



Clinical trial results:

A randomised, single dose, crossover, open label, placebo controlled confirmatory study in healthy volunteers to characterise the acid neutralisation activity of Gaviscon Double Action Liquid in the fasted state, using an intragastric and oesophageal pH catheter.

Summary

EudraCT number	2016-000539-42
Trial protocol	NL
Global end of trial date	07 September 2016

Results information

Result version number	v2 (current)
This version publication date	28 February 2019
First version publication date	20 October 2017
Version creation reason	• Correction of full data set - Slight changes in disposition and title.

Trial information

Trial identification

Sponsor protocol code	RB2-NL-1518
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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, 0044 1482 326 151, clinicalrequests@rb.com
Scientific contact	Clinical Research Director, Clinical Research, Reckitt Benckiser Healthcare (UK) Limited, 0044 1482 326 151, 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	20 March 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 September 2016
Global end of trial reached?	Yes
Global end of trial date	07 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this confirmatory study is to confirm the acid neutralisation action of Gaviscon Double Action Liquid versus placebo liquid within the stomach.

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	06 May 2016
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	Netherlands: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was a single-centre study conducted in the Netherlands.

Pre-assignment

Screening details:

Healthy volunteers of both genders were recruited into this study. Total 20 subjects were randomized.

Period 1

Period 1 title	Period 1: Placebo and Gaviscon
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

This was an open-label study; subjects, clinic staff and consultant gastroenterologist remained unblinded throughout the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo Liquid sachets 20 ml single dose by mouth under fasted condition.

There was a 5 to 14 days washout period between each treatment administration.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension in sachet
Routes of administration	Oral use

Dosage and administration details:

10 ml sachet, for oral use

Arm title	Gaviscon Double Action Liquid Sachets 20 ml
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Arm description:

Gaviscon Double Action Liquid Sachets 20 ml dose of single dose by mouth under fasted condition.

There was a 5 to 14 days washout period between each treatment administration

Arm type	Experimental
Investigational medicinal product name	Gaviscon Double Action Liquid Sachets
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension in sachet
Routes of administration	Oral use

Dosage and administration details:

Gaviscon Double Action Liquid 20 ml sachets (each 10 ml sachet contained sodium alginate 500 mg, sodium bicarbonate 213 mg and calcium carbonate 325 mg) single dose by mouth.

Number of subjects in period 1	Placebo	Gaviscon Double Action Liquid Sachets 20 ml
Started	10	10
Completed	8	6
Not completed	2	4
Physician decision	2	3
Withdrew consent	-	1

Period 2

Period 2 title	Period 2: Gaviscon and Placebo
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

This was an open-label study; subjects, clinic staff and consultant gastroenterologist remained unblinded throughout the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Gaviscon Double Action Liquid Sachets 20 ml

Arm description:

Gaviscon Double Action Liquid Sachets 20 ml dose of single dose by mouth under fasted condition.

Arm type	Active comparator
Investigational medicinal product name	Gaviscon Double Action Liquid Sachets
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension in sachet
Routes of administration	Oral use

Dosage and administration details:

Gaviscon Double Action Liquid 20 ml sachets (each 10 ml sachet contained sodium alginate 500 mg, sodium bicarbonate 213 mg and calcium carbonate 325 mg) single dose by mouth.

Arm title	Placebo
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Arm description:

Placebo Liquid sachets 20 ml single dose by mouth under fasted condition.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension in sachet
Routes of administration	Oral use

Dosage and administration details:

Placebo 10 ml sachet single dose by mouth.

Number of subjects in period 2	Gaviscon Double Action Liquid Sachets 20 ml	Placebo
Started	8	6
Completed	6	6
Not completed	2	0
Physician decision	2	-

Baseline characteristics

Reporting groups

Reporting group title	Period 1: Placebo and Gaviscon
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Reporting group description: -

Reporting group values	Period 1: Placebo and Gaviscon	Total	
Number of subjects	20	20	
Age categorical			
All subjects population			
Units: Subjects			
Adults (18-64 years)	20	20	
Age continuous			
All subjects population			
Units: years			
arithmetic mean	23		
standard deviation	± 3	-	
Gender categorical			
All subjects population			
Units: Subjects			
Female	11	11	
Male	9	9	
Race			
All subjects population			
Units: Subjects			
White	19	19	
Black Or African American	1	1	
Smoking history			
All subjects population			
Units: Subjects			
Never Smoked	17	17	
Currently Smoking	3	3	
Drinking habits			
All subjects population			
Units: Subjects			
Yes	18	18	
No	2	2	
Drug use			
All subjects population			
Units: Subjects			
No	20	20	
Height			
All subjects population			
Units: cm			
arithmetic mean	175.75		
standard deviation	± 9.14	-	
Weight			
All subjects population			

Units: kg			
arithmetic mean	68.41		
standard deviation	± 8.41	-	
BMI			
All subjects population			
Units: kg/m2			
arithmetic mean	22.1		
standard deviation	± 1.54	-	

End points

End points reporting groups

Reporting group title	Placebo
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Reporting group description:

Placebo Liquid sachets 20 ml single dose by mouth under fasted condition.

There was a 5 to 14 days washout period between each treatment administration.

Reporting group title	Gaviscon Double Action Liquid Sachets 20 ml
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Reporting group description:

Gaviscon Double Action Liquid Sachets 20 ml dose of single dose by mouth under fasted condition.

There was a 5 to 14 days washout period between each treatment administration

Reporting group title	Gaviscon Double Action Liquid Sachets 20 ml
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Reporting group description:

Gaviscon Double Action Liquid Sachets 20 ml dose of single dose by mouth under fasted condition.

Reporting group title	Placebo
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Reporting group description:

Placebo Liquid sachets 20 ml single dose by mouth under fasted condition.

Subject analysis set title	Period 1 and 2: Placebo
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

ITT (Intention-to-treat) population: All subjects who were recruited to the study and had some post-treatment pH data for at least one treatment visit.

Subject analysis set title	Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

ITT (Intention-to-treat) population: All subjects who were recruited to the study and had some post-treatment pH data for at least one treatment visit.

Primary: Percentage of time that pH ≥ 4 over 0-30 minutes post-dose across electrodes 5 to 10

End point title	Percentage of time that pH ≥ 4 over 0-30 minutes post-dose across electrodes 5 to 10
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End point description:

ITT population

End point type	Primary
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End point timeframe:

From 0 to 30 minutes post-dose on Day 1 of Period 1 and 2

End point values	Period 1 and 2: Placebo	Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	13		
Units: Percentage of time (%)				
arithmetic mean (standard deviation)	3.5 ($\pm$ 2.7)	50.8 ($\pm$ 28.6)		

Statistical analyses

Statistical analysis title	pH $\geq$ 4 over 0-30 minutes
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0051
Method	Wilcoxon Rank Sum Test

Secondary: Percentage of time that pH $\geq$ 4 over the interval 30-60 minutes post-dose across electrodes 5 to 10

End point title	Percentage of time that pH $\geq$ 4 over the interval 30-60 minutes post-dose across electrodes 5 to 10
End point description:	
ITT population	
End point type	Secondary
End point timeframe:	
From 30 to 60 minutes post-dose on Day 1 of Period 1 and 2	

End point values	Period 1 and 2: Placebo	Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	13		
Units: Percentage of time (%)				
arithmetic mean (standard deviation)	6.6 ($\pm$ 21.1)	8.7 ($\pm$ 15.1)		

Statistical analyses

Statistical analysis title	pH $\geq$ 4 over the interval 30-60 minutes
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml

Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1705
Method	Wilcoxon Rank Sum Test

Secondary: Percentage of time that pH ≥ 3 over the intervals 0-30 minutes and 30-60 minutes post-dose across electrodes 5 to 10

End point title	Percentage of time that pH ≥ 3 over the intervals 0-30 minutes and 30-60 minutes post-dose across electrodes 5 to 10
End point description:	
ITT population	
End point type	Secondary
End point timeframe:	
From 0 to 60 minutes post-dose on Day 1 of Period 1 and 2	

End point values	Period 1 and 2: Placebo	Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	13		
Units: Percentage of time (%)				
arithmetic mean (standard deviation)				
over 0 - 30 minutes	9 ($\pm$ 9.2)	53.1 ($\pm$ 28.7)		
over 30 - 60 minutes	10.5 ($\pm$ 22.7)	10.8 ($\pm$ 16)		

Statistical analyses

Statistical analysis title	pH ≥ 3 over the intervals 0-30 minutes
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA

Statistical analysis title	pH ≥ 3 over the intervals 30-60 minutes
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml

Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5752
Method	Wilcoxon Rank Sum Test

Secondary: Percentage of time that pH ≥ 3 over 10 minute intervals post-dose across electrodes 5 to 10

End point title	Percentage of time that pH ≥ 3 over 10 minute intervals post-dose across electrodes 5 to 10
End point description:	
ITT population	
End point type	Secondary
End point timeframe:	
From 0 to 60 minutes post-dose on Day 1 of Period 1 and 2	

End point values	Period 1 and 2: Placebo	Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	13		
Units: Percentage of time (%)				
arithmetic mean (standard deviation)				
pH ≥ 3 over 0 - 10 minutes	16.3 ($\pm$ 19.2)	59 ($\pm$ 20.3)		
pH ≥ 3 over 10 - 20 minutes	5.7 ($\pm$ 6.7)	63 ($\pm$ 32)		
pH ≥ 3 over 20 - 30 minutes	5.1 ($\pm$ 7.4)	36.7 ($\pm$ 43.2)		
pH ≥ 3 over 30 - 40 minutes	9.4 ($\pm$ 24.9)	24.3 ($\pm$ 33.2)		
pH ≥ 3 over 40 - 50 minutes	10.7 ($\pm$ 27.2)	5.6 ($\pm$ 11.5)		
pH ≥ 3 over 50 - 60 minutes	11.1 ($\pm$ 20)	2.4 ($\pm$ 6.4)		

Statistical analyses

Statistical analysis title	0-10 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA

Statistical analysis title	10-20 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0051
Method	Wilcoxon Rank Sum Test

Statistical analysis title	20-30 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0079
Method	ANCOVA

Statistical analysis title	30-40 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0651
Method	Wilcoxon Rank Sum Test

Statistical analysis title	40-50 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9362
Method	Wilcoxon Rank Sum Test

Statistical analysis title	50-60 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml

Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.376
Method	Wilcoxon Rank Sum Test

Secondary: Percentage of time that pH ≥ 4 over 10 minute intervals post-dose across electrodes 5 to 10

End point title	Percentage of time that pH ≥ 4 over 10 minute intervals post-dose across electrodes 5 to 10
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End point description:

End point type	Secondary
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End point timeframe:

From 0 to 60 minutes post-dose on Day 1 of Period 1 and 2

End point values	Period 1 and 2: Placebo	Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	13		
Units: Percentage of time (%)				
arithmetic mean (standard deviation)				
pH ≥ 4 over 0 - 10 minutes	8.3 ($\pm$ 7.6)	56.8 ($\pm$ 19.7)		
pH ≥ 4 over 10 - 20 minutes	1.4 ($\pm$ 2.1)	59.9 ($\pm$ 33)		
pH ≥ 4 over 20 - 30 minutes	0.9 ($\pm$ 2.1)	35 ($\pm$ 42.4)		
pH ≥ 4 over 30 - 40 minutes	6.8 ($\pm$ 23.7)	20 ($\pm$ 30.9)		
pH ≥ 4 over 40 - 50 minutes	8 ($\pm$ 26.4)	4.2 ($\pm$ 10.3)		
pH ≥ 4 over 50 - 60 minutes	5 ($\pm$ 13)	1.8 ($\pm$ 6.1)		

Statistical analyses

Statistical analysis title	0-10 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA

Statistical analysis title	10-20 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0051
Method	Wilcoxon Rank Sum Test

Statistical analysis title	20-30 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0047
Method	ANCOVA

Statistical analysis title	30-40 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0115
Method	Wilcoxon Rank Sum Test

Statistical analysis title	40-50 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.935
Method	Wilcoxon Rank Sum Test

Statistical analysis title	50-60 minutes post-dose on Day 1 of Period 1 and 2
Comparison groups	Period 1 and 2: Placebo v Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml

Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3717
Method	Wilcoxon Rank Sum Test

Secondary: Percentage of time that pH ≥ 3 and pH ≥ 4 over 10 minute and 30 minute intervals at each electrode

End point title	Percentage of time that pH ≥ 3 and pH ≥ 4 over 10 minute and 30 minute intervals at each electrode
End point description:	
ITT population	
End point type	Secondary
End point timeframe:	
From 0 to 60 minute (post-dose) on Day 1 of Period 1 and 2	

End point values	Period 1 and 2: Placebo	Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	13		
Units: Percentage of time (%)				
arithmetic mean (standard deviation)				
Electrode 1 pH ≥ 3 over >0 - ≤ 30 min	99.6 (± 0.4)	99.7 (± 0.4)		
Electrode 2 pH ≥ 3 over >0 - ≤ 30 min	95.9 (± 9.4)	97.4 (± 6)		
Electrode 3 pH ≥ 3 over >0 - ≤ 30 min	32.4 (± 30.8)	58.8 (± 27.3)		
Electrode 4 pH ≥ 3 over >0 - ≤ 30 min	28.9 (± 25.2)	63.6 (± 25.6)		
Electrode 5 pH ≥ 3 over >0 - ≤ 30 min	17.1 (± 13.7)	66 (± 25)		
Electrode 6 pH ≥ 3 over >0 - ≤ 30 min	8.8 (± 10.6)	57.8 (± 31.8)		
Electrode 7 pH ≥ 3 over >0 - ≤ 30 min	5.1 (± 6.4)	52.4 (± 30.7)		
Electrode 8 pH ≥ 3 over >0 - ≤ 30 min	6.2 (± 8.5)	45.3 (± 35.9)		
Electrode 9 pH ≥ 3 over >0 - ≤ 30 min	7.3 (± 14.6)	47.6 (± 39.2)		
Electrode 10 pH ≥ 3 over >0 - ≤ 30 min	9.7 (± 26.3)	49.4 (± 36)		
Electrode 1 pH ≥ 3 over >30 - ≤ 60 min	99.7 (± 0.3)	96.7 (± 10.9)		
Electrode 2 pH ≥ 3 over >30 - ≤ 60 min	95.5 (± 8.3)	88.3 (± 25.1)		
Electrode 3 pH ≥ 3 over >30 - ≤ 60 min	27 (± 34.6)	31.5 (± 33.6)		
Electrode 4 pH ≥ 3 over >30 - ≤ 60 min	15.5 (± 33.2)	7 (± 9)		
Electrode 5 pH ≥ 3 over >30 - ≤ 60 min	13.6 (± 29)	9.8 (± 13.9)		
Electrode 6 pH ≥ 3 over >30 - ≤ 60 min	9.1 (± 23.8)	10.5 (± 14.8)		
Electrode 7 pH ≥ 3 over >30 - ≤ 60 min	11.4 (± 24.7)	10.7 (± 18)		
Electrode 8 pH ≥ 3 over >30 - ≤ 60 min	10.5 (± 22.2)	9.8 (± 16.5)		
Electrode 9 pH ≥ 3 over >30 - ≤ 60 min	8.3 (± 21.2)	11.7 (± 19.8)		
Electrode 10 pH ≥ 3 over >30 - ≤ 60 min	9.8 (± 22.2)	12.2 (± 25.7)		
Electrode 1 pH ≥ 3 over >0 - ≤ 10 min	99 (± 0.9)	99.2 (± 1.2)		
Electrode 2 pH ≥ 3 over >0 - ≤ 10 min	93.3 (± 18.3)	99.4 (± 0.4)		
Electrode 3 pH ≥ 3 over >0 - ≤ 10 min	40.9 (± 33.8)	87.2 (± 17.4)		

Electrode 4 pH ≥ 3 over $>0 - \leq 10$ min	43.8 (± 32.6)	86.3 (± 12)		
Electrode 5 pH ≥ 3 over $>0 - \leq 10$ min	32.9 (± 29.6)	82.4 (± 10)		
Electrode 6 pH ≥ 3 over $>0 - \leq 10$ min	21.3 (± 27.1)	70.2 (± 23.3)		
Electrode 7 pH ≥ 3 over $>0 - \leq 10$ min	11.8 (± 19.6)	51.6 (± 32)		
Electrode 8 pH ≥ 3 over $>0 - \leq 10$ min	12.6 (± 21)	47.5 (± 34.6)		
Electrode 9 pH ≥ 3 over $>0 - \leq 10$ min	9 (± 26.3)	52.1 (± 37.8)		
Electrode 10 pH ≥ 3 over $>0 - \leq 10$ min	10 (± 26.1)	50.1 (± 33.5)		
Electrode 1 pH ≥ 3 over $>10 - \leq 20$ min	99.4 (± 0.4)	99.5 (± 0)		
Electrode 2 pH ≥ 3 over $>10 - \leq 20$ min	95.6 (± 10.2)	97 (± 5.6)		
Electrode 3 pH ≥ 3 over $>10 - \leq 20$ min	25.6 (± 32.3)	54.5 (± 34.7)		
Electrode 4 pH ≥ 3 over $>10 - \leq 20$ min	23.1 (± 30.9)	68.6 (± 36.1)		
Electrode 5 pH ≥ 3 over $>10 - \leq 20$ min	11 (± 18.7)	69.6 (± 36.3)		
Electrode 6 pH ≥ 3 over $>10 - \leq 20$ min	3.8 (± 7.2)	63.5 (± 40.4)		
Electrode 7 pH ≥ 3 over $>10 - \leq 20$ min	1 (± 2.4)	67.2 (± 32.8)		
Electrode 8 pH ≥ 3 over $>10 - \leq 20$ min	2.8 (± 9.4)	57.3 (± 39.5)		
Electrode 9 pH ≥ 3 over $>10 - \leq 20$ min	5.7 (± 15.6)	57.8 (± 45.1)		
Electrode 10 pH ≥ 3 over $>10 - \leq 20$ min	9.6 (± 26.5)	62.6 (± 42.8)		
Electrode 1 pH ≥ 3 over $>20 - \leq 30$ min	99.3 (± 0.4)	99.3 (± 0.6)		
Electrode 2 pH ≥ 3 over $>20 - \leq 30$ min	97.7 (± 2.5)	94.6 (± 12.7)		
Electrode 3 pH ≥ 3 over $>20 - \leq 30$ min	30.6 (± 39.6)	34.2 (± 38.5)		
Electrode 4 pH ≥ 3 over $>20 - \leq 30$ min	19.6 (± 32)	35.1 (± 40.6)		
Electrode 5 pH ≥ 3 over $>20 - \leq 30$ min	7.4 (± 15.8)	45.2 (± 43.9)		
Electrode 6 pH ≥ 3 over $>20 - \leq 30$ min	1.1 (± 3.4)	39 (± 48.8)		
Electrode 7 pH ≥ 3 over $>20 - \leq 30$ min	2.6 (± 6.7)	37.7 (± 49.6)		
Electrode 8 pH ≥ 3 over $>20 - \leq 30$ min	3.2 (± 9.6)	30.7 (± 47.2)		
Electrode 9 pH ≥ 3 over $>20 - \leq 30$ min	7 (± 18.8)	32.5 (± 46.7)		
Electrode 10 pH ≥ 3 over $>20 - \leq 30$ min	9.4 (± 26.6)	34.9 (± 43.7)		
Electrode 1 pH ≥ 3 over $>30 - \leq 40$ min	99.4 (± 0.4)	98.5 (± 3.1)		
Electrode 2 pH ≥ 3 over $>30 - \leq 40$ min	96.5 (± 6.7)	90.6 (± 20.6)		
Electrode 3 pH ≥ 3 over $>30 - \leq 40$ min	25.8 (± 37)	32.7 (± 38.6)		
Electrode 4 pH ≥ 3 over $>30 - \leq 40$ min	17.9 (± 35.4)	10.6 (± 25.2)		
Electrode 5 pH ≥ 3 over $>30 - \leq 40$ min	11.1 (± 26.9)	23.1 (± 36.9)		
Electrode 6 pH ≥ 3 over $>30 - \leq 40$ min	7.2 (± 25.6)	25.6 (± 35.5)		
Electrode 7 pH ≥ 3 over $>30 - \leq 40$ min	7.4 (± 26.5)	25.7 (± 42)		
Electrode 8 pH ≥ 3 over $>30 - \leq 40$ min	8.1 (± 23.3)	22.9 (± 37.3)		
Electrode 9 pH ≥ 3 over $>30 - \leq 40$ min	10.5 (± 28.5)	26.5 (± 39.1)		
Electrode 10 pH ≥ 3 over $>30 - \leq 40$ min	12 (± 30.5)	21.9 (± 34.3)		
Electrode 1 pH ≥ 3 over $>40 - \leq 50$ min	99.2 (± 0.7)	96.3 (± 10.9)		
Electrode 2 pH ≥ 3 over $>40 - \leq 50$ min	95.6 (± 8.4)	86.6 (± 30)		
Electrode 3 pH ≥ 3 over $>40 - \leq 50$ min	25.1 (± 39.1)	28.2 (± 36.3)		
Electrode 4 pH ≥ 3 over $>40 - \leq 50$ min	16.2 (± 35.5)	4.6 (± 6.9)		
Electrode 5 pH ≥ 3 over $>40 - \leq 50$ min	16.3 (± 35.5)	4.3 (± 8.8)		
Electrode 6 pH ≥ 3 over $>40 - \leq 50$ min	9.1 (± 26.7)	5.1 (± 12)		
Electrode 7 pH ≥ 3 over $>40 - \leq 50$ min	11.5 (± 27.6)	5.8 (± 13.4)		
Electrode 8 pH ≥ 3 over $>40 - \leq 50$ min	10.7 (± 27)	5.5 (± 12.6)		
Electrode 9 pH ≥ 3 over $>40 - \leq 50$ min	9 (± 26.9)	5.6 (± 17.5)		
Electrode 10 pH ≥ 3 over $>40 - \leq 50$ min	7.8 (± 26.5)	7.3 (± 23.2)		
Electrode 1 pH ≥ 3 over $>50 - \leq 60$ min	99.5 (± 0.2)	94.3 (± 18.5)		
Electrode 2 pH ≥ 3 over $>50 - \leq 60$ min	93.6 (± 16.4)	87 (± 28.7)		
Electrode 3 pH ≥ 3 over $>50 - \leq 60$ min	29.7 (± 36.5)	33.3 (± 36.9)		
Electrode 4 pH ≥ 3 over $>50 - \leq 60$ min	12.3 (± 29.5)	5.8 (± 10.1)		
Electrode 5 pH ≥ 3 over $>50 - \leq 60$ min	13.4 (± 27)	1.9 (± 4.3)		

Electrode 6 pH ≥ 3 over >50 - ≤ 60 min	10.9 (± 21.7)	0.8 (± 2.4)		
Electrode 7 pH ≥ 3 over >50 - ≤ 60 min	15.3 (± 29)	0.4 (± 1.3)		
Electrode 8 pH ≥ 3 over >50 - ≤ 60 min	12.6 (± 28)	0.9 (± 3)		
Electrode 9 pH ≥ 3 over >50 - ≤ 60 min	5.1 (± 11.9)	2.9 (± 10)		
Electrode 10 pH ≥ 3 over >50 - ≤ 60 min	9.5 (± 19)	7.3 (± 26.1)		
Electrode 1 pH ≥ 4 over >0 - ≤ 30 min	99.4 (± 0.6)	99.6 (± 0.5)		
Electrode 2 pH ≥ 4 over >0 - ≤ 30 min	94.9 (± 10.8)	97 (± 6.9)		
Electrode 3 pH ≥ 4 over >0 - ≤ 30 min	28 (± 32.1)	54.4 (± 27.5)		
Electrode 4 pH ≥ 4 over >0 - ≤ 30 min	21.2 (± 25.1)	59.2 (± 24.9)		
Electrode 5 pH ≥ 4 over >0 - ≤ 30 min	10.1 (± 10.6)	63.2 (± 24.5)		
Electrode 6 pH ≥ 4 over >0 - ≤ 30 min	3.4 (± 4.9)	55.8 (± 31.6)		
Electrode 7 pH ≥ 4 over >0 - ≤ 30 min	1.2 (± 1.8)	49.3 (± 30.6)		
Electrode 8 pH ≥ 4 over >0 - ≤ 30 min	1.9 (± 4)	42.9 (± 36.1)		
Electrode 9 pH ≥ 4 over >0 - ≤ 30 min	0.9 (± 1.9)	45.8 (± 38.6)		
Electrode 10 pH ≥ 4 over >0 - ≤ 30 min	3.8 (± 9.6)	47.7 (± 35.8)		
Electrode 1 pH ≥ 4 over >30 - ≤ 60 min	99.6 (± 0.5)	95.3 (± 15.8)		
Electrode 2 pH ≥ 4 over >30 - ≤ 60 min	94 (± 11.4)	86.1 (± 27.6)		
Electrode 3 pH ≥ 4 over >30 - ≤ 60 min	25.1 (± 34.6)	26.5 (± 33.8)		
Electrode 4 pH ≥ 4 over >30 - ≤ 60 min	14.8 (± 32.9)	4.4 (± 7.9)		
Electrode 5 pH ≥ 4 over >30 - ≤ 60 min	9.6 (± 24.3)	7.6 (± 12.6)		
Electrode 6 pH ≥ 4 over >30 - ≤ 60 min	6.3 (± 22.1)	7.6 (± 13.7)		
Electrode 7 pH ≥ 4 over >30 - ≤ 60 min	6.3 (± 22)	8.6 (± 15.7)		
Electrode 8 pH ≥ 4 over >30 - ≤ 60 min	5 (± 18.5)	8.1 (± 15.4)		
Electrode 9 pH ≥ 4 over >30 - ≤ 60 min	5.7 (± 21)	9.8 (± 18.8)		
Electrode 10 pH ≥ 4 over >30 - ≤ 60 min	6.9 (± 20.1)	10.5 (± 24.9)		
Electrode 1 pH ≥ 4 over >0 - ≤ 10 min	98.9 (± 1)	99.1 (± 1.5)		
Electrode 2 pH ≥ 4 over >0 - ≤ 10 min	92.7 (± 19.3)	99.3 (± 0.4)		
Electrode 3 pH ≥ 4 over >0 - ≤ 10 min	35.9 (± 35.9)	82.4 (± 19)		
Electrode 4 pH ≥ 4 over >0 - ≤ 10 min	36.4 (± 34.5)	81.8 (± 14.5)		
Electrode 5 pH ≥ 4 over >0 - ≤ 10 min	25 (± 28)	79.7 (± 12.2)		
Electrode 6 pH ≥ 4 over >0 - ≤ 10 min	8.9 (± 12.6)	69 (± 23.1)		
Electrode 7 pH ≥ 4 over >0 - ≤ 10 min	2.8 (± 4.9)	47.2 (± 32.1)		
Electrode 8 pH ≥ 4 over >0 - ≤ 10 min	5.5 (± 12.1)	44.9 (± 35.3)		
Electrode 9 pH ≥ 4 over >0 - ≤ 10 min	1.1 (± 3.2)	36.9 (± 36.9)		
Electrode 10 pH ≥ 4 over >0 - ≤ 10 min	6.3 (± 17.5)	49.2 (± 33.6)		
Electrode 1 pH ≥ 4 over >10 - ≤ 20 min	99.4 (± 0.4)	99.5 (± 0)		
Electrode 2 pH ≥ 4 over >10 - ≤ 20 min	94.7 (± 12.9)	96.4 (± 7.2)		
Electrode 3 pH ≥ 4 over >10 - ≤ 20 min	21.3 (± 33.9)	48.7 (± 36.7)		
Electrode 4 pH ≥ 4 over >10 - ≤ 20 min	13 (± 26.2)	64.1 (± 36)		
Electrode 5 pH ≥ 4 over >10 - ≤ 20 min	3.3 (± 7.2)	67.3 (± 37.4)		
Electrode 6 pH ≥ 4 over >10 - ≤ 20 min	1.2 (± 3.1)	61.2 (± 41.3)		
Electrode 7 pH ≥ 4 over >10 - ≤ 20 min	0.2 (± 0.7)	63 (± 35.1)		
Electrode 8 pH ≥ 4 over >10 - ≤ 20 min	0 (± 0)	53.4 (± 39.7)		
Electrode 9 pH ≥ 4 over >10 - ≤ 20 min	0 (± 0.2)	54.6 (± 44.6)		
Electrode 10 pH ≥ 4 over >10 - ≤ 20 min	3.8 (± 10.7)	60.2 (± 43.2)		
Electrode 1 pH ≥ 4 over >20 - ≤ 30 min	99 (± 1.1)	99.3 (± 0.6)		
Electrode 2 pH ≥ 4 over >20 - ≤ 30 min	96.3 (± 5.4)	94.2 (± 13.4)		
Electrode 3 pH ≥ 4 over >20 - ≤ 30 min	26.6 (± 38.3)	31.6 (± 39.6)		
Electrode 4 pH ≥ 4 over >20 - ≤ 30 min	14.1 (± 25.7)	31.1 (± 40.9)		
Electrode 5 pH ≥ 4 over >20 - ≤ 30 min	1.8 (± 4.7)	41.7 (± 42)		
Electrode 6 pH ≥ 4 over >20 - ≤ 30 min	0 (± 0)	36.5 (± 46.7)		
Electrode 7 pH ≥ 4 over >20 - ≤ 30 min	0.6 (± 2.3)	37.1 (± 48.9)		

Electrode 8 pH ≥ 4 over >20 - ≤ 30 min	0.1 ($\pm$ 0.4)	30.1 ($\pm$ 46.6)		
Electrode 9 pH ≥ 4 over >20 - ≤ 30 min	1.5 ($\pm$ 5)	31.6 ($\pm$ 46.6)		
Electrode 10 pH ≥ 4 over >20 - ≤ 30 min	1.4 ($\pm$ 5.2)	33.2 ($\pm$ 43.9)		
Electrode 1 pH ≥ 4 over >30 - ≤ 40 min	99.4 ($\pm$ 0.4)	97.4 ($\pm$ 6.8)		
Electrode 2 pH ≥ 4 over >30 - ≤ 40 min	95.4 ($\pm$ 9.5)	88.8 ($\pm$ 23.1)		
Electrode 3 pH ≥ 4 over >30 - ≤ 40 min	23.6 ($\pm$ 36.9)	26.9 ($\pm$ 38.3)		
Electrode 4 pH ≥ 4 over >30 - ≤ 40 min	17.4 ($\pm$ 35.4)	9.3 ($\pm$ 24.6)		
Electrode 5 pH ≥ 4 over >30 - ≤ 40 min	9.1 ($\pm$ 25.9)	20.7 ($\pm$ 36.1)		
Electrode 6 pH ≥ 4 over >30 - ≤ 40 min	6.4 ($\pm$ 22.6)	19.8 ($\pm$ 34.2)		
Electrode 7 pH ≥ 4 over >30 - ≤ 40 min	7.1 ($\pm$ 26.4)	21.6 ($\pm$ 37.7)		
Electrode 8 pH ≥ 4 over >30 - ≤ 40 min	5.6 ($\pm$ 20.6)	18.8 ($\pm$ 34.4)		
Electrode 9 pH ≥ 4 over >30 - ≤ 40 min	7.2 ($\pm$ 26.6)	21.7 ($\pm$ 35.4)		
Electrode 10 pH ≥ 4 over >30 - ≤ 40 min	5.5 ($\pm$ 20.5)	17.6 ($\pm$ 30.2)		
Electrode 1 pH ≥ 4 over >40 - ≤ 50 min	99 ($\pm$ 1.4)	94.4 ($\pm$ 17.9)		
Electrode 2 pH ≥ 4 over >40 - ≤ 50 min	93.9 ($\pm$ 11)	84 ($\pm$ 32.1)		
Electrode 3 pH ≥ 4 over >40 - ≤ 50 min	23.3 ($\pm$ 38.9)	23.7 ($\pm$ 35.2)		
Electrode 4 pH ≥ 4 over >40 - ≤ 50 min	15.3 ($\pm$ 35.7)	1.7 ($\pm$ 2.2)		
Electrode 5 pH ≥ 4 over >40 - ≤ 50 min	12.1 ($\pm$ 29.5)	1.4 ($\pm$ 3.4)		
Electrode 6 pH ≥ 4 over >40 - ≤ 50 min	7.3 ($\pm$ 26.6)	2.9 ($\pm$ 7.9)		
Electrode 7 pH ≥ 4 over >40 - ≤ 50 min	7.1 ($\pm$ 26.6)	4 ($\pm$ 10)		
Electrode 8 pH ≥ 4 over >40 - ≤ 50 min	7.1 ($\pm$ 26.6)	4.8 ($\pm$ 11.8)		
Electrode 9 pH ≥ 4 over >40 - ≤ 50 min	7.2 ($\pm$ 26.6)	5.2 ($\pm$ 16.8)		
Electrode 10 pH ≥ 4 over >40 - ≤ 50 min	7.4 ($\pm$ 26)	6.7 ($\pm$ 22.9)		
Electrode 1 pH ≥ 4 over >50 - ≤ 60 min	99.4 ($\pm$ 0.4)	93.1 ($\pm$ 22.4)		
Electrode 2 pH ≥ 4 over >50 - ≤ 60 min	91.8 ($\pm$ 19.5)	84.7 ($\pm$ 29.9)		
Electrode 3 pH ≥ 4 over >50 - ≤ 60 min	28.2 ($\pm$ 36.3)	28.5 ($\pm$ 37)		
Electrode 4 pH ≥ 4 over >50 - ≤ 60 min	11.5 ($\pm$ 28.3)	2.2 ($\pm$ 2.7)		
Electrode 5 pH ≥ 4 over >50 - ≤ 60 min	7.5 ($\pm$ 18.5)	0.7 ($\pm$ 2.4)		
Electrode 6 pH ≥ 4 over >50 - ≤ 60 min	5.2 ($\pm$ 16.9)	0.1 ($\pm$ 0.2)		
Electrode 7 pH ≥ 4 over >50 - ≤ 60 min	4.6 ($\pm$ 13.1)	0.1 ($\pm$ 0.2)		
Electrode 8 pH ≥ 4 over >50 - ≤ 60 min	2.3 ($\pm$ 8)	0.8 ($\pm$ 2.8)		
Electrode 9 pH ≥ 4 over >50 - ≤ 60 min	2.7 ($\pm$ 9.5)	2.5 ($\pm$ 9.1)		
Electrode 10 pH ≥ 4 over >50 - ≤ 60 min	7.7 ($\pm$ 16.7)	7 ($\pm$ 25)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Adverse Events (AEs)

End point title	Number of subjects with Adverse Events (AEs)
End point description:	
Safety population.	
TEAE = Treatment Emergent Adverse Event	
SAE = Serious Adverse Event	
End point type	Secondary
End point timeframe:	
Up to follow-up (Day 7, Period 2)	

End point values	Period 1 and 2: Placebo	Period 1 and 2: Gaviscon Double Action Liquid Sachets 20 ml		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	13		
Units: Participants				
Any TEAE	3	0		
Any SAE	0	0		
Discontinued due to AE	0	0		
AE of mild intensity	2	0		
AE of moderate intensity	1	0		
AE of severe intensity	0	0		
Possibly related AE	1	0		
Unlikely related AE	0	0		
Unrelated AE	2	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to follow-up (Day 7, Period 2)

Adverse event reporting additional description:

Treatment-emergent adverse events (TEAE) for Safety population.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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Reporting groups

Reporting group title	Overall trial
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Reporting group description: -

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 15 (20.00%)		
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Infections and infestations			
Cystitis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Rhinitis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		

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