellitus non-insulin-dependent			
subjects affected / exposed	0 / 239 (0.00%)	1 / 236 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Fluticasone propionate/salmeterol 100/50 mcg	Fluticasone propionate 100 mcg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	118 / 239 (49.37%)	130 / 236 (55.08%)	
Nervous system disorders			
Headache			
subjects affected / exposed	34 / 239 (14.23%)	41 / 236 (17.37%)	
occurrences (all)	192	144	
Sinus headache			
subjects affected / exposed	5 / 239 (2.09%)	8 / 236 (3.39%)	
occurrences (all)	6	14	
General disorders and administration site conditions			
Pain			
subjects affected / exposed	4 / 239 (1.67%)	9 / 236 (3.81%)	
occurrences (all)	7	9	
Gastrointestinal disorders			
Toothache			
subjects affected / exposed	13 / 239 (5.44%)	8 / 236 (3.39%)	
occurrences (all)	20	11	
Abdominal pain upper			

subjects affected / exposed occurrences (all)	12 / 239 (5.02%) 16	7 / 236 (2.97%) 14	
Nausea subjects affected / exposed occurrences (all)	9 / 239 (3.77%) 10	7 / 236 (2.97%) 7	
Respiratory, thoracic and mediastinal disorders			
Pharyngolaryngeal pain subjects affected / exposed occurrences (all)	20 / 239 (8.37%) 25	17 / 236 (7.20%) 28	
Cough subjects affected / exposed occurrences (all)	15 / 239 (6.28%) 19	17 / 236 (7.20%) 27	
Rhinitis allergic subjects affected / exposed occurrences (all)	10 / 239 (4.18%) 32	2 / 236 (0.85%) 3	
Sinus congestion subjects affected / exposed occurrences (all)	7 / 239 (2.93%) 13	9 / 236 (3.81%) 14	
Nasal congestion subjects affected / exposed occurrences (all)	9 / 239 (3.77%) 11	6 / 236 (2.54%) 6	
Musculoskeletal and connective tissue disorders			
Back pain subjects affected / exposed occurrences (all)	11 / 239 (4.60%) 20	21 / 236 (8.90%) 25	
Arthralgia subjects affected / exposed occurrences (all)	10 / 239 (4.18%) 12	6 / 236 (2.54%) 8	
Neck pain subjects affected / exposed occurrences (all)	3 / 239 (1.26%) 3	8 / 236 (3.39%) 10	
Myalgia subjects affected / exposed occurrences (all)	9 / 239 (3.77%) 9	3 / 236 (1.27%) 3	
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	18 / 239 (7.53%)	41 / 236 (17.37%)	
occurrences (all)	33	53	
Upper respiratory tract infection			
subjects affected / exposed	32 / 239 (13.39%)	32 / 236 (13.56%)	
occurrences (all)	42	44	
Sinusitis			
subjects affected / exposed	17 / 239 (7.11%)	27 / 236 (11.44%)	
occurrences (all)	22	32	
Bronchitis			
subjects affected / exposed	6 / 239 (2.51%)	12 / 236 (5.08%)	
occurrences (all)	7	12	
Influenza			
subjects affected / exposed	9 / 239 (3.77%)	4 / 236 (1.69%)	
occurrences (all)	12	4	
Gastroenteritis viral			
subjects affected / exposed	6 / 239 (2.51%)	9 / 236 (3.81%)	
occurrences (all)	6	9	

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