Clinical trial results:
A Multi-Center, Double-Blind, Parallel-Group Study to Evaluate Short-term Safety and Efficacy and Long-Term Maintenance of Two Dose Levels of Rabeprazole Sodium Delayed-Release Pediatric Bead Formulation in 1- to 11-Year Old Pediatric Subjects With Endoscopically Proven GERD

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2008-004837-54
Trial protocol	DK BE FR NL IT BG
Global end of trial date	25 January 2011

Results information

Result version number	v2 (current)
This version publication date	15 July 2016
First version publication date	01 August 2015
Version creation reason	• Correction of full data set Review of data

Trial information

Trial identification

Sponsor protocol code	RABGRD3003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00787891
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Johnson & Johnson Pharmaceutical Research & Development, LLC
Sponsor organisation address	920 US Route 202 , Raritan, New Jersey 08869-0602, United States,
Public contact	Janssen Research & Development, Clinical Registry Group, ClinicalTrialsEU@its.jnj.com
Scientific contact	Janssen Research & Development, Clinical Registry Group, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000055-PIP01-07
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	25 January 2011
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 January 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this study were to evaluate the efficacy (endoscopic/histological healing) and safety of 2 dose levels (0.5 milligram per kilogram (mg/kg) [10 mg max dose] and 1.0 mg/kg [20 mg max dose]) of a pediatric bead formulation of rabeprazole sodium (which can be administered orally mixed with food as needed) in a 12-week, parallel-group, double-blind design followed by a long-term safety and efficacy assessment in a 24-week, double-blind maintenance treatment phase in subjects, 1 to11 years of age, with endoscopically proven Gastroesophageal Reflux Disease (GERD).

Protection of trial subjects:

An Independent Data Safety Monitoring Board (DSMB) was commissioned for the study as well as for the whole pediatric program, and monitored serious adverse events (SAEs), subject withdrawals, and other safety data. Safety variables included adverse events (AEs), clinical laboratory tests, and urinalysis, vital sign measurements (Oral or tympanic temperature, pulse and respiration rate, diastolic and systolic blood pressure measurement), physical examinations (including body weight and height), and Tanner Staging.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 January 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	Denmark: 4
Country: Number of subjects enrolled	France: 5
Country: Number of subjects enrolled	India: 3
Country: Number of subjects enrolled	Israel: 10
Country: Number of subjects enrolled	Italy: 3
Country: Number of subjects enrolled	Poland: 16
Country: Number of subjects enrolled	United States: 74
Country: Number of subjects enrolled	South Africa: 7
Worldwide total number of subjects	127
EEA total number of subjects	33

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)	14
Children (2-11 years)	113
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:

In the study, 127 subjects were enrolled at 30 sites from 8 countries.

Pre-assignment

Screening details:

In the study, 108 subjects completed the 12-week phase (Part 1) and were counted for the primary outcome measure (OM). Subjects with healing at Week 12 had the option to continue the treatment for 24 weeks. Among the 87 with healing, 64 enrolled into Part 2. Only 52 had the primary efficacy endpoint available and were included in the primary OM

Period 1

Period 1 title	Short-term Double-blind Phase (Part 1)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Rabeprazole Sodium 0.5 mg/kg

Arm description:

Pediatric micro-bead formulation of rabeprazole sodium orally administered.

Arm type	Experimental
Investigational medicinal product name	Rabeprazole sodium
Investigational medicinal product code	R128546
Other name	
Pharmaceutical forms	Granules for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Pediatric micro-bead formulation of rabeprazole sodium 0.5 mg/kg orally administered.

Arm title	Rabeprazole Sodium 1.0 mg/kg

Arm description:

Pediatric micro-bead formulation of rabeprazole sodium orally administered.

Arm type	Experimental
Investigational medicinal product name	Rabeprazole sodium
Investigational medicinal product code	R128546
Other name	
Pharmaceutical forms	Granules for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Pediatric micro-bead formulation of rabeprazole sodium 1.0 mg/kg orally administered.

Number of subjects in period 1	Rabeprazole Sodium 0.5 mg/kg	Rabeprazole Sodium 1.0 mg/kg
Started	65	62
Completed	55	53
Not completed	10	9
Physician decision	1	-
Consent withdrawn by subject	6	2
Other	-	2
Adverse event	1	2
Lost to follow-up	2	2
Protocol deviation	-	1

Period 2

Period 2 title	Maintenance Double-blind Phase (Part 2)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	No
Arm title	Rabeprazole Sodium 0.5 mg/kg

Arm description:

Pediatric micro-bead formulation of rabeprazole sodium orally administered.

