Clinical trial results:
A 26-Week, Multicentre, Randomised, Placebo-Controlled, Double-Blind, Parallel-Group, Phase III Trial with a 26-Week Safety Extension Period Evaluating the Safety and Efficacy of Dapagliflozin 5 and 10 mg, and Saxagliptin 2.5 and 5 mg in Paediatric Patients with Type 2 Diabetes Mellitus Who Are Between 10 and Below 18 Years of Age

Summary

EudraCT number	2015-005042-66
Trial protocol	FI GB PL IT RO
Global end of trial date	03 January 2024

Results information

Result version number	v1 (current)
This version publication date	19 June 2024
First version publication date	19 June 2024

Trial information

Trial identification

Sponsor protocol code	D1680C00019

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03199053
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AstraZeneca
Sponsor organisation address	One Medimmune Way, Gaithersburg, United States, MD 20878
Public contact	Global Clinical Lead, AstraZeneca, +1 877-240-9479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, +1 877-240-9479, information.center@astrazeneca.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 January 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 January 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to determine if there was a greater mean reduction from Baseline in HbA1c achieved after 26 weeks of oral double-blind add-on therapy of dapagliflozin (5 mg or 10 mg [all doses and regimens combined]) or saxagliptin (2.5 mg or 5 mg [all doses and regimens combined]) compared to placebo in paediatric patients with type 2 diabetes mellitus (T2DM) and HbA1c levels of 6.5 to 10.5% on diet and exercise and metformin (IR or XR), insulin, or metformin (IR or XR) plus insulin.

Protection of trial subjects:

This study was performed in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with International Conference on Harmonisation/Good Clinical Practice (GCP), applicable regulatory requirements and the AstraZeneca policy on Bioethics.

Background therapy: -

Evidence for comparator:

Participants were randomised to receive dapagliflozin 5 mg or saxagliptin 2.5 mg (low-dose) or placebo administered orally once daily.

At Week 14, participants initially randomised to dapagliflozin or saxagliptin with Week 12 glycated haemoglobin (HbA1c) values < 7% remained on low-dose dapagliflozin or saxagliptin. Participants with Week 12 HbA1c values ≥ 7% were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to dapagliflozin 10 mg or saxagliptin 5 mg administered orally once daily (high-dose).

At Week 14, all participants randomised to placebo continued on placebo. To maintain blinding, all participants underwent a dummy second randomisation process that was undistinguishable from the actual second randomisation.

Actual start date of recruitment	11 October 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 1
Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Brazil: 14
Country: Number of subjects enrolled	Colombia: 2
Country: Number of subjects enrolled	Finland: 1
Country: Number of subjects enrolled	India: 10
Country: Number of subjects enrolled	Israel: 7

Country: Number of subjects enrolled	Italy: 9
Country: Number of subjects enrolled	Malaysia: 31
Country: Number of subjects enrolled	Mexico: 80
Country: Number of subjects enrolled	New Zealand: 5
Country: Number of subjects enrolled	Philippines: 6
Country: Number of subjects enrolled	Poland: 2
Country: Number of subjects enrolled	Russian Federation: 2
Country: Number of subjects enrolled	Korea, Republic of: 7
Country: Number of subjects enrolled	Taiwan: 5
Country: Number of subjects enrolled	Thailand: 3
Country: Number of subjects enrolled	Türkiye: 14
Country: Number of subjects enrolled	Ukraine: 4
Country: Number of subjects enrolled	United Kingdom: 4
Country: Number of subjects enrolled	United States: 37
Worldwide total number of subjects	245
EEA total number of subjects	12

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)	10
Adolescents (12-17 years)	235
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 245 participants were randomised from 94 sites in 21 countries. Participants were initially randomised in a 1:1:1 ratio to receive dapagliflozin 5 mg, saxagliptin 2.5 mg, or placebo.

11 participants were excluded from analysis due to GCP considerations at the site they originated from (see limitations and caveats for further details).

Pre-assignment

Screening details:

An initial 26-week short-term (ST) period was followed by a 26-week long-term (LT) safety extension period. The study drug was discontinued at Week 52, after which participant continued in the Non-treatment Follow-up Period until Week 104.

Period 1

Period 1 title	ST Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Dapagliflozin

Arm description:

Participants were randomised to receive dapagliflozin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Arm type	Experimental
Investigational medicinal product name	Dapagliflozin
Investigational medicinal product code	
Other name	Forxiga
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Tablets, oral, once daily.

Arm title	Saxagliptin

Arm description:

Participants were randomised to receive saxagliptin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c <

7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Arm type	Experimental
Investigational medicinal product name	Saxagliptin
Investigational medicinal product code	
Other name	Onglyza
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Tablets, oral, once daily.

Arm title	Placebo

Arm description:

Participants were randomised to receive placebo administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

At either Week 32 or Week 40 eligible participants receiving placebo (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.

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

Dosage and administration details:

Tablets, oral, once daily.

Number of subjects in period 1	Dapagliflozin	Saxagliptin	Placebo
Started	81	88	76
Week 14 no uptitration randomisation	39 [1]	36 [2]	0 [3]
Week 14 uptitration randomisation	42 [4]	52 [5]	0 [6]
Completed	76	83	68
Not completed	5	5	8
Consent withdrawn by subject	2	4	6
Lost to follow-up	2	-	1
Withdrawal by parent/guardian	1	1	1

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Inclusive of participants that were eligible for background medication discontinuation only.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Inclusive of participants that were not eligible for background medication discontinuation only.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Eligible participants were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Inclusive of participants that were not eligible for background medication discontinuation only.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Inclusive of participants that were eligible for background medication discontinuation only.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Inclusive of participants that were eligible for background medication discontinuation only.

Period 2

Period 2 title	LT Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Dapagliflozin

Arm description:

Participants were randomised to receive dapagliflozin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Arm type	Experimental
Investigational medicinal product name	Dapagliflozin
Investigational medicinal product code	
Other name	Forxiga
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Tablets, oral, once daily.

Arm title	Saxagliptin

Arm description:

Participants were randomised to receive saxagliptin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Arm type	Experimental
Investigational medicinal product name	Saxagliptin
Investigational medicinal product code	
Other name	Onglyza
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Tablets, oral, once daily.

Arm title	Placebo

Arm description:

Participants were randomised to receive placebo administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

At either Week 32 or Week 40 eligible participants receiving placebo (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.

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

Dosage and administration details:

Tablets, oral, once daily.

Investigational medicinal product name	Saxagliptin
Investigational medicinal product code	
Other name	Onglyza
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details: Tablets, oral, once daily.	
Investigational medicinal product name	Dapagliflozin
Investigational medicinal product code	
Other name	Forxiga
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: Tablets, oral, once daily.	

Number of subjects in period 2	Dapagliflozin	Saxagliptin	Placebo
Started	76	83	68
Randomised Withdrawal Patients Data Set	13 [7]	25 [8]	8 [9]
Excluded Withdrawal Patients Data Set	68 [10]	63 [11]	68
Randomised to Continue Metformin	6 [12]	12 [13]	2 [14]
Randomised Metformin Withdrawal	7 [15]	13 [16]	6 [17]
Completed	75	79	61
Not completed	1	4	7
Consent withdrawn by subject	1	3	3
Miscellaneous	-	-	2
Lost to follow-up	-	1	1
Withdrawal by parent/guardian	-	-	1

Notes:

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to high-dose treatment.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Eligible participants were randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Eligible participants were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Eligible participants were randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin.

[11] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Eligible participants were randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin.

[12] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Participants were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to high-dose treatment.
[13] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Participants were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to high-dose treatment.
[14] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Participants randomised into the placebo arm were not eligible for uptitration randomisation.
[15] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Five participants withdrew following the LT Period, prior to starting the Non-treatment Follow-up Period.

[16] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Participants were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to high-dose treatment.
[17] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Participants randomised into the placebo arm were not eligible for uptitration randomisation.

Period 3

Period 3 title	Non-treatment Follow-up Period
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Dapagliflozin

Arm description:

Participants were randomised to receive dapagliflozin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Saxagliptin

Arm description:

Participants were randomised to receive saxagliptin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or

insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Placebo

Arm description:

Participants were randomised to receive placebo administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

At either Week 32 or Week 40 eligible participants receiving placebo (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 3[18]	Dapagliflozin	Saxagliptin	Placebo
Started	74	77	59
Completed	67	68	52
Not completed	7	9	7
Consent withdrawn by subject	2	1	-
Miscellaneous	-	1	-
Lost to follow-up	3	4	5
Withdrawal by parent/guardian	2	3	2

Notes:

[18] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Five participants withdrew following the LT Period, prior to starting the Non-treatment Follow-up Period.

Baseline characteristics

Reporting groups	
Reporting group title	Dapagliflozin

Reporting group description:

Participants were randomised to receive dapagliflozin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Reporting group title	Saxagliptin

Reporting group description:

Participants were randomised to receive saxagliptin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Reporting group title	Placebo

Reporting group description:

Participants were randomised to receive placebo administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

At either Week 32 or Week 40 eligible participants receiving placebo (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.

Reporting group values	Dapagliflozin	Saxagliptin	Placebo
Number of subjects	81	88	76
Age categorical Units: Subjects			
≥ 10 and < 15 years	38	43	35
≥ 15 and < 18 years	43	45	41
Age Continuous Units: years			
arithmetic mean	14.4	14.5	14.7

standard deviation	± 2.00	± 1.75	± 1.64

Sex: Female, Male Units:			
Female	49	53	44
Male	32	35	32
Race/Ethnicity, Customized Units: Subjects			
White	42	50	32
Black or African American	7	4	3
Asian	18	23	24
Native Hawaiian or Other Pacific Islander	0	0	3
American Indian or Alaska Native	11	7	12
Other	3	4	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	45	43	34
Not Hispanic or Latino	36	45	42
Unknown or Not Reported	0	0	0
Mean Baseline HbA1c Units: Percentage HbA1c			
arithmetic mean	8.22	8.02	7.96
standard deviation	± 1.459	± 1.431	± 1.629

Reporting group values	Total		
Number of subjects	245		
Age categorical Units: Subjects			
≥ 10 and < 15 years	116		
≥ 15 and < 18 years	129		
Age Continuous Units: years arithmetic mean standard deviation	- -		
Sex: Female, Male Units:			
Female	146		
Male	99		
Race/Ethnicity, Customized Units: Subjects			
White	124		
Black or African American	14		
Asian	65		
Native Hawaiian or Other Pacific Islander	3		
American Indian or Alaska Native	30		
Other	9		
Ethnicity (NIH/OMB) Units: Subjects			

Hispanic or Latino	122		
Not Hispanic or Latino	123		
Unknown or Not Reported	0		
Mean Baseline HbA1c			
Units: Percentage HbA1c			
arithmetic mean			
standard deviation	-		

End points reporting groups

Reporting group title	Dapagliflozin

Reporting group description:

Participants were randomised to receive dapagliflozin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Reporting group title	Saxagliptin

Reporting group description:

Participants were randomised to receive saxagliptin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Reporting group title	Placebo

Reporting group description:

Participants were randomised to receive placebo administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

At either Week 32 or Week 40 eligible participants receiving placebo (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.

Reporting group title	Dapagliflozin

Reporting group description:

Participants were randomised to receive dapagliflozin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-

dose treatment.

Reporting group title	Saxagliptin

Reporting group description:

Participants were randomised to receive saxagliptin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Reporting group title	Placebo

Reporting group description:

Participants were randomised to receive placebo administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

At either Week 32 or Week 40 eligible participants receiving placebo (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.

Reporting group title	Dapagliflozin

Reporting group description:

Participants were randomised to receive dapagliflozin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Reporting group title	Saxagliptin

Reporting group description:

Participants were randomised to receive saxagliptin administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Reporting group title	Placebo

Reporting group description:

Participants were randomised to receive placebo administered orally once daily in the ST treatment period.

In the LT treatment period, participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation.

At either Week 32 or Week 40 eligible participants receiving placebo (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.

Subject analysis set title	Dapagliflozin 5 mg/10 mg (weighted)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were randomised to receive dapagliflozin 5 mg administered orally once daily (low-dose). At Week 14, participants with Week 12 HbA1c values < 7% remained on low-dose dapagliflozin (weight = 1). Participants with Week 12 HbA1c values ≥ 7% were re-randomised in a 1:1 ratio to continue on low-dose treatment (weight = 0) or to uptitrate to dapagliflozin 10 mg administered orally once daily (high-dose) (weight = 2).

After completion of the ST treatment period, participants could enter the LT treatment period.

Subject analysis set title	Saxagliptin 2.5 mg/5 mg (weighted)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were randomised to receive saxagliptin 2.5 mg administered orally once daily (low-dose). At Week 14, participants with Week 12 HbA1c values < 7% remained on low-dose saxagliptin (weight = 1). Participants with Week 12 HbA1c values ≥ 7% were re-randomised in a 1:1 ratio to continue on low-dose treatment (weight = 0) or to uptitrate to saxagliptin 5 mg administered orally once daily (high-dose) (weight = 2).

After completion of the ST treatment period, participants could enter the LT treatment period.

Subject analysis set title	Placebo (weight = 1)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were randomised to receive placebo administered orally once daily. At Week 14, all participants continued on placebo. To maintain blinding, all participants underwent a dummy second randomisation process that was undistinguishable from the actual second randomisation.

After completion of the ST treatment period, participants could enter the LT treatment period.

Subject analysis set title	Dapagliflozin 10 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were randomised to receive dapagliflozin 5 mg administered orally once daily (low-dose). At Week 14, participants with Week 12 HbA1c values ≥ 7% were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to dapagliflozin 10 mg administered orally once daily (high-dose).

After completion of the ST treatment period, participants could enter the LT treatment period.

Subject analysis set title	Dapagliflozin 5 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were randomised to receive dapagliflozin 5 mg administered orally once daily (low-dose). At Week 14, participants with Week 12 HbA1c values < 7% remained on low-dose dapagliflozin. Participants with Week 12 HbA1c values ≥ 7% were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to dapagliflozin 10 mg administered orally once daily (high-dose).

After completion of the ST treatment period, participants could enter the LT treatment period.

Subject analysis set title	Saxagliptin 5 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were randomised to receive saxagliptin 2.5 mg administered orally once daily (low-dose). At

Week 14, participants with Week 12 HbA1c values ≥ 7% were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to saxagliptin 5 mg administered orally once daily (high-dose).

After completion of the ST treatment period, participants could enter the LT treatment period.

Subject analysis set title	Saxagliptin 2.5 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were randomised to receive saxagliptin 2.5 mg administered orally once daily (low-dose). At Week 14, participants with Week 12 HbA1c values < 7% remained on low-dose saxagliptin. Participants with Week 12 HbA1c values ≥ 7% were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to saxagliptin 5 mg administered orally once daily (high-dose).

After completion of the ST treatment period, participants could enter the LT treatment period.

Primary: Dapagliflozin Versus Placebo: Adjusted Mean Change From Baseline in HbA1c at Week 26

End point title	Dapagliflozin Versus Placebo: Adjusted Mean Change From Baseline in HbA1c at Week 26[1]

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline HbA1c as covariate. Missing Week 26 data was handled based on multiple imputation washout (MI-WO) within each arm using the data from placebo participants with Week 26 data.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period.

End point type	Primary

End point timeframe:

Baseline and Week 26

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: All arms in the baseline period could not be reported here due to the adjusted mean placebo results.

End point values	Dapagliflozin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	70		
Units: Percentage HbA1c				
arithmetic mean (standard error)	-0.62 (± 0.218)	0.41 (± 0.218)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Dapagliflozin v Placebo
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-1.03

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.57
upper limit	-0.49
Variability estimate	Standard error of the mean
Dispersion value	0.274

Primary: Saxagliptin Versus Placebo: Adjusted Mean Change From Baseline in HbA1c at Week 26

End point title	Saxagliptin Versus Placebo: Adjusted Mean Change From Baseline in HbA1c at Week 26[2]

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline HbA1c as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period.

End point type	Primary

End point timeframe:

Baseline and Week 26

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: All arms in the baseline period could not be reported here due to the adjusted mean placebo results.

End point values	Saxagliptin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	70		
Units: Percentage HbA1c				
arithmetic mean (standard error)	0.06 (± 0.198)	0.50 (± 0.202)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin v Placebo
Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.078
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-0.44

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.93
upper limit	0.05
Variability estimate	Standard error of the mean
Dispersion value	0.251

Secondary: Dapagliflozin Low-dose/High-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in HbA1c at Week 26

End point title	Dapagliflozin Low-dose/High-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in HbA1c at Week 26

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline HbA1c as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Dapagliflozin participants were weighted as follows: participants who had HbA1c < 7% at Week 12 and remained on low-dose were assigned a weight of 1; participants who had HbA1c >= 7% at Week 12 and continued on the low-dose were assigned a weight of 0; participants who had HbA1c >= 7% at Week 12 and received the high-dose were assigned a weight of 2; all participants who do not undergo second randomisation were assigned a weight of 1. Placebo participants were assigned a weight of 1.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Dapagliflozin 5 mg/10 mg (weighted)	Placebo (weight = 1)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	54	70		
Units: Percentage HbA1c				
arithmetic mean (standard error)	-0.42 (± 0.214)	0.43 (± 0.207)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Dapagliflozin 5 mg/10 mg (weighted) v Placebo (weight = 1)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.44
upper limit	-0.27
Variability estimate	Standard error of the mean
Dispersion value	0.3

Secondary: Saxagliptin Low-dose/High-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in HbA1c at Week 26

End point title	Saxagliptin Low-dose/High-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in HbA1c at Week 26

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline HbA1c as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Saxagliptin participants were weighted as follows: participants who had HbA1c < 7% at Week 12 and remained on low-dose were assigned a weight of 1; participants who had HbA1c >= 7% at Week 12 and continued on the low-dose were assigned a weight of 0; participants who had HbA1c >= 7% at Week 12 and received the high-dose were assigned a weight of 2; all participants who do not undergo second randomisation were assigned a weight of 1. Placebo participants were assigned a weight of 1.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Saxagliptin 2.5 mg/5 mg (weighted)	Placebo (weight = 1)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	58	70		
Units: Percentage HbA1c				
arithmetic mean (standard error)	-0.04 (± 0.190)	0.47 (± 0.200)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin 2.5 mg/5 mg (weighted) v Placebo (weight = 1)
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.067
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.05
upper limit	0.04
Variability estimate	Standard error of the mean
Dispersion value	0.277

Secondary: Dapagliflozin Low-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in HbA1c at Week 26

End point title	Dapagliflozin Low-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in HbA1c at Week 26

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline HbA1c as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Dapagliflozin participants were weighted as follows: participants who had HbA1c < 7% at Week 12 and remained on low-dose were assigned a weight of 1; participants who had HbA1c >= 7% at Week 12 and continued on the low-dose were assigned a weight of 2; participants who had HbA1c >= 7% at Week 12 and received the high-dose were assigned a weight of 0; all participants who do not undergo second randomisation were assigned a weight of 1. Placebo participants were assigned a weight of 1.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Dapagliflozin 5 mg/10 mg (weighted)	Placebo (weight = 1)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	56	70		
Units: Percentage HbA1c				
arithmetic mean (standard error)	-0.79 (± 0.202)	0.40 (± 0.205)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Dapagliflozin 5 mg/10 mg (weighted) v Placebo (weight = 1)
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.76
upper limit	-0.62
Variability estimate	Standard error of the mean
Dispersion value	0.29

Secondary: Saxagliptin Low-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in HbA1c at Week 26

End point title	Saxagliptin Low-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in HbA1c at Week 26

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline HbA1c as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Saxagliptin participants were weighted as follows: participants who had HbA1c < 7% at Week 12 and remained on low-dose were assigned a weight of 1; participants who had HbA1c >= 7% at Week 12 and continued on the low-dose were assigned a weight of 2; participants who had HbA1c >= 7% at Week 12 and received the high-dose were assigned a weight of 0; all participants who do not undergo second randomisation were assigned a weight of 1. Placebo participants were assigned a weight of 1.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Saxagliptin 2.5 mg/5 mg (weighted)	Placebo (weight = 1)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	57	70		
Units: Percentage HbA1c				
arithmetic mean (standard error)	0.07 (± 0.188)	0.47 (± 0.194)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin 2.5 mg/5 mg (weighted) v Placebo (weight = 1)
Number of subjects included in analysis	127
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.146
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.92
upper limit	0.14
Variability estimate	Standard error of the mean
Dispersion value	0.27

Secondary: Dapagliflozin Versus Placebo: Adjusted Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Week 26

End point title	Dapagliflozin Versus Placebo: Adjusted Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Week 26[3]

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline FPG as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms in the baseline period could not be reported here due to the adjusted mean placebo results.

End point values	Dapagliflozin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	68		
Units: mmol/L				
arithmetic mean (standard error)	-0.57 (± 0.374)	0.51 (± 0.384)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Dapagliflozin v Placebo
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.024
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.02
upper limit	-0.14
Variability estimate	Standard error of the mean
Dispersion value	0.479

Secondary: Dapagliflozin Low-dose/High-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in FPG at Week 26

End point title	Dapagliflozin Low-dose/High-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in FPG at Week 26

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline FPG as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Dapagliflozin participants were weighted as follows: participants who had HbA1c < 7% at Week 12 and remained on low-dose were assigned a weight of 1; participants who had HbA1c >= 7% at Week 12 and continued on the low-dose were assigned a weight of 0; participants who had HbA1c >= 7% at Week 12 and received the high-dose were assigned a weight of 2; all participants who do not undergo second randomisation were assigned a weight of 1. Placebo participants were assigned a weight of 1.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Dapagliflozin 5 mg/10 mg (weighted)	Placebo (weight = 1)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	54	68		
Units: mmol/L				
arithmetic mean (standard error)	-0.34 (± 0.365)	0.70 (± 0.369)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Dapagliflozin 5 mg/10 mg (weighted) v Placebo (weight = 1)
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.047
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.07
upper limit	-0.01
Variability estimate	Standard error of the mean
Dispersion value	0.525

Secondary: Saxagliptin Versus Placebo: Adjusted Mean Change From Baseline in FPG at Week 26

End point title	Saxagliptin Versus Placebo: Adjusted Mean Change From Baseline in FPG at Week 26[4]

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline FPG as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms in the baseline period could not be reported here due to the adjusted mean placebo results.

End point values	Saxagliptin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	68		
Units: mmol/L				
arithmetic mean (standard error)	0.08 (± 0.413)	0.19 (± 0.428)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin v Placebo

Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.833
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.15
upper limit	0.92
Variability estimate	Standard error of the mean
Dispersion value	0.528

Secondary: Saxagliptin Low-dose/High-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in FPG at Week 26

End point title	Saxagliptin Low-dose/High-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in FPG at Week 26

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline FPG as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Saxagliptin participants were weighted as follows: participants who had HbA1c < 7% at Week 12 and remained on low-dose were assigned a weight of 1; participants who had HbA1c >= 7% at Week 12 and continued on the low-dose were assigned a weight of 0; participants who had HbA1c >= 7% at Week 12 and received the high-dose were assigned a weight of 2; all participants who do not undergo second randomisation were assigned a weight of 1. Placebo participants were assigned a weight of 1.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Saxagliptin 2.5 mg/5 mg (weighted)	Placebo (weight = 1)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	57	68		
Units: mmol/L				
arithmetic mean (standard error)	0.18 (± 0.331)	0.73 (± 0.359)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin 2.5 mg/5 mg (weighted) v Placebo (weight = 1)

Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.268
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	0.42
Variability estimate	Standard error of the mean
Dispersion value	0.49

Secondary: Dapagliflozin Low-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in FPG at Week 26

End point title	Dapagliflozin Low-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in FPG at Week 26

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline FPG as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Dapagliflozin participants were weighted as follows: participants who had HbA1c < 7% at Week 12 and remained on low-dose were assigned a weight of 1; participants who had HbA1c >= 7% at Week 12 and continued on the low-dose were assigned a weight of 2; participants who had HbA1c >= 7% at Week 12 and received the high-dose were assigned a weight of 0; all participants who do not undergo second randomisation were assigned a weight of 1. Placebo participants were assigned a weight of 1.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Dapagliflozin 5 mg/10 mg (weighted)	Placebo (weight = 1)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	56	68		
Units: mmol/L				
arithmetic mean (standard error)	-0.56 (± 0.347)	0.56 (± 0.363)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Dapagliflozin 5 mg/10 mg (weighted) v Placebo (weight = 1)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.026
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.11
upper limit	-0.13
Variability estimate	Standard error of the mean
Dispersion value	0.505

Secondary: Saxagliptin Low-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in FPG at Week 26

End point title	Saxagliptin Low-dose Versus Placebo (Weighted): Adjusted Mean Change From Baseline in FPG at Week 26

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline FPG as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Saxagliptin participants were weighted as follows: participants who had HbA1c < 7% at Week 12 and remained on low-dose were assigned a weight of 1; participants who had HbA1c >= 7% at Week 12 and continued on the low-dose were assigned a weight of 2; participants who had HbA1c >= 7% at Week 12 and received the high-dose were assigned a weight of 0; all participants who do not undergo second randomisation were assigned a weight of 1. Placebo participants were assigned a weight of 1.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Saxagliptin 2.5 mg/5 mg (weighted)	Placebo (weight = 1)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	55	68		
Units: mmol/L				
arithmetic mean (standard error)	0.63 (± 0.424)	0.34 (± 0.446)		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin 2.5 mg/5 mg (weighted) v Placebo (weight = 1)
Number of subjects included in analysis	123
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.644
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.92
upper limit	1.5
Variability estimate	Standard error of the mean
Dispersion value	0.618

Secondary: Percentage of Participants with Baseline HbA1c ≥ 7% who achieved HbA1c < 7% at Week 26

End point title	Percentage of Participants with Baseline HbA1c ≥ 7% who achieved HbA1c < 7% at Week 26

End point description:

A logistic regression model adjusting for sex, age group, background antidiabetes medication and Baseline HbA1c was used. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with Baseline HbA1c >= 7% and available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Dapagliflozin	Saxagliptin	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	61	50	
Units: Percentage of participants				
number (not applicable)	26.6	21.3	10.0	

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin v Placebo

Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.114
Method	Regression, Logistic
Parameter estimate	Adjusted Odds Ratio
Point estimate	2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	8.6

Statistical analysis title	Comparison between groups
Comparison groups	Dapagliflozin v Placebo
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.019
Method	Regression, Logistic
Parameter estimate	Adjusted Odds Ratio
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	11.7

Secondary: Low-dose/High-dose Versus Placebo (Weighted): Percentage of Participants with Baseline HbA1c ≥ 7% who achieved HbA1c < 7% at Week 26

End point title	Low-dose/High-dose Versus Placebo (Weighted): Percentage of Participants with Baseline HbA1c ≥ 7% who achieved HbA1c < 7% at Week 26

End point description:

A weighted logistic regression model adjusting for sex, age group, background antidiabetes medication and Baseline HbA1c was used. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Participants were weighted as follows: participants who had HbA1c < 7% at Week 12 and remained on low-dose were assigned a weight of 1; participants who had HbA1c >= 7% at Week 12 and continued on the low-dose were assigned a weight of 0; participants who had HbA1c >= 7% at Week 12 and received the high-dose were assigned a weight of 2; all participants who do not undergo second randomisation were assigned a weight of 1. Placebo participants were assigned a weight of 1.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with Baseline HbA1c >= 7% and available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Dapagliflozin 5 mg/10 mg (weighted)	Saxagliptin 2.5 mg/5 mg (weighted)	Placebo (weight = 1)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	44	41	50	
Units: Percentage of participants				
number (not applicable)	27.3	24.4	10.0	

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin 2.5 mg/5 mg (weighted) v Placebo (weight = 1)
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.175
Method	Weighted Logistic Regression
Parameter estimate	Adjusted Odds Ratio
Point estimate	2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	7.4

Statistical analysis title	Comparison between groups
Comparison groups	Dapagliflozin 5 mg/10 mg (weighted) v Placebo (weight = 1)
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.042
Method	Weighted Logistic Regression
Parameter estimate	Adjusted Odds Ratio
Point estimate	3.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	11.4

Secondary: Low-dose Versus Placebo (Weighted): Percentage of Participants with

Baseline HbA1c ≥ 7% who achieved HbA1c < 7% at Week 26

End point title	Low-dose Versus Placebo (Weighted): Percentage of Participants with Baseline HbA1c ≥ 7% who achieved HbA1c < 7% at Week 26

End point description:

A weighted logistic regression model adjusting for sex, age group, background antidiabetes medication and Baseline HbA1c was used. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Participants were weighted as follows: participants who had HbA1c < 7% at Week 12 and remained on low-dose were assigned a weight of 1; participants who had HbA1c >= 7% at Week 12 and continued on the low-dose were assigned a weight of 2; participants who had HbA1c >= 7% at Week 12 and received the high-dose were assigned a weight of 0; all participants who do not undergo second randomisation were assigned a weight of 1. Placebo participants were assigned a weight of 1.

Randomised Participants Data Set: consisted of all randomised participants who receive at least one dose of study medication during the treatment period. Includes participants with Baseline HbA1c >= 7% and available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Dapagliflozin 5 mg/10 mg (weighted)	Saxagliptin 2.5 mg/5 mg (weighted)	Placebo (weight = 1)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	45	38	50	
Units: Percentage of participants				
number (not applicable)	35.6	28.9	10.0	

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin 2.5 mg/5 mg (weighted) v Placebo (weight = 1)
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.042
Method	Weighted Logistic Regression
Parameter estimate	Adjusted Odds Ratio
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	13.5

Statistical analysis title	Comparison between groups

Comparison groups	Dapagliflozin 5 mg/10 mg (weighted) v Placebo (weight = 1)
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Weighted Logistic Regression
Parameter estimate	Adjusted Odds Ratio
Point estimate	4.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	13.2

Secondary: Low-dose Versus Uptitration to the High Dose: Adjusted Mean Change From Baseline in HbA1c at Week 26

End point title	Low-dose Versus Uptitration to the High Dose: Adjusted Mean Change From Baseline in HbA1c at Week 26

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline HbA1c as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Uptitration Randomised Participants Data Set: consisted of the subset of randomised participants who were up-titration randomised because their HbA1c is greater than or equal to 7% at Week 12 (regardless of rescue medication initiation). Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Dapagliflozin 10 mg	Dapagliflozin 5 mg	Saxagliptin 5 mg	Saxagliptin 2.5 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	21	25	24
Units: Percentage HbA1c				
arithmetic mean (standard error)	-0.74 (± 0.368)	-0.71 (± 0.384)	-0.16 (± 0.361)	0.07 (± 0.372)

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin 5 mg v Saxagliptin 2.5 mg

Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.64
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	0.74
Variability estimate	Standard error of the mean
Dispersion value	0.495

Statistical analysis title	Comparison between groups
Comparison groups	Dapagliflozin 10 mg v Dapagliflozin 5 mg
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.955
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0.94
Variability estimate	Standard error of the mean
Dispersion value	0.496

Secondary: Low-dose Versus Uptitration to the High Dose: Adjusted Mean Change From Baseline in FPG at Week 26

End point title	Low-dose Versus Uptitration to the High Dose: Adjusted Mean Change From Baseline in FPG at Week 26

End point description:

Data was analysed with an ANCOVA model with treatment, sex, age group and background antidiabetes medication as factors and Baseline FPG as covariate. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Uptitration Randomised Participants Data Set: consisted of the subset of randomised participants who were up-titration randomised because their HbA1c is greater than or equal to 7% at Week 12 (regardless of rescue medication initiation). Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Dapagliflozin 10 mg	Dapagliflozin 5 mg	Saxagliptin 5 mg	Saxagliptin 2.5 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	21	25	23
Units: mmol/L				
arithmetic mean (standard error)	-1.62 (± 0.689)	-0.98 (± 0.683)	-2.38 (± 0.734)	-0.56 (± 0.763)

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Dapagliflozin 10 mg v Dapagliflozin 5 mg
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.476
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.39
upper limit	1.12
Variability estimate	Standard error of the mean
Dispersion value	0.896

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin 5 mg v Saxagliptin 2.5 mg
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.075
Method	ANCOVA
Parameter estimate	Adjusted mean difference
Point estimate	-1.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.81
upper limit	0.18
Variability estimate	Standard error of the mean
Dispersion value	1.017

Secondary: Dapagliflozin Low-dose Versus Uptitration to the High Dose: Percentage of Participants with Baseline HbA1c ≥ 7% who achieved HbA1c < 7% at Week 26

End point title	Dapagliflozin Low-dose Versus Uptitration to the High Dose: Percentage of Participants with Baseline HbA1c ≥ 7% who achieved HbA1c < 7% at Week 26

End point description:

A Fisher's exact test was used and unadjusted difference in percentage of participants and Clopper-Pearson CIs presented using imputed data. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Uptitration Randomised Participants Data Set: consisted of the subset of randomised participants who were up-titration randomised because their HbA1c is greater than or equal to 7% at Week 12 (regardless of rescue medication initiation). Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Dapagliflozin 10 mg	Dapagliflozin 5 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19	20		
Units: Percentage of participants				
number (not applicable)	5.3	25.0		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Dapagliflozin 10 mg v Dapagliflozin 5 mg
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.182
Method	Fisher exact
Parameter estimate	Unadjusted Difference in Percentage
Point estimate	-19.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.5
upper limit	5.7

Secondary: Saxagliptin Low-dose Versus Uptitration to the High Dose: Percentage of Participants with Baseline HbA1c ≥ 7% who achieved HbA1c < 7% at Week 26

End point title	Saxagliptin Low-dose Versus Uptitration to the High Dose: Percentage of Participants with Baseline HbA1c ≥ 7% who achieved HbA1c < 7% at Week 26

End point description:

A Fisher's exact test was used and unadjusted difference in percentage of participants and Clopper-Pearson CIs presented using imputed data. Missing Week 26 data was handled based on MI-WO within each arm using the data from placebo participants with Week 26 data.

Uptitration Randomised Participants Data Set: consisted of the subset of randomised participants who were up-titration randomised because their HbA1c is greater than or equal to 7% at Week 12 (regardless of rescue medication initiation). Includes participants with available data only.

End point type	Secondary

End point timeframe:

Baseline and Week 26

End point values	Saxagliptin 5 mg	Saxagliptin 2.5 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	23	20		
Units: Percentage of participants				
number (not applicable)	8.7	15.0		

Statistical analyses

Statistical analysis title	Comparison between groups
Comparison groups	Saxagliptin 5 mg v Saxagliptin 2.5 mg
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.65
Method	Fisher exact
Parameter estimate	Unadjusted Difference in Percentage
Point estimate	-6.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.8
upper limit	16.5

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality: Up to Week 104
Serious and other adverse events (AEs): Up to 52 Weeks + 30 days (Week 56)

Adverse event reporting additional description:

Treated Participants Data Set: consisted of all participants who received at least one dose of study medication. As pre-specified in the statistical analysis plan, AEs data for participants continuing on metformin following third randomization and for participants who were not eligible for the third randomization were not collected separately.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Weeks 1 to 14: Saxagliptin 2.5 mg

Reporting group description:

Participants were randomised to receive saxagliptin 2.5 mg administered orally once daily (low-dose).

Reporting group title	Weeks 14 to 26: Saxagliptin 5 mg

Reporting group description:

At Week 14, participants with Week 12 HbA1c values ≥ 7% were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to saxagliptin 5 mg administered orally once daily (high-dose).

Reporting group title	Weeks 1 to 14: Dapagliflozin 5 mg

Reporting group description:

Participants were randomised to receive dapagliflozin 5 mg administered orally once daily (low-dose).

Reporting group title	Weeks 14 to 26: Dapagliflozin 5 mg

Reporting group description:

At Week 14, participants with Week 12 HbA1c values < 7% remained on low-dose dapagliflozin. Participants with Week 12 HbA1c values ≥ 7% were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to dapagliflozin 10 mg administered orally once daily (high-dose).

Reporting group title	Weeks 32/40 to 56: Dapagliflozin 10 mg + Metformin Withdrawal

Reporting group description:

After completion of the ST treatment period, participants could enter the LT treatment period. A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Reporting group title	Weeks 14 to 26: Saxagliptin 2.5 mg

Reporting group description:

At Week 14, participants with Week 12 HbA1c values < 7% remained on low-dose saxagliptin. Participants with Week 12 HbA1c values ≥ 7% were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to saxagliptin 5 mg administered orally once daily (high-dose).

Reporting group title	Weeks 26 to 56: Dapagliflozin 5 mg

Reporting group description:

After completion of the ST treatment period, participants could enter the LT treatment period. Participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation. A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. Participants who were randomized to continue background medication with metformin continued with their current dose of

dapagliflozin.

Reporting group title	Weeks 26 to 56: Dapagliflozin 10 mg

Reporting group description:

After completion of the ST treatment period, participants could enter the LT treatment period. Participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation. A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. Participants who were randomized to continue background medication with metformin continued with their current dose of dapagliflozin.

Reporting group title	Weeks 14 to 26: Dapagliflozin 10 mg

Reporting group description:

At Week 14, participants with Week 12 HbA1c values ≥ 7% were re-randomised in a 1:1 ratio to continue on low-dose treatment or to uptitrate to dapagliflozin 10 mg administered orally once daily (high-dose).

Reporting group title	Weeks 32 or 40 to 56: Placebo

Reporting group description:

Participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation. At either Week 32 or Week 40 eligible participants receiving placebo were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.

Reporting group title	W32/40 to 56: Placebo to Dapagliflozin + Metformin Withdrawal

Reporting group description:

At either Week 32 or Week 40 eligible participants receiving placebo were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.

Reporting group title	Weeks 26 to 56: Saxagliptin 2.5 mg

Reporting group description:

After completion of the ST treatment period, participants could enter the LT treatment period. Participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation. A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. Participants who were randomized to continue background medication with metformin continued with their current dose of saxagliptin.

Reporting group title	Weeks 26 to 56: Saxagliptin 5 mg

Reporting group description:

After completion of the ST treatment period, participants could enter the LT treatment period. Participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation. A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin and dapagliflozin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. Participants who were randomized to continue background medication with metformin continued with their current dose of saxagliptin.

Reporting group title	Weeks 32/40 to 56: Saxagliptin 5 mg + Metformin Withdrawal

Reporting group description:

After completion of the ST treatment period, participants could enter the LT treatment period. A subset of eligible participants (on background treatment with metformin only and who had HbA1c < 7.5% at Week 26 or Week 32) were grouped into 2 separate strata for saxagliptin, and then randomised 1:1 within each of the strata to either continue or discontinue background medication with metformin at either Week 32 or Week 40. For participants randomised to withdraw background treatment with metformin, those receiving high-dose treatment continued to receive high-dose treatment, whereas those currently receiving low-dose treatment had their doses uptitrated to high-dose treatment.

Reporting group title	Weeks 1 to 14: Placebo
Reporting group description:	
Participants were randomised to receive placebo administered orally once daily.	

Reporting group title	Weeks 14 to 26: Placebo
Reporting group description:	
At Week 14, all participants continued on placebo. To maintain blinding, all participants underwent a dummy second randomisation process that was undistinguishable from the actual second randomisation.	

Reporting group title	Week 56 to 104: Non-treatment Follow-up Period
Reporting group description:	
Safety monitoring continued in the Non-treatment Follow-up Period quarterly between the Week 56 and Week 104 visits.	

Reporting group title	W32/40 to 56: Placebo to Saxagliptin + Metformin Withdrawal
Reporting group description:	
At either Week 32 or Week 40 eligible participants receiving placebo were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.	

Reporting group title	Weeks 26 to 32 or 40: Placebo
Reporting group description:	
After completion of the ST treatment period, participants could enter the LT treatment period. Participants who were receiving background medication with insulin only or insulin and metformin (not eligible for the third randomisation) continued with their randomised study drug assigned after the second randomisation. At either Week 32 or Week 40 eligible participants receiving placebo were randomised 1:1:1 to either withdraw background medication with metformin and switch to active treatment with either saxagliptin 5 mg or dapagliflozin 10 mg or to remain on background medication with metformin and continue with placebo.	

Serious adverse events	Weeks 1 to 14: Saxagliptin 2.5 mg	Weeks 14 to 26: Saxagliptin 5 mg	Weeks 1 to 14: Dapagliflozin 5 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 88 (2.27%)	0 / 26 (0.00%)	1 / 81 (1.23%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
Transaminases increased			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (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
Injury, poisoning and procedural complications			
Splenic rupture			

subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
Accidental overdose			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
Nervous system disorders			
Presyncope			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (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
Abdominal pain upper			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
Gastritis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
Reproductive system and breast disorders			
Ovarian cyst			

subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
Gastroenteritis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
Urinary tract infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
COVID-19			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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
Euglycaemic diabetic ketoacidosis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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

Hyperglycaemia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (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

Serious adverse events	Weeks 14 to 26: Dapagliflozin 5 mg	Weeks 32/40 to 56: Dapagliflozin 10 mg + Metformin Withdrawal	Weeks 14 to 26: Saxagliptin 2.5 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Transaminases increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Injury, poisoning and procedural complications			
Splenic rupture			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Accidental overdose			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Nervous system disorders			
Presyncope			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Abdominal pain upper			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Gastritis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Gastroenteritis			

subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Urinary tract infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
COVID-19			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Euglycaemic diabetic ketoacidosis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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
Hyperglycaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (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

Serious adverse events	Weeks 26 to 56: Dapagliflozin 5 mg	Weeks 26 to 56: Dapagliflozin 10 mg	Weeks 14 to 26: Dapagliflozin 10 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 55 (9.09%)	1 / 21 (4.76%)	0 / 21 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Glycosylated haemoglobin increased			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (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

Transaminases increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (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
Injury, poisoning and procedural complications			
Splenic rupture			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (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
Accidental overdose			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Presyncope			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (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	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (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
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (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
Abdominal pain upper			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (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
Gastritis			

subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (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
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 55 (0.00%)	1 / 21 (4.76%)	0 / 21 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (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
Gastroenteritis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (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
Urinary tract infection			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (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
Metabolism and nutrition disorders			
Diabetic ketoacidosis			

subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (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
Euglycaemic diabetic ketoacidosis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (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

Serious adverse events	Weeks 32 or 40 to 56: Placebo	W32/40 to 56: Placebo to Dapagliflozin + Metformin Withdrawal	Weeks 26 to 56: Saxagliptin 2.5 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	3 / 61 (4.92%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Transaminases increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Injury, poisoning and procedural complications			
Splenic rupture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Accidental overdose			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Nervous system disorders			
Presyncope			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Abdominal pain upper			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Gastritis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Renal and urinary disorders			
Haematuria			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Urinary tract infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
COVID-19			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Euglycaemic diabetic ketoacidosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (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
Hyperglycaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	2 / 61 (3.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Weeks 26 to 56: Saxagliptin 5 mg	Weeks 32/40 to 56: Saxagliptin 5 mg + Metformin Withdrawal	Weeks 1 to 14: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	1 / 76 (1.32%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Transaminases increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Injury, poisoning and procedural complications			
Splenic rupture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Accidental overdose			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Nervous system disorders			
Presyncope			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Gastrointestinal disorders			

Abdominal pain lower			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Abdominal pain upper			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Gastritis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	0 / 76 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Gastroenteritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Urinary tract infection			

subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
COVID-19			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Euglycaemic diabetic ketoacidosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (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
Hyperglycaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Weeks 14 to 26: Placebo	Week 56 to 104: Non-treatment Follow-up Period	W32/40 to 56: Placebo to Saxagliptin + Metformin Withdrawal
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Transaminases increased			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Injury, poisoning and procedural complications			
Splenic rupture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Accidental overdose			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Nervous system disorders			
Presyncope			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Abdominal pain upper			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Gastritis			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Gastroenteritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Urinary tract infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
COVID-19			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Metabolism and nutrition disorders			
Diabetic ketoacidosis			

subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (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
Euglycaemic diabetic ketoacidosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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
Hyperglycaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (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

Serious adverse events	Weeks 26 to 32 or 40: Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 70 (4.29%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Investigations			
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transaminases increased			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Splenic rupture			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accidental overdose			

subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Presyncope			
subjects affected / exposed	1 / 70 (1.43%)		
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 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Haematuria			

subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Euglycaemic diabetic ketoacidosis			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Weeks 1 to 14: Saxagliptin 2.5 mg	Weeks 14 to 26: Saxagliptin 5 mg	Weeks 1 to 14: Dapagliflozin 5 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	37 / 88 (42.05%)	10 / 26 (38.46%)	35 / 81 (43.21%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
Adenoidectomy			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Nasal septal operation			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Tonsillectomy			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Sphenoid sinus operation			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Drug intolerance			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	1	0	1
Swelling face			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Dysmenorrhoea			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	2	0	0
Premenstrual pain			

subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Vulvovaginal pruritus			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 88 (0.00%)	1 / 26 (3.85%)	0 / 81 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Nasal obstruction			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Obstructive airways disorder			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Rhinorrhoea			

subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	2	0	1
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Anxiety disorder			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Persistent depressive disorder			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Tic			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Albumin urine present			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Bacterial test			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood glucose normal			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
C-telopeptide increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0

Hepatic enzyme increased			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Mean cell haemoglobin concentration decreased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Mean cell haemoglobin decreased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
White blood cells urine positive			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	2 / 81 (2.47%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			

Limb injury			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Radius fracture			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Scratch			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	1	0	1
Tooth fracture			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Thermal burn			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 88 (0.00%)	1 / 26 (3.85%)	0 / 81 (0.00%)
occurrences (all)	0	1	0
Closed globe injury			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Joint dislocation			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0

Ligament sprain			
subjects affected / exposed	1 / 88 (1.14%)	1 / 26 (3.85%)	0 / 81 (0.00%)
occurrences (all)	1	1	0
Cardiac disorders			
Left ventricular hypertrophy			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 88 (2.27%)	0 / 26 (0.00%)	6 / 81 (7.41%)
occurrences (all)	2	0	7
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			

subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 88 (2.27%)	0 / 26 (0.00%)	2 / 81 (2.47%)
occurrences (all)	2	0	2
Abdominal pain upper			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Aphthous ulcer			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	3 / 81 (3.70%)
occurrences (all)	1	0	3
Gastritis			

subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Food poisoning			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	3 / 88 (3.41%)	0 / 26 (0.00%)	3 / 81 (3.70%)
occurrences (all)	3	0	4
Tooth impacted			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 88 (0.00%)	2 / 26 (7.69%)	0 / 81 (0.00%)
occurrences (all)	0	2	0
Vomiting			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	3 / 81 (3.70%)
occurrences (all)	1	0	3
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	2 / 88 (2.27%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	2	0	1
Hepatomegaly			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 88 (0.00%)	1 / 26 (3.85%)	1 / 81 (1.23%)
occurrences (all)	0	1	1
Alopecia			

subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Dermatitis allergic			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 88 (0.00%)	1 / 26 (3.85%)	1 / 81 (1.23%)
occurrences (all)	0	1	1
Dermatitis contact			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Dermatitis atopic			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Ingrown hair			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			

subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Diabetic nephropathy			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Microalbuminuria			
subjects affected / exposed	2 / 88 (2.27%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	2	0	0
Nocturia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Nephropathy			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Nephrolithiasis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Polyuria			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0

Renal colic			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Primary hypothyroidism			
subjects affected / exposed	0 / 88 (0.00%)	1 / 26 (3.85%)	0 / 81 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Acute sinusitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Balanitis candida			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Fungal balanitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0

Fungal skin infection			
subjects affected / exposed	0 / 88 (0.00%)	1 / 26 (3.85%)	0 / 81 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Gastritis viral			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	2 / 88 (2.27%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	2	0	1
Gastrointestinal infection			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	2 / 88 (2.27%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	2	0	1
Hordeolum			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Nail infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 88 (2.27%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	2	0	1
Norovirus infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0

Otitis externa			
subjects affected / exposed	0 / 88 (0.00%)	1 / 26 (3.85%)	0 / 81 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Otitis media bacterial			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	1	0	1
Pericoronitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	3 / 81 (3.70%)
occurrences (all)	1	0	3
Respiratory tract infection viral			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Soft tissue infection			
subjects affected / exposed	0 / 88 (0.00%)	1 / 26 (3.85%)	0 / 81 (0.00%)
occurrences (all)	0	1	0
Subcutaneous abscess			
subjects affected / exposed	1 / 88 (1.14%)	1 / 26 (3.85%)	0 / 81 (0.00%)
occurrences (all)	1	1	0

Tinea versicolour			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Tinea cruris			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Tonsillitis bacterial			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	3 / 88 (3.41%)	1 / 26 (3.85%)	3 / 81 (3.70%)
occurrences (all)	3	1	3
Upper respiratory tract infection			
subjects affected / exposed	2 / 88 (2.27%)	1 / 26 (3.85%)	1 / 81 (1.23%)
occurrences (all)	2	1	1
Viral infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0

Vulvovaginal candidiasis			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Dyslipidaemia			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 88 (0.00%)	1 / 26 (3.85%)	0 / 81 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	4 / 81 (4.94%)
occurrences (all)	1	0	4
Hypermagnesaemia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Hypoglycaemia			
subjects affected / exposed	1 / 88 (1.14%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	2	0	0
Metabolic disorder			

subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 88 (0.00%)	0 / 26 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	4 / 88 (4.55%)	0 / 26 (0.00%)	2 / 81 (2.47%)
occurrences (all)	4	0	2

Non-serious adverse events	Weeks 14 to 26: Dapagliflozin 5 mg	Weeks 32/40 to 56: Dapagliflozin 10 mg + Metformin Withdrawal	Weeks 14 to 26: Saxagliptin 2.5 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 55 (25.45%)	2 / 7 (28.57%)	18 / 61 (29.51%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
Adenoidectomy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nasal septal operation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tonsillectomy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Sphenoid sinus operation			

subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Drug intolerance			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Amenorrhoea			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	1
Premenstrual pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Obstructive airways disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Anxiety disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Generalised anxiety disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Nervousness			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Persistent depressive disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Albumin urine present			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Bacterial test			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood glucose normal			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
C-telopeptide increased			

subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Mean cell haemoglobin concentration decreased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Mean cell haemoglobin decreased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
White blood cells urine positive			

subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Animal bite			

subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Closed globe injury			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Left ventricular hypertrophy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Wolff-Parkinson-White syndrome			
subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	5 / 55 (9.09%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	5	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Somnolence			

subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			

subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	1
Food poisoning			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tooth impacted			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Hepatomegaly			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			

subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Ingrown hair			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Diabetic nephropathy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Microalbuminuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Nephrolithiasis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Primary hypothyroidism			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			

subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	1
Balanitis candida			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Croup infectious			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1

Ear infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fungal balanitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Gastritis viral			
subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Gastrointestinal infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	3 / 61 (4.92%)
occurrences (all)	0	0	3
Hordeolum			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 55 (3.64%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	2	0	1
Norovirus infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Otitis media bacterial			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pericoronitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 7 (14.29%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Rhinitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Tinea cruris			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 7 (14.29%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Tonsillitis bacterial			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Tooth abscess			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Viral infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dyslipidaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			

subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	1
Hypermagnesaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Metabolic disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 55 (1.82%)	0 / 7 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	1

Non-serious adverse events	Weeks 26 to 56: Dapagliflozin 5 mg	Weeks 26 to 56: Dapagliflozin 10 mg	Weeks 14 to 26: Dapagliflozin 10 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 55 (47.27%)	8 / 21 (38.10%)	4 / 21 (19.05%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			

Adenoidectomy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nasal septal operation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tonsillectomy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Sphenoid sinus operation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Drug intolerance			
subjects affected / exposed	0 / 55 (0.00%)	1 / 21 (4.76%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Swelling face			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			

Seasonal allergy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Hypersensitivity			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 55 (0.00%)	2 / 21 (9.52%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Premenstrual pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Nasal obstruction			

subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Obstructive airways disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Anxiety disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Persistent depressive disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Albumin urine present			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Bacterial test			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Blood glucose normal			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood parathyroid hormone increased			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Blood pressure increased			

subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
C-telopeptide increased			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Crystal urine present			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Mean cell haemoglobin concentration decreased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Mean cell haemoglobin decreased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			

subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Weight increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Tooth fracture			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Thermal burn			

subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Animal bite			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Closed globe injury			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Left ventricular hypertrophy			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	2 / 55 (3.64%)	2 / 21 (9.52%)	0 / 21 (0.00%)
occurrences (all)	2	3	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 55 (0.00%)	1 / 21 (4.76%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Ocular hyperaemia			

subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	2 / 55 (3.64%)	0 / 21 (0.00%)	1 / 21 (4.76%)
occurrences (all)	2	0	1
Aphthous ulcer			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Gastritis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Tooth impacted			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 55 (1.82%)	1 / 21 (4.76%)	0 / 21 (0.00%)
occurrences (all)	1	1	0

Vomiting			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Hepatomegaly			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Alopecia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			

subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ingrown hair			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Diabetic nephropathy			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Microalbuminuria			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0

Nocturia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Primary hypothyroidism			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 55 (0.00%)	1 / 21 (4.76%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Balanitis candida			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Chronic sinusitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fungal balanitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Fungal foot infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastritis viral			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 55 (0.00%)	1 / 21 (4.76%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	3 / 55 (5.45%)	0 / 21 (0.00%)	1 / 21 (4.76%)
occurrences (all)	3	0	1
Hordeolum			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 55 (1.82%)	1 / 21 (4.76%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Norovirus infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Otitis media bacterial			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Pericoronitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Pharyngotonsillitis			
subjects affected / exposed	1 / 55 (1.82%)	1 / 21 (4.76%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tinea cruris			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tonsillitis bacterial			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Viral pharyngitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dyslipidaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			

subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 55 (0.00%)	1 / 21 (4.76%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hypermagnesaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Metabolic disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	1 / 55 (1.82%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Vitamin D deficiency			
subjects affected / exposed	2 / 55 (3.64%)	0 / 21 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Weeks 32 or 40 to 56: Placebo	W32/40 to 56: Placebo to Dapagliflozin + Metformin Withdrawal	Weeks 26 to 56: Saxagliptin 2.5 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 53 (3.77%)	1 / 3 (33.33%)	23 / 61 (37.70%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1

Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Adenoidectomy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Nasal septal operation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Tonsillectomy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Sphenoid sinus operation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Drug intolerance			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Pyrexia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Premenstrual pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 53 (1.89%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0

Epistaxis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Nasal septum deviation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Obstructive airways disorder			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	4
Oropharyngeal pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Anxiety disorder			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Persistent depressive disorder			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tic			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Albumin urine present			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Bacterial test			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Blood glucose increased			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood glucose normal			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
C-telopeptide increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Mean cell haemoglobin concentration decreased			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Mean cell haemoglobin decreased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Scratch			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	1 / 53 (1.89%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Wound complication			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Closed globe injury			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 53 (0.00%)	1 / 3 (33.33%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Left ventricular hypertrophy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Cataract			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Tooth impacted			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Erythema			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Ingrown hair			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Diabetic nephropathy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Dysuria			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Microalbuminuria			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Renal colic			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Primary hypothyroidism			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Bronchitis			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Balanitis candida			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fungal balanitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Gastritis viral			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Norovirus infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Otitis media bacterial			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pericoronitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tinea cruris			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			

subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tonsillitis bacterial			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	3 / 61 (4.92%)
occurrences (all)	0	0	3
Upper respiratory tract infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	4 / 61 (6.56%)
occurrences (all)	0	0	4
Viral infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	4 / 61 (6.56%)
occurrences (all)	0	0	4
Metabolism and nutrition disorders			

Diabetic ketoacidosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dyslipidaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Hypertriglyceridaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Hypermagnesaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Metabolic disorder			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 53 (0.00%)	0 / 3 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Weeks 26 to 56: Saxagliptin 5 mg	Weeks 32/40 to 56: Saxagliptin 5 mg + Metformin Withdrawal	Weeks 1 to 14: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 26 (46.15%)	3 / 13 (23.08%)	39 / 76 (51.32%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Adenoidectomy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nasal septal operation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tonsillectomy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sphenoid sinus operation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Drug intolerance			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	2 / 76 (2.63%)
occurrences (all)	0	0	2
Swelling face			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Immunisation reaction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Dysmenorrhoea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	2 / 76 (2.63%)
occurrences (all)	0	0	2
Premenstrual pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			

subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 26 (0.00%)	1 / 13 (7.69%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 13 (7.69%)	1 / 76 (1.32%)
occurrences (all)	0	1	2
Nasal congestion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Nasal obstruction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Obstructive airways disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	4	0	1
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Anxiety disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Persistent depressive disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	2 / 76 (2.63%)
occurrences (all)	0	0	2
Albumin urine present			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	2 / 76 (2.63%)
occurrences (all)	0	0	2
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bacterial test			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood glucose normal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
C-telopeptide increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	2
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Low density lipoprotein increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Mean cell haemoglobin concentration decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Mean cell haemoglobin decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	2 / 76 (2.63%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Radius fracture			

subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Road traffic accident			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Closed globe injury			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Left ventricular hypertrophy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	2
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Lymphadenopathy			

subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	2 / 76 (2.63%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Colitis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	3 / 76 (3.95%)
occurrences (all)	0	0	3
Gastritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Food poisoning			

subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tooth impacted			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	2
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Hepatomegaly			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dermatitis			

subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Dermatitis contact			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Ingrowing nail			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ingrown hair			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			

subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Diabetic nephropathy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Microalbuminuria			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Nocturia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Primary hypothyroidism			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	2 / 76 (2.63%)
occurrences (all)	1	0	2
Joint swelling			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	2
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Asymptomatic bacteriuria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Balanitis candida			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Fungal balanitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Fungal infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Gastritis viral			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	2 / 76 (2.63%)
occurrences (all)	1	0	2
Hordeolum			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Nail infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 26 (0.00%)	2 / 13 (15.38%)	2 / 76 (2.63%)
occurrences (all)	0	2	2
Norovirus infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Otitis media			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Otitis media bacterial			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	2 / 76 (2.63%)
occurrences (all)	0	0	2
Pericoronitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Tinea cruris			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tonsillitis bacterial			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	4 / 76 (5.26%)
occurrences (all)	1	0	5
Upper respiratory tract infection			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	2 / 76 (2.63%)
occurrences (all)	1	0	2
Viral infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1

COVID-19			
subjects affected / exposed	0 / 26 (0.00%)	1 / 13 (7.69%)	2 / 76 (2.63%)
occurrences (all)	0	1	2
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Dyslipidaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Hypermagnesaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	3 / 76 (3.95%)
occurrences (all)	0	0	4
Hypoglycaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Metabolic disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Obesity			

subjects affected / exposed	0 / 26 (0.00%)	0 / 13 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 26 (3.85%)	0 / 13 (0.00%)	5 / 76 (6.58%)
occurrences (all)	1	0	5

Non-serious adverse events	Weeks 14 to 26: Placebo	Week 56 to 104: Non-treatment Follow-up Period	W32/40 to 56: Placebo to Saxagliptin + Metformin Withdrawal
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 70 (34.29%)	0 / 210 (0.00%)	1 / 3 (33.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Adenoidectomy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal septal operation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tonsillectomy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sphenoid sinus operation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Chest discomfort			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug intolerance			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Swelling face			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Premenstrual pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Obstructive airways disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 70 (2.86%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anxiety disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Persistent depressive disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tic			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Albumin urine present			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacterial test			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood glucose normal			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood triglycerides increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
C-telopeptide increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mean cell haemoglobin concentration decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mean cell haemoglobin decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			

subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Scratch			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Closed globe injury			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ligament sprain			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Left ventricular hypertrophy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 70 (2.86%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 70 (2.86%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Food poisoning			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth impacted			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Hypertransaminasaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ingrown hair			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Diabetic nephropathy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Microalbuminuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nephropathy			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Pollakiuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Primary hypothyroidism			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 70 (2.86%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balanitis candida			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Cystitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal balanitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal foot infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis viral			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	2 / 70 (2.86%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hordeolum			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Nail infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Norovirus infection			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otitis media bacterial			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pericoronitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Respiratory tract infection viral			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Tinea versicolour			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Tinea cruris			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tonsillitis bacterial			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 70 (2.86%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Viral infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyslipidaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	2 / 70 (2.86%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hypermagnesaemia			

subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolic disorder			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 70 (0.00%)	0 / 210 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 70 (1.43%)	0 / 210 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1

Non-serious adverse events	Weeks 26 to 32 or 40: Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 70 (41.43%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hot flush			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Hypertension			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Surgical and medical procedures			
Adenoidectomy			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		

Nasal septal operation subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Tonsillectomy subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Sphenoid sinus operation subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
General disorders and administration site conditions Chest discomfort subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Pain subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Fatigue subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1		
Drug intolerance subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Chest pain subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Pyrexia subjects affected / exposed occurrences (all)	2 / 70 (2.86%) 3		
Swelling face subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Immunisation reaction			

subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Hypersensitivity			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Dysmenorrhoea			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	2		
Premenstrual pain			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Vulvovaginal pruritus			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences (all)	2		
Epistaxis			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Nasal obstruction			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Nasal septum deviation			

subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Obstructive airways disorder			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Rhinitis allergic			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Anxiety disorder			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Generalised anxiety disorder			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Nervousness			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Persistent depressive disorder			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		

Tic			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences (all)	2		
Albumin urine present			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Bacterial test			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Blood cholesterol increased			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Blood glucose increased			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Blood glucose normal			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Blood parathyroid hormone increased			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Blood pressure increased			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Blood triglycerides increased			

subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	1			
C-telopeptide increased				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Crystal urine present				
subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	1			
Glycosylated haemoglobin increased				
subjects affected / exposed	2 / 70 (2.86%)			
occurrences (all)	2			
Hepatic enzyme increased				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Low density lipoprotein increased				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Liver function test increased				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Mean cell haemoglobin concentration decreased				
subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	1			
Transaminases increased				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Mean cell haemoglobin decreased				
subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	1			
Urine albumin/creatinine ratio increased				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Weight increased				

subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
White blood cells urine positive			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Vitamin D decreased			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Radius fracture			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Road traffic accident			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Scratch			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Skin abrasion			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Tooth fracture			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Thermal burn			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Wound complication			

subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Animal bite			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Closed globe injury			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Joint dislocation			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Left ventricular hypertrophy			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Peripheral sensory neuropathy			

subjects affected / exposed occurrences (all) Somnolence subjects affected / exposed occurrences (all) Syncope subjects affected / exposed occurrences (all) Tremor subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0 0 / 70 (0.00%) 0 0 / 70 (0.00%) 0 0 / 70 (0.00%) 0		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) Iron deficiency anaemia subjects affected / exposed occurrences (all) Lymphadenopathy subjects affected / exposed occurrences (all)	 0 / 70 (0.00%) 0 1 / 70 (1.43%) 1 0 / 70 (0.00%) 0		
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	 0 / 70 (0.00%) 0		
Eye disorders Cataract subjects affected / exposed occurrences (all) Conjunctivitis allergic subjects affected / exposed occurrences (all) Ocular hyperaemia subjects affected / exposed occurrences (all)	 0 / 70 (0.00%) 0 0 / 70 (0.00%) 0 0 / 70 (0.00%) 0		
Gastrointestinal disorders			

Abdominal pain				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Abdominal pain upper				
subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	1			
Aphthous ulcer				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Colitis				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Diarrhoea				
subjects affected / exposed	2 / 70 (2.86%)			
occurrences (all)	2			
Gastritis				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Food poisoning				
subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	1			
Irritable bowel syndrome				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	3 / 70 (4.29%)			
occurrences (all)	3			
Tooth impacted				
subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	1			
Toothache				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Vomiting				
subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	2			

Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Hepatomegaly			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Hypertransaminasaemia			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Alopecia			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Dermatitis			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Dermatitis allergic			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Eczema			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Dermatitis contact			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Dermatitis atopic			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			

subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Ingrowing nail			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Ingrown hair			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Rash maculo-papular			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Diabetic nephropathy			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Haematuria			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Microalbuminuria			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Nocturia			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		

Nephropathy			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Nephrolithiasis			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Pollakiuria			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Polyuria			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Proteinuria			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Renal colic			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Hypothyroidism			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Primary hypothyroidism			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Joint swelling			

subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences (all)	2		
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Asymptomatic bacteriuria			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Bronchitis			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Balanitis candida			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Chronic sinusitis			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		

Croup infectious				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Ear infection				
subjects affected / exposed	2 / 70 (2.86%)			
occurrences (all)	2			
Cystitis				
subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	1			
Fungal balanitis				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Fungal foot infection				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Fungal skin infection				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Fungal infection				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Gastritis viral				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Gastrointestinal infection				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Gastroenteritis viral				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	2 / 70 (2.86%)			
occurrences (all)	2			

Hordeolum				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Hand-foot-and-mouth disease				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Nail infection				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	3 / 70 (4.29%)			
occurrences (all)	4			
Norovirus infection				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Otitis media				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Otitis media bacterial				
subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	1			
Pharyngitis				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Pericoronitis				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Paronychia				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Pharyngotonsillitis				
subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	1			

Respiratory tract infection				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	1 / 70 (1.43%)			
occurrences (all)	1			
Respiratory tract infection viral				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Soft tissue infection				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Subcutaneous abscess				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Tinea versicolour				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Tinea cruris				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Tonsillitis				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Tonsillitis bacterial				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Tooth abscess				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Tooth infection				
subjects affected / exposed	0 / 70 (0.00%)			
occurrences (all)	0			
Urinary tract infection				
subjects affected / exposed	5 / 70 (7.14%)			
occurrences (all)	6			

Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 2		
Viral infection subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Viral pharyngitis subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1		
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Vulvovaginal candidiasis subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
COVID-19 subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1		
Metabolism and nutrition disorders Diabetic ketoacidosis subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Diabetes mellitus subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Dyslipidaemia subjects affected / exposed occurrences (all)	0 / 70 (0.00%) 0		
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 70 (1.43%) 1		
Hypercholesterolaemia			

subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Hypertriglyceridaemia			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Hypermagnesaemia			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Hyperuricaemia			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Hypoglycaemia			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Metabolic disorder			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences (all)	1		
Obesity			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 October 2016	The original study design was entirely revised in accordance with Food and Drug Administration (FDA)-specified preferred study objectives and design.
04 April 2017	Protocol revised to reflect cessation of Bristol-Myers Squibb's role in the study, and the specified preferred objectives and procedures following European Medicines Agency and FDA review. A post treatment visit was also added at Week 104.
04 October 2018	Protocol revised to reflect modifications in study design based on recommendations from FDA, i.e., addition of randomised withdrawal of background medication in a subset of eligible participants from the active treatment groups, and randomised withdrawal of background medication or switch to active treatment in a subset of eligible participants in the placebo group. Collection of vital status removed.
27 June 2019	Protocol revised to reflect modifications in study design, i.e., extension of the screening period and change in the screening/retesting design, update of safety concerns and monitoring of AEs of interest, revision of fasting blood glucose, growth, bone and maturation marker measurements, as well as Tanner staging schedules in participants who discontinued study drug early, and clarification of initiation or uptitration of insulin at the Rescue Visit and AE/serious AE collection until study completion. In addition, correction of the study drug dispensation schedule was incorporated and some common language added or revised in several sections for harmonisation across all AstraZeneca clinical study protocols.
24 September 2020	Protocol revised to specify that visits should be delayed to maintain an interval of at least 12 weeks between the Week 14 and Week 26 visits and between the third randomisation visit (for participants undergoing third randomisation) and the Week 52 visit in case the Week 14 or third randomisation visit was delayed. This change was instituted because HbA1c is derived from the average of the blood glucose fluctuation in the preceding 3 months and therefore, approximately 12 weeks of exposure to a new dose is needed to demonstrate efficacy. Short- and long-term period study visits could be delayed by a maximum of 11 months in total. If the duration of study drug administration was longer than 52 (+1) weeks, the safety follow-up period was to be shortened such that the complete study duration did not exceed 104 weeks. The Week-104 visit was not to be delayed. If more than 12 weeks elapsed between the HbA1c collection at Week 26 and the third randomisation at Week 32, or the HbA1c collection at Week 32 and the third randomisation at Week 40, the participant was not to go through this randomisation since the HbA1c value would no longer be reliable to ascertain eligibility for the third randomisation.

07 February 2022	Following changes made to the protocol: To allow for flexibility in scheduling, the window period for the Week 104 post-dose visit was modified from "± 7 days" to "-28 days to +7 days" from the original scheduled date. Based on discussions with FDA, the primary objective was modified to assess the effect of all doses and regimens combined for each drug vs placebo. In line with this, the primary and secondary objectives were reordered and updated. The reordering was done to make overall analysis (all doses for each treatment) as the primary objective. The secondary objectives were updated to follow the order/hierarchy of overall, followed by low-dose/high-dose regimen testing, followed by low-dose regimen testing. Corresponding to the change in primary objective, the primary analysis was updated as: "The primary analysis will be performed using an analysis of covariance (ANCOVA)". Other key changes: Based on discussions with FDA, the analyses were updated to use a fully alpha of 0.05 to test each drug vs placebo rather than the current split into 0.025. For power analysis, the assumption of an effect size of 0.75% rather than 0.5% was used.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to legal dispute, the source documents could not be accessed for 11 participants at 1 site. All data from this site were excluded as documented in the statistical analysis plan.

Notes: