



Clinical trial results:

A multi-centre, randomised, double-blind, two arm, parallel group, placebo-controlled study to assess the effect of Sodium Alginate Chewable Tablets on symptoms of gastro-oesophageal reflux disease.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2014-005261-69 |
| Trial protocol | GB DE IT |
| Global end of trial date | 30 August 2016 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v1 (current) |
| This version publication date | 17 September 2017 |
| First version publication date | 17 September 2017 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | GA1402 |
|-----------------------|--------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--------------------------------------------------------------------------------------------------------------------|
| Sponsor organisation name | Reckitt Benckiser Healthcare (UK) Ltd |
| Sponsor organisation address | Dansom Lane, Hull, United Kingdom, HU8 7DS |
| Public contact | Clinical Research Director, Clinical Research, Reckitt Benckiser Healthcare (UK) Limited, clinicalrequests@rb.com |
| Scientific contact | Clinical Research Director, Clinical Research , Reckitt Benckiser Healthcare (UK) Limited, clinicalrequests@rb.com |

Notes:

Paediatric regulatory details

| | |
|----------------------------------------------------------------------|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|------------------------------------------------------|----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 07 April 2017 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 30 August 2016 |
| Global end of trial reached? | Yes |
| Global end of trial date | 30 August 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to assess the efficacy of Sodium Alginate Chewable Tablets compared to matched placebo tablets in the reduction of the symptoms of GORD as assessed using the Reflux Disease Questionnaire (RDQ).

Protection of trial subjects:

This study was conducted in accordance with the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) and the ethical principles contained within the Declaration of Helsinki, as referenced in EU Directive 2001/20/EC.

Background therapy: -

Evidence for comparator: -

| | |
|-----------------------------------------------------------|-------------------|
| Actual start date of recruitment | 21 September 2015 |
| 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 Kingdom: 93 |
| Country: Number of subjects enrolled | Germany: 288 |
| Country: Number of subjects enrolled | Italy: 43 |
| Worldwide total number of subjects | 424 |
| EEA total number of subjects | 424 |

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) | 0 |
| Adults (18-64 years) | 333 |
| From 65 to 84 years | 88 |

| | |
|-------------------|---|
| 85 years and over | 3 |
|-------------------|---|

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited at sites in the United Kingdom, Germany and Italy.

Pre-assignment

Screening details:

Total 526 subjects were screened; 99 subjects were screening failures; 427 subjects were randomized & 426 subjects were treated (1 subject was randomized in error). Subject included in analysis were 424 (2 lost to follow-up subjects from both groups were also excluded from analysis due to no treatment evidence & evaluable data for any visits).

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall trial (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 | Gaviscon |

Arm description:

Gaviscon Double Action Tablets, 4 tablets by mouth 4 times daily for 7 - 10 days

| | |
|----------------------------------------|----------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Gaviscon Double Action Tablets |
| Investigational medicinal product code | |
| Other name | Sodium alginate chewable tablets |
| Pharmaceutical forms | Chewable tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Gaviscon Double Action Tablets, 4 tablets by mouth 4 times daily for 7 - 10 days

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

Placebo (matching tablets) 4 tablets 4 times daily for 7 - 10 days

| | |
|----------------------------------------|-----------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Chewable tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Placebo (matching tablets), 4 tablets 4 times daily for 7 - 10 days

| Number of subjects in period 1 | Gaviscon | Placebo |
|---------------------------------------|----------|---------|
| Started | 212 | 212 |
| Completed | 200 | 199 |
| Not completed | 12 | 13 |
| Consent withdrawn by subject | 1 | - |
| Adverse event, non-fatal | 9 | 9 |
| Lack of efficacy | 1 | 2 |
| Protocol deviation | 1 | 2 |

Baseline characteristics

Reporting groups

| | |
|----------------------------------------------------------------------------------|----------|
| Reporting group title | Gaviscon |
| Reporting group description: | |
| Gaviscon Double Action Tablets, 4 tablets by mouth 4 times daily for 7 - 10 days | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Placebo (matching tablets) 4 tablets 4 times daily for 7 - 10 days | |

| Reporting group values | Gaviscon | Placebo | Total |
|---------------------------|----------|---------|-------|
| Number of subjects | 212 | 212 | 424 |
| Age categorical | | | |
| ITT population | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 172 | 161 | 333 |
| From 65-84 years | 38 | 50 | 88 |
| 85 years and over | 2 | 1 | 3 |
| Age continuous | | | |
| ITT population | | | |
| Units: years | | | |
| arithmetic mean | 50 | 50.1 | |
| standard deviation | ± 15.51 | ± 16.47 | - |
| Gender categorical | | | |
| ITT population | | | |
| Units: Subjects | | | |
| Female | 110 | 115 | 225 |
| Male | 102 | 97 | 199 |
| Ethnicity | | | |
| ITT population | | | |
| Units: Subjects | | | |
| Asian | 2 | 2 | 4 |
| Black or African American | 1 | 1 | 2 |
| Other | 0 | 0 | 0 |
| White | 209 | 209 | 418 |
| Smoking history | | | |
| ITT population | | | |
| Units: Subjects | | | |
| Current smoker | 45 | 46 | 91 |
| Ex-smoker | 58 | 52 | 110 |
| Never smoked | 109 | 114 | 223 |
| Alcohol consumer | | | |
| ITT population | | | |
| Units: Subjects | | | |
| No | 91 | 107 | 198 |
| Yes | 121 | 105 | 226 |

| | | | |
|--------------------|---------|---------|---|
| Height | | | |
| ITT population | | | |
| Units: cm | | | |
| arithmetic mean | 171.3 | 170.1 | |
| standard deviation | ± 9.39 | ± 10.32 | - |
| Weight | | | |
| ITT population | | | |
| Units: kg | | | |
| arithmetic mean | 82.2 | 80.2 | |
| standard deviation | ± 18.07 | ± 17.56 | - |

End points

End points reporting groups

| | |
|------------------------------------------------------------------------------------------------------------------|----------|
| Reporting group title | Gaviscon |
| Reporting group description: Gaviscon Double Action Tablets, 4 tablets by mouth 4 times daily for 7 - 10 days | |
| Reporting group title | Placebo |
| Reporting group description: Placebo (matching tablets) 4 tablets 4 times daily for 7 - 10 days | |

Primary: Number of subjects with a reduction of at least 1.5 points in the RDQ GORD dimension from baseline

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| End point title | Number of subjects with a reduction of at least 1.5 points in the RDQ GORD dimension from baseline |
| End point description: Intent-to-treat (ITT) population: All randomized subjects (minus three subjects with no evaluable data). Reflux Disease Questionnaire (RDQ) is a validated 12-item self-assessment questionnaire in which subjects are asked to rate the frequency and severity of 6 symptoms covering the two dimensions of Gastro-Oesophageal Reflux Disease (GORD) – regurgitation and heartburn – and dyspepsia on 6-point Likert scales ranging from 0 = None to 5 = Daily and 0 = none to 5 = Severe, respectively. Response = Reduction of RDQ GORD dimension score ≥ 1.5 . Responder = Subject with a reduction from baseline of 1.5 points in the RDQ GORD dimension score. | |
| End point type | Primary |
| End point timeframe: Visit 2 (baseline) to visit 3 | |

| End point values | Gaviscon | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 212 | 212 | | |
| Units: Participants | | | | |
| Non-responders | 101 | 132 | | |
| Responders | 111 | 80 | | |

Statistical analyses

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Statistical analysis title | RDQ GORD responses |
| Statistical analysis description: Number of subjects with a reduction of at least 1.5 points in the RDQ GORD dimension from baseline | |
| Comparison groups | Gaviscon v Placebo |

| | |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 424 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0031 |
| Method | ANCOVA |

Secondary: Change from baseline in RDQ GORD dimension score

| | |
|-------------------------------|--------------------------------------------------|
| End point title | Change from baseline in RDQ GORD dimension score |
| End point description: | |
| ITT population | |
| End point type | Secondary |
| End point timeframe: | |
| Visit 2 (baseline) to visit 3 | |

| End point values | Gaviscon | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 212 | 212 | | |
| Units: Participants | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Visit 2) | 3.1 (± 0.93) | 3 (± 0.9) | | |
| End of treatment (Visit 3) | 1.4 (± 1.2) | 1.7 (± 1.21) | | |
| Change from Baseline | -1.7 (± 1.27) | -1.3 (± 1.16) | | |

Statistical analyses

| | |
|-----------------------------------------|--------------------------|
| Statistical analysis title | RDQ GORD dimension score |
| Comparison groups | Gaviscon v Placebo |
| Number of subjects included in analysis | 424 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.009 |
| Method | ANCOVA |

Secondary: Change from baseline in RDQ heartburn score

| | |
|-------------------------------|---------------------------------------------|
| End point title | Change from baseline in RDQ heartburn score |
| End point description: | |
| ITT population | |
| End point type | Secondary |
| End point timeframe: | |
| Visit 2 (baseline) to visit 3 | |

| End point values | Gaviscon | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 212 | 212 | | |
| Units: Unit on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Visit 2) | 3 (± 1.29) | 2.9 (± 1.19) | | |
| End of treatment (Visit 3) | 1.5 (± 1.37) | 1.8 (± 1.41) | | |
| Change from Baseline | -1.6 (± 1.58) | -1.2 (± 1.36) | | |

Statistical analyses

| | |
|-----------------------------------------|---------------------|
| Statistical analysis title | RDQ heartburn score |
| Comparison groups | Gaviscon v Placebo |
| Number of subjects included in analysis | 424 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.019 |
| Method | ANCOVA |

Secondary: Change from baseline in RDQ regurgitation score

| | |
|-------------------------------|-------------------------------------------------|
| End point title | Change from baseline in RDQ regurgitation score |
| End point description: | |
| ITT population | |
| End point type | Secondary |
| End point timeframe: | |
| Visit 2 (baseline) to visit 3 | |

| End point values | Gaviscon | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 212 | 212 | | |
| Units: Unit on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Visit 2) | 3.1 (± 1.16) | 3.1 (± 1.19) | | |
| End of treatment (Visit 3) | 1.3 (± 1.4) | 1.7 (± 1.39) | | |
| Change from Baseline | -1.8 (± 1.45) | -1.5 (± 1.45) | | |

Statistical analyses

| | |
|-----------------------------------------|-------------------------|
| Statistical analysis title | RDQ regurgitation score |
| Comparison groups | Gaviscon v Placebo |
| Number of subjects included in analysis | 424 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.029 |
| Method | ANCOVA |

Secondary: Change from baseline in RDQ dyspepsia score

| | |
|-------------------------------|---------------------------------------------|
| End point title | Change from baseline in RDQ dyspepsia score |
| End point description: | |
| ITT population | |
| End point type | Secondary |
| End point timeframe: | |
| Visit 2 (baseline) to visit 3 | |

| | | | | |
|--------------------------------------|-----------------|-----------------|--|--|
| End point values | Gaviscon | Placebo | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 212 | 212 | | |
| Units: Unit on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Visit 2) | 2.6 (± 1.41) | 2.5 (± 1.29) | | |
| End of treatment (Visit 3) | 1.3 (± 1.36) | 1.6 (± 1.41) | | |
| Change from Baseline | -1.4 (± 1.51) | -1 (± 1.44) | | |

Statistical analyses

| | |
|-----------------------------------------|---------------------|
| Statistical analysis title | RDQ dyspepsia score |
| Comparison groups | Gaviscon v Placebo |
| Number of subjects included in analysis | 424 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.005 |
| Method | ANCOVA |

Secondary: Overall Treatment Evaluation (OTE)

| | |
|------------------------|------------------------------------|
| End point title | Overall Treatment Evaluation (OTE) |
| End point description: | |
| ITT population. | |

OTE questionnaire is a validated scale which asks subjects to rate the degree of changes in their symptoms after 7 days of drug administration on a 15-point Likert-scale ranging from -7 = Extremely deteriorated to +7 = Extremely improved. In case of change, subjects are asked to rate the importance of the change on a 7-point scale ranging from 1 = Not important to 7 = Extremely important.

| | |
|-------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Visit 2 (baseline) to visit 3 | |

| End point values | Gaviscon | Placebo | | |
|-------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 212 | 212 | | |
| Units: Participants | | | | |
| -7 extremely deteriorated | 1 | 4 | | |
| -6 significantly deteriorated | 2 | 4 | | |
| -5 relatively deteriorated | 4 | 6 | | |
| -4 moderately deteriorated | 1 | 4 | | |
| -3 a little deteriorated | 1 | 5 | | |
| -2 slightly deteriorated | 4 | 3 | | |
| -1 almost not deteriorated | 1 | 2 | | |
| 0 no change | 34 | 37 | | |
| +1 almost not improved | 12 | 16 | | |
| +2 slightly improved | 24 | 17 | | |
| +3 a little improved | 13 | 25 | | |
| +4 moderately improved | 21 | 26 | | |
| +5 relatively improved | 27 | 29 | | |
| +6 significantly improved | 39 | 25 | | |
| +7 extremely improved | 26 | 7 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in number of nights (out of the last 7 nights) when the subject experienced night time symptoms

| | |
|-----------------|----------------------------------------------------------------------------------------------------------------------|
| End point title | Change from baseline in number of nights (out of the last 7 nights) when the subject experienced night time symptoms |
|-----------------|----------------------------------------------------------------------------------------------------------------------|

End point description:

ITT population.

Before treatment, subjects were asked as to how many nights over the last 7 nights they had experienced night time symptoms ('How many nights did you have night time symptoms over the last 7 nights?'). The answer was documented in the eCRF. During the treatment period, subjects recorded night time symptoms in the subject diary, prompted by the question 'Did you have any night time symptoms last night?' The number of nights with night time symptoms during treatment was calculated from these data.

| | |
|-------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Visit 2 (baseline) to visit 3 | |

| End point values | Gaviscon | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 212 | 212 | | |
| Units: Night | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (Visit 2) | 4 (± 2.67) | 3.9 (± 2.55) | | |
| End of treatment (Visit 3) | 1.7 (± 2.2) | 1.7 (± 2.13) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in subject ratings of the degree (magnitude) and the importance of changes in symptoms

| | |
|-----------------|-------------------------------------------------------------------------------------------------------------|
| End point title | Change from baseline in subject ratings of the degree (magnitude) and the importance of changes in symptoms |
|-----------------|-------------------------------------------------------------------------------------------------------------|

End point description:

ITT population.

'Symptom change after 7 days administration' ranged from -7 = Extremely deteriorated over 0 = No change to +7 = Extremely improved.

'Importance of symptom change to subject' ranged from 0 = No improvement to 7 = extremely important.

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

End point timeframe:

Visit 2 (baseline) to visit 3

| End point values | Gaviscon | Placebo | | |
|--------------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 212 | 212 | | |
| Units: Unit on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Symptom change after 7 days administration | 3.2 (± 3.08) | 2.2 (± 3.34) | | |
| Importance of symptom change for subject | 4 (± 2.6) | 3.5 (± 2.72) | | |

Statistical analyses

| | |
|-----------------------------------|--------------------------------------------|
| Statistical analysis title | Symptom change after 7 days administration |
| Comparison groups | Gaviscon v Placebo |

| | |
|-----------------------------------------|------------------------------------|
| Number of subjects included in analysis | 424 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | two-sided Wilcoxon two-sample test |

| | |
|-----------------------------------------|------------------------------------------|
| Statistical analysis title | Importance of symptom change for subject |
| Comparison groups | Gaviscon v Placebo |
| Number of subjects included in analysis | 424 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.068 |
| Method | two-sided Wilcoxon two-sample test |

Secondary: Number of subjects with Adverse Events (AEs)

| | |
|------------------------------------------------------------|----------------------------------------------|
| End point title | Number of subjects with Adverse Events (AEs) |
| End point description: Safety population. | |
| ADR = Adverse Drug Reaction SAE = Serious Adverse Event | |
| End point type | Secondary |
| End point timeframe: Up to Visit 3 | |

| End point values | Gaviscon | Placebo | | |
|--------------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 212 | 212 | | |
| Units: Participants | | | | |
| All Adverse Events (AEs): | 109 | 115 | | |
| Non-treatment emergent adverse events: | 12 | 14 | | |
| Treatment emergent adverse events (TEAEs): | 104 | 107 | | |
| IMP-related adverse events (ADRs): | 66 | 54 | | |
| Serious TEAEs (SAEs): | 0 | 1 | | |
| IMP-related serious TEAEs (serious ADRs): | 0 | 0 | | |
| TEAEs with death as outcome: | 0 | 0 | | |
| TEAEs leading to dose withdrawal: | 9 | 8 | | |

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Visit 3

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 18.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | Gaviscon |
|-----------------------|----------|

Reporting group description: -

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description: -

| Serious adverse events | Gaviscon | Placebo | |
|---------------------------------------------------|-----------------|-----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 212 (0.00%) | 1 / 212 (0.47%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 212 (0.00%) | 1 / 212 (0.47%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 212 (0.00%) | 1 / 212 (0.47%) | |
| 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: 5 %

| Non-serious adverse events | Gaviscon | Placebo | |
|-------------------------------------------------------|--------------------|--------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 104 / 212 (49.06%) | 107 / 212 (50.47%) | |
| Nervous system disorders | | | |
| Headache | | | |

| | | | |
|--------------------------------------------------|-------------------------|-------------------------|--|
| subjects affected / exposed occurrences (all) | 28 / 212 (13.21%) 29 | 30 / 212 (14.15%) 31 | |
| Gastrointestinal disorders | | | |
| Flatulence | | | |
| subjects affected / exposed | 36 / 212 (16.98%) | 37 / 212 (17.45%) | |
| occurrences (all) | 37 | 38 | |
| Diarrhoea | | | |
| subjects affected / exposed | 23 / 212 (10.85%) | 17 / 212 (8.02%) | |
| occurrences (all) | 23 | 17 | |
| Nausea | | | |
| subjects affected / exposed | 16 / 212 (7.55%) | 20 / 212 (9.43%) | |
| occurrences (all) | 17 | 21 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 17 / 212 (8.02%) | 18 / 212 (8.49%) | |
| occurrences (all) | 18 | 25 | |

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