Arm type	Experimental
Investigational medicinal product name	Rabeprazole sodium
Investigational medicinal product code	R128546
Other name	
Pharmaceutical forms	Granules for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Pediatric micro-bead formulation of rabeprazole sodium 0.5 mg/kg orally administered.

Arm title	Rabeprazole Sodium 1.0 mg/kg

Arm description:

Pediatric micro-bead formulation of rabeprazole sodium orally administered.

Arm type	Experimental
Investigational medicinal product name	Rabeprazole sodium
Investigational medicinal product code	R128546
Other name	
Pharmaceutical forms	Granules for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Pediatric micro-bead formulation of rabeprazole sodium 1.0 mg/kg orally administered.

Number of subjects in period 2	Rabeprazole Sodium 0.5 mg/kg	Rabeprazole Sodium 1.0 mg/kg
Started	33	31
Completed	26	24
Not completed	7	7
Consent withdrawn by subject	1	3
Other	5	2
Adverse event	-	1
Noncompliance with study drug	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Rabeprazole Sodium 0.5 mg/kg
Reporting group description:	
Pediatric micro-bead formulation of rabeprazole sodium orally administered.	
Reporting group title	Rabeprazole Sodium 1.0 mg/kg
Reporting group description:	
Pediatric micro-bead formulation of rabeprazole sodium orally administered.	

Reporting group values	Rabeprazole Sodium 0.5 mg/kg	Rabeprazole Sodium 1.0 mg/kg	Total
Number of subjects	65	62	127
Title for AgeCategorical			
Units: subjects			
infants and toddlers(28 days-23 months)	5	9	14
Children (2-11 years)	60	53	113
Title for AgeContinuous			
Units: years			
arithmetic mean	5.9	5.4	
standard deviation	± 3.49	± 3.26	-
Title for Gender			
Units: subjects			
Female	31	25	56
Male	34	37	71

End points

End points reporting groups

Reporting group title	Rabeprazole Sodium 0.5 mg/kg
Reporting group description:	
Pediatric micro-bead formulation of rabeprazole sodium orally administered.	
Reporting group title	Rabeprazole Sodium 1.0 mg/kg
Reporting group description:	
Pediatric micro-bead formulation of rabeprazole sodium orally administered.	
Reporting group title	Rabeprazole Sodium 0.5 mg/kg
Reporting group description:	
Pediatric micro-bead formulation of rabeprazole sodium orally administered.	
Reporting group title	Rabeprazole Sodium 1.0 mg/kg
Reporting group description:	
Pediatric micro-bead formulation of rabeprazole sodium orally administered.	

Primary: The Percentage of Participants With Healing by Week 12 (Short-term Double-blind Treatment Phase)

End point title	The Percentage of Participants With Healing by Week 12 (Short-term Double-blind Treatment Phase)[1]
End point description:	
Healing is defined as macroscopically normal esophageal mucosa or histologic normal esophageal mucosa. ITT (Intent-to-treat) analysis set included all participants randomized into the study and who had at least 1 postbaseline efficacy measurement.	
End point type	Primary
End point timeframe:	
12 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: Descriptive statistics were done, no inferential statistical analyses were performed

End point values	Rabeprazole Sodium 0.5 mg/kg	Rabeprazole Sodium 1.0 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55	53		
Units: percentage of participants				
number (confidence interval 95%)	78 (67 to 89)	83 (73 to 93)		

Statistical analyses

No statistical analyses for this end point

Primary: The Percentage of Participants With Healing by Week 36 (Double-blind Maintenance Treatment Phase)

End point title	The Percentage of Participants With Healing by Week 36 (Double-blind Maintenance Treatment Phase)[2]

End point description:

Healing is defined as macroscopically normal esophageal mucosa or histologic normal esophageal mucosa. ITT analysis set included all participants randomized into the study and who had at least 1 postbaseline efficacy measurement.

End point type	Primary

End point timeframe:

36 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: Descriptive statistics were done, no inferential statistical analyses were performed

End point values	Rabeprazole Sodium 0.5 mg/kg	Rabeprazole Sodium 1.0 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	26		
Units: percentage of participants				
number (confidence interval 95%)	92 (82 to 100)	88 (76 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: The Change From Baseline in the Hetzel and Dent Endoscopic Classification Grade Score (Short-term Double-blind Treatment Phase)

End point title	The Change From Baseline in the Hetzel and Dent Endoscopic Classification Grade Score (Short-term Double-blind Treatment Phase)

End point description:

The Hetzel and Dent Classification grades range from 0 (normal esophageal mucosa, no abnormalities noted) to 4 (deep ulcers anywhere in the esophagus or ulceration of more than half of the esophageal mucosa). Higher observed scores indicate more serious condition. For change of baseline, a score of 0 indicates no change; a positive score indicates the condition is worsening, while a negative score indicates an improvement. ITT analysis set included all participants randomized into the study and who had at least 1 postbaseline efficacy measurement.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Rabeprazole Sodium 0.5 mg/kg	Rabeprazole Sodium 1.0 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55	53		
Units: scores on a scale				
arithmetic mean (standard deviation)	-1.3 (± 0.85)	-1 (± 0.81)		

Statistical analyses

No statistical analyses for this end point

Secondary: The Change From Baseline in the Total Gastroesophageal Reflux Disease (GERD) Symptom and Severity Score (Short-term Double-blind Treatment Phase)

End point title	The Change From Baseline in the Total Gastroesophageal Reflux Disease (GERD) Symptom and Severity Score (Short-term Double-blind Treatment Phase)

End point description:

The GERD symptom and severity scale measures the frequency (0= Never; 1= 1-2 times; 2= 3-4 times; 3= 5-6 times; 4= 7 or more times) and the severity (1= Mild; 2= Moderate; 3=Severe) of GERD symptoms. The score is defined as the sum of the frequency (0-4) and severity (1-3) of that symptom. The total score is the sum of the scores of all the symptoms and ranges from 12 to 84. Higher scores indicate more serious condition. For change from baseline, 0 indicates no change; a positive score indicates worsening and negative score indicates improvement. ITT analysis set included all participants randomized into the study and who had at least 1 postbaseline efficacy measurement.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Rabeprazole Sodium 0.5 mg/kg	Rabeprazole Sodium 1.0 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	59		
Units: scores on a scale				
arithmetic mean (standard deviation)	-11.5 (± 11.7)	-8.5 (± 9.75)		

Statistical analyses

No statistical analyses for this end point

Secondary: The Change From Baseline in the Hetzel and Dent Endoscopic Classification Grade Score (Double-blind Maintenance Treatment Phase)

End point title	The Change From Baseline in the Hetzel and Dent Endoscopic Classification Grade Score (Double-blind Maintenance Treatment Phase)

End point description:

The Hetzel and Dent Classification grades range from 0 (normal esophageal mucosa, no abnormalities noted) to 4 (deep ulcers anywhere in the esophagus or ulceration of more than half of the esophageal mucosa). Higher observed scores indicate more serious condition. For change of baseline, a score of 0 indicates no change; a positive score indicates the condition is worsening and a negative score indicates an improvement. ITT analysis set included all participants randomized into the study and who had at least 1 postbaseline efficacy measurement.

End point type	Secondary

End point timeframe:

Baseline, Week 36

End point values	Rabeprazole Sodium 0.5 mg/kg	Rabeprazole Sodium 1.0 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	26		
Units: scores on a scale				
arithmetic mean (standard deviation)	0.2 (± 0.49)	0.2 (± 0.54)		

Statistical analyses

No statistical analyses for this end point

Secondary: The Change From Baseline in the Total Gastroesophageal Reflux Disease (GERD) Symptom and Severity Score (Double-blind Maintenance Treatment Phase)

End point title	The Change From Baseline in the Total Gastroesophageal Reflux Disease (GERD) Symptom and Severity Score (Double-blind Maintenance Treatment Phase)

End point description:

The GERD symptom and severity scale measures the frequency (0= Never; 1= 1-2 times; 2= 3-4 times; 3= 5-6 times; 4= 7 or more times) and the severity (1= Mild; 2= Moderate; 3=Severe) of GERD symptoms. The score is defined as the sum of the frequency (0-4) and severity (1-3) of that symptom. The total score is the sum of the scores of all the symptoms and ranges from 12 to 84. Higher scores indicate more serious condition. For change from baseline, 0 indicates no change; a positive score indicates worsening and a negative score indicates improvement. ITT analysis set included all participants randomized into the study and who had at least 1 postbaseline efficacy measurement.

End point type	Secondary

End point timeframe:

Baseline, Week 36

End point values	Rabeprazole Sodium 0.5 mg/kg	Rabeprazole Sodium 1.0 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	29		
Units: scores on a scale				
arithmetic mean (standard deviation)	-2.9 (± 4.82)	-1.4 (± 9.59)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Up to 30 days after the last dose of study drug	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	12.0

Reporting groups	
Reporting group title	Rabeprazole Sodium 0.5 mg/kg (Short-term Double-blind Phase)
Reporting group description: Pediatric micro-bead formulation of rabeprazole sodium orally administered.	
Reporting group title	Rabeprazole Sodium 1.0 mg/kg (Short-term Double-blind Phase)
Reporting group description: Pediatric micro-bead formulation of rabeprazole sodium orally administered.	
Reporting group title	Rabeprazole Sodium 1.0 mg/kg (Double-blind Maintenance Phase)
Reporting group description: Pediatric micro-bead formulation of rabeprazole sodium orally administered.	
Reporting group title	Rabeprazole Sodium 0.5 mg/kg (Double-blind Maintenance Phase)
Reporting group description: Pediatric micro-bead formulation of rabeprazole sodium orally administered.	

Serious adverse events	Rabeprazole Sodium 0.5 mg/kg (Short-term Double-blind Phase)	Rabeprazole Sodium 1.0 mg/kg (Short-term Double-blind Phase)	Rabeprazole Sodium 1.0 mg/kg (Double-blind Maintenance Phase)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 65 (7.69%)	1 / 62 (1.61%)	3 / 31 (9.68%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head Injury			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (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

Nervous system disorders			
Partial Seizures with Secondary Generalisation			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Conversion Disorder			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (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
Bronchopneumonia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Infection			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (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
Pneumonia			

subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (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

Serious adverse events	Rabeprazole Sodium 0.5 mg/kg (Double-blind Maintenance Phase)		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 33 (6.06%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head Injury			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Humerus Fracture			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Partial Seizures with Secondary Generalisation			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			

Conversion Disorder			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal Infection			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Rabeprazole Sodium 0.5 mg/kg (Short-term Double-blind Phase)	Rabeprazole Sodium 1.0 mg/kg (Short-term Double-blind Phase)	Rabeprazole Sodium 1.0 mg/kg (Double-blind Maintenance Phase)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	47 / 65 (72.31%)	47 / 62 (75.81%)	21 / 31 (67.74%)
Surgical and medical procedures			
Suture Insertion			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Tooth Extraction			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Chills			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Influenza Like Illness			
subjects affected / exposed	1 / 65 (1.54%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	2	1	0
Pyrexia			
subjects affected / exposed	8 / 65 (12.31%)	5 / 62 (8.06%)	3 / 31 (9.68%)
occurrences (all)	9	9	3
Immune system disorders			
Atopy			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Social circumstances			

Menarche			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Breast Mass			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Adenoidal Hypertrophy			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Asthma			
subjects affected / exposed	0 / 65 (0.00%)	2 / 62 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Asthma Exercise Induced			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Bronchial Hyperreactivity			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Choking			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Cough			
subjects affected / exposed	9 / 65 (13.85%)	9 / 62 (14.52%)	0 / 31 (0.00%)
occurrences (all)	10	11	0
Dysphonia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Epistaxis			

subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Hyperventilation			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Increased Upper Airway Secretion			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Nasal Congestion			
subjects affected / exposed	4 / 65 (6.15%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	6	1	0
Oropharyngeal Pain			
subjects affected / exposed	2 / 65 (3.08%)	6 / 62 (9.68%)	2 / 31 (6.45%)
occurrences (all)	2	8	2
Pharyngeal Erythema			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Postnasal Drip			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Productive Cough			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Rhinitis Allergic			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	1 / 31 (3.23%)
occurrences (all)	0	1	1
Insomnia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0

Mental Disorder			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Sleep Disorder			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Investigations			
Beta 2 Microglobulin Urine Increased			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Body Temperature Increased			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Blood Iron Decreased			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Serum Ferritin Decreased			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod Sting			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Concussion			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	1 / 65 (1.54%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	1	1	0

Excoriation			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Fall			
subjects affected / exposed	2 / 65 (3.08%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	2	0	1
Humerus Fracture			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Procedural Vomiting			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Skin Laceration			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Ulna Fracture			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 65 (1.54%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Dysgeusia			
subjects affected / exposed	1 / 65 (1.54%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Febrile Convulsion			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	4 / 65 (6.15%)	7 / 62 (11.29%)	0 / 31 (0.00%)
occurrences (all)	4	10	0
Lethargy			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 65 (1.54%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Ear and labyrinth disorders			
Ear Pain			
subjects affected / exposed	0 / 65 (0.00%)	3 / 62 (4.84%)	0 / 31 (0.00%)
occurrences (all)	0	3	0
Eustachian Tube Obstruction			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Tympanic Membrane Perforation			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 65 (0.00%)	2 / 62 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Vision Blurred			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	7 / 65 (10.77%)	8 / 62 (12.90%)	2 / 31 (6.45%)
occurrences (all)	11	8	2
Abdominal Pain Upper			
subjects affected / exposed	2 / 65 (3.08%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	2	1	0
Constipation			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	1 / 31 (3.23%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	7 / 65 (10.77%)	7 / 62 (11.29%)	3 / 31 (9.68%)
occurrences (all)	8	7	3
Dyspepsia			

subjects affected / exposed	1 / 65 (1.54%)	1 / 62 (1.61%)	2 / 31 (6.45%)
occurrences (all)	1	1	2
Eosinophilic Oesophagitis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Eructation			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 65 (0.00%)	2 / 62 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Gastritis			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Haematochezia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Hiatus Hernia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Irritable Bowel Syndrome			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Mouth Ulceration			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 65 (0.00%)	3 / 62 (4.84%)	0 / 31 (0.00%)
occurrences (all)	0	4	0
Regurgitation			
subjects affected / exposed	1 / 65 (1.54%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	1	2	0
Toothache			

subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	8 / 65 (12.31%)	10 / 62 (16.13%)	3 / 31 (9.68%)
occurrences (all)	9	13	3
Skin and subcutaneous tissue disorders			
Dermatitis Allergic			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dermatitis Contact			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Dermatitis Diaper			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Prurigo			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Rash Pruritic			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Skin Exfoliation			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Back Pain			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Pain in Extremity			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	1 / 31 (3.23%)
occurrences (all)	0	1	1
Infections and infestations			
Acute Tonsillitis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Bronchitis			
subjects affected / exposed	1 / 65 (1.54%)	2 / 62 (3.23%)	0 / 31 (0.00%)
occurrences (all)	1	2	0
Conjunctivitis Infective			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Coxsackie Viral Infection			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Croup Infectious			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Ear Infection			
subjects affected / exposed	0 / 65 (0.00%)	2 / 62 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Folliculitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Fungal Oesophagitis			

subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis Rotavirus			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 65 (0.00%)	2 / 62 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Localised Infection			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection Viral			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Molluscum Contagiosum			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	3 / 65 (4.62%)	3 / 62 (4.84%)	1 / 31 (3.23%)
occurrences (all)	3	3	2
Pharyngitis			
subjects affected / exposed	3 / 65 (4.62%)	1 / 62 (1.61%)	1 / 31 (3.23%)
occurrences (all)	3	1	2
Otitis Media			
subjects affected / exposed	3 / 65 (4.62%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	3	0	0
Pharyngitis Streptococcal			
subjects affected / exposed	1 / 65 (1.54%)	1 / 62 (1.61%)	1 / 31 (3.23%)
occurrences (all)	1	1	1

Pneumonia			
subjects affected / exposed	0 / 65 (0.00%)	2 / 62 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Rash Pustular			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	3 / 65 (4.62%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	3	1	0
Sinusitis			
subjects affected / exposed	2 / 65 (3.08%)	3 / 62 (4.84%)	1 / 31 (3.23%)
occurrences (all)	2	3	1
Tooth Abscess			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Tracheitis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Upper Respiratory Tract Infection			
subjects affected / exposed	6 / 65 (9.23%)	4 / 62 (6.45%)	4 / 31 (12.90%)
occurrences (all)	7	4	4
Urinary Tract Infection			
subjects affected / exposed	2 / 65 (3.08%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	2	1	0
Viral Infection			
subjects affected / exposed	1 / 65 (1.54%)	2 / 62 (3.23%)	1 / 31 (3.23%)
occurrences (all)	1	2	1
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	2 / 65 (3.08%)	1 / 62 (1.61%)	0 / 31 (0.00%)
occurrences (all)	2	1	0
Acidosis			

subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Iron Deficiency			
subjects affected / exposed	0 / 65 (0.00%)	0 / 62 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Rabeprazole Sodium 0.5 mg/kg (Double-blind Maintenance Phase)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 33 (54.55%)		
Surgical and medical procedures			
Suture Insertion			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Tooth Extraction			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Influenza Like Illness			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		

Immune system disorders			
Atopy			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Hypersensitivity			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Social circumstances			
Menarche			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Breast Mass			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Adenoidal Hypertrophy			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Asthma			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Asthma Exercise Induced			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Bronchial Hyperreactivity			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Choking			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Cough			

subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Dysphonia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Dyspnoea				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Epistaxis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Hyperventilation				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Increased Upper Airway Secretion				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Nasal Congestion				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Oropharyngeal Pain				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Pharyngeal Erythema				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Postnasal Drip				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Productive Cough				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Rhinitis Allergic				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Rhinorrhoea				

subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all) Mental Disorder subjects affected / exposed occurrences (all) Sleep Disorder subjects affected / exposed occurrences (all)	 0 / 33 (0.00%) 0 0 / 33 (0.00%) 0 0 / 33 (0.00%) 0 1 / 33 (3.03%) 1		
Investigations Beta 2 Microglobulin Urine Increased subjects affected / exposed occurrences (all) Blood Alkaline Phosphatase Increased subjects affected / exposed occurrences (all) Blood Creatine Phosphokinase Increased subjects affected / exposed occurrences (all) Body Temperature Increased subjects affected / exposed occurrences (all) Blood Iron Decreased subjects affected / exposed occurrences (all) Serum Ferritin Decreased subjects affected / exposed occurrences (all)	 1 / 33 (3.03%) 1 0 / 33 (0.00%) 0 0 / 33 (0.00%) 0 0 / 33 (0.00%) 0 0 / 33 (0.00%) 0 1 / 33 (3.03%) 1		
Injury, poisoning and procedural complications			

Arthropod Sting subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Concussion subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Contusion subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Excoriation subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Fall subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Humerus Fracture subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Procedural Vomiting subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1		
Skin Laceration subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Ulna Fracture subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Dysgeusia subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0		
Febrile Convulsion			

subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Lethargy			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear Pain			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Eustachian Tube Obstruction			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Tympanic Membrane Perforation			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Vision Blurred			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	3 / 33 (9.09%)		
occurrences (all)	4		
Abdominal Pain Upper			

subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Diarrhoea				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Eosinophilic Oesophagitis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Eructation				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Flatulence				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Gastritis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Gastrooesophageal Reflux Disease				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Haematochezia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Hiatus Hernia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Irritable Bowel Syndrome				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Mouth Ulceration				

subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Regurgitation			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	4 / 33 (12.12%)		
occurrences (all)	4		
Skin and subcutaneous tissue disorders			
Dermatitis Allergic			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Dermatitis Contact			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Dermatitis Diaper			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Eczema			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Prurigo			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		

Rash Pruritic			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Skin Exfoliation			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Back Pain			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Pain in Extremity			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Acute Tonsillitis			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Conjunctivitis Infective			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Coxsackie Viral Infection			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Croup Infectious			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	2		
Ear Infection			

subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Folliculitis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Fungal Oesophagitis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Gastroenteritis Rotavirus				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Localised Infection				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Lower Respiratory Tract Infection				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Lower Respiratory Tract Infection Viral				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Molluscum Contagiosum				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Pharyngitis				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	2			

Otitis Media				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	3			
Pharyngitis Streptococcal				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Pneumonia				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Rash Pustular				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Sinusitis				
subjects affected / exposed	2 / 33 (6.06%)			
occurrences (all)	2			
Tooth Abscess				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Tracheitis				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Upper Respiratory Tract Infection				
subjects affected / exposed	4 / 33 (12.12%)			
occurrences (all)	4			
Urinary Tract Infection				
subjects affected / exposed	0 / 33 (0.00%)			
occurrences (all)	0			
Viral Infection				
subjects affected / exposed	1 / 33 (3.03%)			
occurrences (all)	1			
Viral Upper Respiratory Tract Infection				

subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Acidosis			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		
Hypercholesterolaemia			
subjects affected / exposed	0 / 33 (0.00%)		
occurrences (all)	0		
Iron Deficiency			
subjects affected / exposed	1 / 33 (3.03%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 December 2008	The overall reason for the amendment INT-1 was to allow assent to the informed consent process (as minors were included in the study), to add updated information, and to correct textual inconsistencies within the protocol.
05 March 2009	The overall reason for the amendment INT-2 was to extend the end of study visit window and to expand the list of antacids allowed during the study; several sections also were revised to provide further text clarification.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported