

**Clinical trial results:****An Open Label, Intravenous to Oral Switch, Multiple Dose Study to Evaluate the Pharmacokinetics, Safety and Tolerability of Voriconazole in Immunocompromised Children Aged 2 to Below 12 Years who are at High Risk for Systemic Fungal Infection****Summary**

EudraCT number	2012-001133-14
Trial protocol	Outside EU/EEA
Global end of trial date	26 October 2009

Results information

Result version number	v1 (current)
This version publication date	23 May 2016
First version publication date	22 July 2015

Trial information**Trial identification**

Sponsor protocol code	A1501088
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00739934
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 East 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center , Pfizer, Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center , Pfizer, Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-000191-PIP01-08
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	23 March 2010
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	26 October 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To characterize the pharmacokinetics of voriconazole following an intravenous (IV) to oral switch regimen in immunocompromised children aged 2 to below 12 years who were at high risk for systemic fungal infection.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 December 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 40
Worldwide total number of subjects	40
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	40
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects were recruited from 11 centers in United States. Study was started from 09 Dec 2008 and completed on 26 Oct 2009.

Period 1

Period 1 title	Baseline period
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	All Subjects
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Arm description:

Voriconazole intravenous (IV) dosing regimen was administered on Days 1 to 7 (up to Day 20 or more if clinically indicated). The oral maintenance dosing regimen was administered following voriconazole IV and lasted 6.5 days (up to Day 30 if clinically indicated).

Arm type	Experimental
Investigational medicinal product name	Voriconazole
Investigational medicinal product code	
Other name	Vfend
Pharmaceutical forms	Infusion, Oral suspension
Routes of administration	Oral use, Intravenous use

Dosage and administration details:

Voriconazole IV dosing regimen (7 mg/kg every 12 hours) was administered in the morning and evening on Days 1 to 7 (up to Day 20 or more if clinically indicated) with a maximum infusion rate of 3 mg/kg/hr. The oral maintenance dosing regimen (200 mg every 12 hours) was administered following voriconazole IV in the morning and evening and lasted 6.5 days (up to Day 30 if clinically indicated).

Number of subjects in period 1	All Subjects
Started	40
Completed	40

Period 2

Period 2 title	Voriconazole IV
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Voriconazole IV
Arm description: Voriconazole IV doses were administered.	
Arm type	Experimental
Investigational medicinal product name	Voriconazole
Investigational medicinal product code	
Other name	Vfend
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Voriconazole IV dosing regimen (7 mg/kg every 12 hours) was administered in the morning and evening on Days 2 to 7 (up to Day 20 or more if clinically indicated) with a maximum infusion rate of 3 mg/kg/hr.

Number of subjects in period 2	Voriconazole IV
Started	40
Completed	34
Not completed	6
Adverse Event	6

Period 3

Period 3 title	Voriconazole Oral
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Voriconazole Oral
Arm description: Voriconazole oral doses were administered following voriconazole IV.	
Arm type	Experimental
Investigational medicinal product name	Voriconazole
Investigational medicinal product code	
Other name	Vfend
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

The oral maintenance dosing regimen (200 mg every 12 hours) was administered following voriconazole IV in the morning and evening and lasted 6.5 days (up to Day 30 if clinically indicated).

Number of subjects in period 3	Voriconazole Oral
Started	34
Completed	31
Not completed	3
Unspecified	3

Baseline characteristics

Reporting groups

Reporting group title	Baseline period
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Reporting group description: -

Reporting group values	Baseline period	Total	
Number of subjects	40	40	
Age categorical			
Units: Subjects			
2 to less than (<) 6 years	24	24	
6 to <12 years	16	16	
Gender categorical			
Units: Subjects			
Female	17	17	
Male	23	23	

End points

End points reporting groups

Reporting group title	All Subjects
Reporting group description: Voriconazole intravenous (IV) dosing regimen was administered on Days 1 to 7 (up to Day 20 or more if clinically indicated). The oral maintenance dosing regimen was administered following voriconazole IV and lasted 6.5 days (up to Day 30 if clinically indicated).	
Reporting group title	Voriconazole IV
Reporting group description: Voriconazole IV doses were administered.	
Reporting group title	Voriconazole Oral
Reporting group description: Voriconazole oral doses were administered following voriconazole IV.	

Primary: Area Under the Curve Over Dosing Interval at Steady State (AUC_{12,ss}) Following IV Administration

End point title	Area Under the Curve Over Dosing Interval at Steady State (AUC _{12,ss}) Following IV Administration ^[1]
End point description: AUC _{12,ss} = Area under the plasma concentration-time profile from time zero (predose) to twelve hours at steady-state. AUC _{12,ss} was obtained by the Linear or Log trapezoidal method. This analysis included the intent-to-treat (ITT) population- subjects who had completed PK blood sampling for at least one day.	
End point type	Primary
End point timeframe: Day 7 (up to Day 20 or more) at predose, 60 and 138 minutes, 4, 6, 8 and 12 hours postdose	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Only descriptive data was planned to be reported for this endpoint.	

End point values	Voriconazole IV			
Subject group type	Reporting group			
Number of subjects analysed	36 ^[2]			
Units: microgram*hour per milliliter (µg*h/mL)				
geometric mean (standard deviation)	21.42 (± 35.05)			

Notes:

[2] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Primary: Peak Plasma Concentration at Steady State (C_{max,ss}) Following IV Administration

End point title	Peak Plasma Concentration at Steady State (C _{max,ss}) Following IV Administration ^[3]
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End point description:

This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type Primary

End point timeframe:

Day 7 (up to Day 20 or more) at predose, 60 and 138 minutes, 4, 6, 8 and 12 hours postdose

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Voriconazole IV			
Subject group type	Reporting group			
Number of subjects analysed	36 ^[4]			
Units: µg/mL				
geometric mean (standard deviation)	4.26 (± 3.73)			

Notes:

[4] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Primary: Time to Reach Cmax (Tmax) Following IV Administration

End point title Time to Reach Cmax (Tmax) Following IV Administration^[5]

End point description:

This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type Primary

End point timeframe:

Day 7 (up to Day 20 or more) at predose, 60 and 138 minutes, 4, 6, 8 and 12 hours postdose

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Voriconazole IV			
Subject group type	Reporting group			
Number of subjects analysed	36 ^[6]			
Units: hours				
median (full range (min-max))	2.3 (1 to 4.07)			

Notes:

[6] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Primary: AUC_{12,ss} Following Oral Administration

End point title AUC_{12,ss} Following Oral Administration^[7]

End point description:

AUC_{12,ss} = Area under the plasma concentration-time profile from time zero (predose) to twelve hours at steady-state. AUC_{12,ss} was obtained by the Linear or Log trapezoidal method. This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type Primary

End point timeframe:

Day 7 (or later) predose, 1, 2, 4, 6, 8 and 12 hours postdose

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Voriconazole Oral			
Subject group type	Reporting group			
Number of subjects analysed	33 ^[8]			
Units: µg*h/mL				
geometric mean (standard deviation)	18.64 (± 50.63)			

Notes:

[8] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Primary: C_{max,ss} Following Oral Administration

End point title C_{max,ss} Following Oral Administration^[9]

End point description:

This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type Primary

End point timeframe:

Day 7 (or later) predose, 1, 2, 4, 6, 8 and 12 hours postdose

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Voriconazole Oral			
Subject group type	Reporting group			
Number of subjects analysed	33 ^[10]			
Units: µg/mL				
geometric mean (standard deviation)	3.62 (± 4.66)			

Notes:

[10] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Primary: Tmax Following Oral Administration

End point title	Tmax Following Oral Administration ^[11]
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End point description:

This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type	Primary
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End point timeframe:

Day 7 (or later) predose, 1, 2, 4, 6, 8 and 12 hours postdose

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Voriconazole Oral			
Subject group type	Reporting group			
Number of subjects analysed	33 ^[12]			
Units: hours				
median (full range (min-max))	1.07 (0.73 to 8.03)			

Notes:

[12] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC12 Following an IV Loading Dose

End point title	AUC12 Following an IV Loading Dose
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End point description:

AUC12 = Area under the plasma concentration-time profile from time zero (predose) to twelve hours. AUC12 was obtained by the Linear or Log trapezoidal method. This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type	Secondary
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End point timeframe:

Day 1 predose, 60 and 138 minutes, 4, 6, 8 and 12 hours postdose

End point values	Voriconazole IV			
Subject group type	Reporting group			
Number of subjects analysed	33 ^[13]			
Units: µg*h/mL				
geometric mean (standard deviation)	7.85 (± 6.71)			

Notes:

[13] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax Following an IV Loading Dose

End point title	Cmax Following an IV Loading Dose
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End point description:

This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type	Secondary
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End point timeframe:

Day 1 predose, 60 and 138 minutes, 4, 6, 8 and 12 hours postdose

End point values	Voriconazole IV			
Subject group type	Reporting group			
Number of subjects analysed	33 ^[14]			
Units: µg/mL				
geometric mean (standard deviation)	2.15 (± 1.1)			

Notes:

[14] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax Following an IV Loading Dose

End point title	Tmax Following an IV Loading Dose
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End point description:

This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type	Secondary
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End point timeframe:

Day 1 predose, 60 and 138 minutes, 4, 6, 8 and 12 hours postdose

End point values	Voriconazole IV			
Subject group type	Reporting group			
Number of subjects analysed	33 ^[15]			
Units: hours				
median (full range (min-max))	2.3 (1.72 to 4.08)			

Notes:

[15] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Concentrations (Cmin)

End point title	Trough Concentrations (Cmin)
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End point description:

This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day. Here, n = number of subjects who contributed to data.

End point type Secondary

End point timeframe:

Day 7 (up to Day 20 or more) for IV; Day 7 (or later) for oral at predose

End point values	All Subjects			
Subject group type	Reporting group			
Number of subjects analysed	36 ^[16]			
Units: µg/mL				
geometric mean (standard deviation)				
IV Day 7 (up to Day 20) (n=36)	0.61 (± 2.56)			
Oral Day 7 (up to Day 30) (n=32)	0.52 (± 3.32)			

Notes:

[16] - N = number of subjects with analyzable data

Statistical analyses

No statistical analyses for this end point

Secondary: AUC_{12,ss} of N-oxide Voriconazole Metabolite (UK-121, 265) Following IV Administration

End point title AUC_{12,ss} of N-oxide Voriconazole Metabolite (UK-121, 265) Following IV Administration

End point description:

AUC_{12,ss} = Area under the plasma concentration-time profile from time zero (predose) to twelve hours at steady-state. AUC_{12,ss} was obtained by the Linear or Log trapezoidal method. This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type Secondary

End point timeframe:

Days 1 and 7 (up to Day 20 or more) predose, 60 and 138 minutes, 4, 6, 8 and 12 hours postdose

End point values	Voriconazole IV			
Subject group type	Reporting group			
Number of subjects analysed	39 ^[17]			
Units: µg*h/mL				
geometric mean (standard deviation)				
Day 1	20.98 (± 8.05)			
Day 7 (up to Day 20)	41.95 (± 14.3)			

Notes:

[17] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Secondary: C_{max,ss} of N-oxide Voriconazole Metabolite (UK-121, 265) Following IV Administration

End point title	C _{max,ss} of N-oxide Voriconazole Metabolite (UK-121, 265) Following IV Administration
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End point description:

This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type	Secondary
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End point timeframe:

Days 1 and 7 (up to Day 20 or more) predose, 60 and 138 minutes, 4, 6, 8 and 12 hours postdose

End point values	Voriconazole IV			
Subject group type	Reporting group			
Number of subjects analysed	39 ^[18]			
Units: µg/mL				
geometric mean (standard deviation)				
Day 7	2.97 (± 0.94)			
Day 7 (up to Day 20)	4.47 (± 1.44)			

Notes:

[18] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Secondary: T_{max} of N-oxide Voriconazole Metabolite (UK-121, 265) Following IV Administration

End point title	T _{max} of N-oxide Voriconazole Metabolite (UK-121, 265) Following IV Administration
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End point description:

Zero T_{max} refers to the highest concentration observed for one subject at predose. The profile of the metabolite is relatively flat, which could result in slight variation in sample collection or assay process. This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type	Secondary
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End point timeframe:

Days 1 and 7 (up to Day 20 or more) predose, 60 and 138 minutes, 4, 6, 8 and 12 hours postdose

End point values	Voriconazole IV			
Subject group type	Reporting group			
Number of subjects analysed	39 ^[19]			
Units: hours				
median (full range (min-max))				
Day 1	4 (1.72 to 8)			

Day 7 (up to Day 20)	4 (0 to 12.05)			
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Notes:

[19] - N=number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC_{12,ss} of N-oxide Voriconazole Metabolite (UK-121, 265) Following Oral Administration

End point title	AUC _{12,ss} of N-oxide Voriconazole Metabolite (UK-121, 265) Following Oral Administration
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End point description:

AUC_{12,ss} = Area under the plasma concentration-time profile from time zero (predose) to twelve hours at steady-state. AUC_{12,ss} was obtained by the Linear or Log trapezoidal method. This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type	Secondary
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End point timeframe:

Day 7 (or later) predose, 1, 2, 4, 6, 8 and 12 hours postdose

End point values	Voriconazole Oral			
Subject group type	Reporting group			
Number of subjects analysed	33 ^[20]			
Units: µg*h/mL				
geometric mean (standard deviation)	51.65 (± 27.88)			

Notes:

[20] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Secondary: C_{max,ss} of N-oxide Voriconazole Metabolite (UK-121, 265) Following Oral Administration

End point title	C _{max,ss} of N-oxide Voriconazole Metabolite (UK-121, 265) Following Oral Administration
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End point description:

This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type	Secondary
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End point timeframe:

Day 7 (or later) predose, 1, 2, 4, 6, 8 and 12 hours postdose

End point values	Voriconazole Oral			
Subject group type	Reporting group			
Number of subjects analysed	33 ^[21]			
Units: µg/mL				
geometric mean (standard deviation)	5.62 (± 2.54)			

Notes:

[21] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax of N-oxide Voriconazole Metabolite (UK-121, 265) Following Oral Administration

End point title	Tmax of N-oxide Voriconazole Metabolite (UK-121, 265) Following Oral Administration
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End point description:

This analysis included the ITT population- subjects who had completed PK blood sampling for at least one day.

End point type	Secondary
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End point timeframe:

Day 7 (or later) predose, 1, 2, 4, 6, 8 and 12 hours postdose

End point values	Voriconazole Oral			
Subject group type	Reporting group			
Number of subjects analysed	33 ^[22]			
Units: hours				
median (full range (min-max))	3.97 (0.92 to 8.03)			

Notes:

[22] - N = number of subjects with analyzable data.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 1 month after last dose of investigational product

Adverse event reporting additional description:

Same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one subject and as non-serious in another subject.

EU BR specific AE tables were generated separately as per EU format using latest coding.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.1
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Reporting groups

Reporting group title	Voriconazole Oral
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Reporting group description:

Voriconazole oral maintenance dosing regimen (200 mg every 12 hours) was administered following voriconazole IV in the morning and evening and lasted 6.5 days (up to Day 30 if clinically indicated).

Reporting group title	Voriconazole IV
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Reporting group description:

Voriconazole IV dosing regimen (7 mg/kg every 12 hours) was administered on Days 1 to 7 (up to Day 20 or more if clinically indicated).

Serious adverse events	Voriconazole Oral	Voriconazole IV	
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 34 (38.24%)	6 / 40 (15.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Aspartate aminotransferase increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus test			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Transplant failure			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypotension			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venoocclusive disease			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Posterior reversible encephalopathy syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration			

site conditions			
Medical device complication			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 34 (14.71%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Graft versus host disease in skin			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			

Hypoxia alternative assessment type: Non-systematic subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress alternative assessment type: Non-systematic subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders Renal failure alternative assessment type: Non-systematic subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations Cytomegalovirus infection alternative assessment type: Non-systematic subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis alternative assessment type: Non-systematic subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection alternative assessment type: Non-systematic subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter bacteraemia alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter sepsis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Voriconazole Oral	Voriconazole IV	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 34 (100.00%)	39 / 40 (97.50%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant mesenchymoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)	
occurrences (all)	1	1	
Vascular disorders			
Capillary leak syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)	
occurrences (all)	1	1	
Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Hypotension			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	2 / 40 (5.00%)	
occurrences (all)	1	2	
Hypertension			
alternative assessment type: Non-systematic			

subjects affected / exposed	11 / 34 (32.35%)	13 / 40 (32.50%)	
occurrences (all)	11	13	
Venoocclusive disease			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Catheter site erythema			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Catheter site haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Catheter site pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Chest pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Chills			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Drug withdrawal syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 34 (5.88%)	0 / 40 (0.00%)	
occurrences (all)	2	0	
Face oedema			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Facial pain		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Gravitational oedema		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Fatigue		
alternative assessment type: Non-systematic		
subjects affected / exposed	3 / 34 (8.82%)	2 / 40 (5.00%)
occurrences (all)	3	2
Localised oedema		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Mucosal inflammation		
alternative assessment type: Non-systematic		
subjects affected / exposed	11 / 34 (32.35%)	20 / 40 (50.00%)
occurrences (all)	11	24
Medical device complication		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Oedema peripheral		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Pain		
alternative assessment type: Non-systematic		
subjects affected / exposed	4 / 34 (11.76%)	7 / 40 (17.50%)
occurrences (all)	4	7

<p>Pyrexia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>11 / 34 (32.35%)</p> <p>11</p>	<p>15 / 40 (37.50%)</p> <p>19</p>	
<p>Suprapubic pain</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 34 (0.00%)</p> <p>0</p>	<p>1 / 40 (2.50%)</p> <p>1</p>	
<p>Immune system disorders</p> <p>Engraftment syndrome</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Acute graft versus host disease in skin</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Graft versus host disease</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Multiple allergies</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 34 (5.88%)</p> <p>2</p> <p>1 / 34 (2.94%)</p> <p>1</p> <p>4 / 34 (11.76%)</p> <p>4</p> <p>0 / 34 (0.00%)</p> <p>0</p>	<p>4 / 40 (10.00%)</p> <p>4</p> <p>0 / 40 (0.00%)</p> <p>0</p> <p>3 / 40 (7.50%)</p> <p>3</p> <p>1 / 40 (2.50%)</p> <p>1</p>	
<p>Reproductive system and breast disorders</p> <p>Genital erythema</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pelvic pain</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 34 (2.94%)</p> <p>1</p> <p>1 / 34 (2.94%)</p> <p>1</p>	<p>1 / 40 (2.50%)</p> <p>1</p> <p>1 / 40 (2.50%)</p> <p>1</p>	

Pruritus genital alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 40 (2.50%) 1	
Respiratory, thoracic and mediastinal disorders			
Apnoea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 40 (2.50%) 1	
Atelectasis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 40 (2.50%) 1	
Epistaxis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	5 / 34 (14.71%) 5	3 / 40 (7.50%) 4	
Cough alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	3 / 40 (7.50%) 3	
Hypoxia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	2 / 40 (5.00%) 2	
Lung infiltration alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 40 (0.00%) 0	
Nasal congestion alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 40 (2.50%) 1	
Nasal disorder alternative assessment type: Non-			

systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Nasal dryness		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Oropharyngeal pain		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Paranasal sinus mucosal hypertrophy		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Pharyngeal inflammation		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Pulmonary oedema		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Rhinorrhoea		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Sinus disorder		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Tachypnoea		
alternative assessment type: Non-systematic		

subjects affected / exposed	2 / 34 (5.88%)	6 / 40 (15.00%)	
occurrences (all)	2	6	
Wheezing			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Psychiatric disorders			
Aggression			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Agitation			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 34 (5.88%)	1 / 40 (2.50%)	
occurrences (all)	2	1	
Anxiety			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Confusional state			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Hallucination			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Insomnia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Irritability			
alternative assessment type: Non-systematic			

subjects affected / exposed	3 / 34 (8.82%)	1 / 40 (2.50%)	
occurrences (all)	3	1	
Staring			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Investigations			
Alanine aminotransferase increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 34 (23.53%)	6 / 40 (15.00%)	
occurrences (all)	9	8	
Aspartate aminotransferase increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 34 (20.59%)	5 / 40 (12.50%)	
occurrences (all)	9	8	
Bacterial test positive			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Blood albumin decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)	
occurrences (all)	1	1	
Blood alkaline phosphatase increased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Blood bicarbonate decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	2 / 40 (5.00%)	
occurrences (all)	1	3	
Blood bilirubin increased			
alternative assessment type: Non-systematic			

subjects affected / exposed	3 / 34 (8.82%)	2 / 40 (5.00%)
occurrences (all)	3	2
Blood creatinine increased		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	2 / 40 (5.00%)
occurrences (all)	1	2
Blood immunoglobulin G decreased		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Blood lactate dehydrogenase increased		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Blood pressure increased		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Blood urea increased		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	3 / 40 (7.50%)
occurrences (all)	1	3
Chest X-ray abnormal		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
CSF virus identified		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Clostridium test positive		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	0 / 40 (0.00%)
occurrences (all)	2	0

Cytomegalovirus test alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Cytomegalovirus test positive alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Electrocardiogram QT prolonged alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Gamma-glutamyltransferase increased alternative assessment type: Non-systematic		
subjects affected / exposed	5 / 34 (14.71%)	3 / 40 (7.50%)
occurrences (all)	6	3
Heart rate increased alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Hepatic enzyme decreased alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Hepatic enzyme increased alternative assessment type: Non-systematic		
subjects affected / exposed	4 / 34 (11.76%)	3 / 40 (7.50%)
occurrences (all)	4	5
Human herpes virus 6 serology positive alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Liver function test abnormal alternative assessment type: Non-systematic		

subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Lipase increased		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Oxygen saturation decreased		
alternative assessment type: Non-systematic		
subjects affected / exposed	3 / 34 (8.82%)	4 / 40 (10.00%)
occurrences (all)	3	4
Transaminases increased		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Urine output decreased		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	3 / 40 (7.50%)
occurrences (all)	2	3
Viral test positive		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	2 / 40 (5.00%)
occurrences (all)	2	2
Visual tracking test abnormal		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Weight decreased		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Weight increased		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	2 / 40 (5.00%)
occurrences (all)	1	2

White blood cell count decreased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 40 (0.00%) 0	
Injury, poisoning and procedural complications			
Contusion alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	2 / 40 (5.00%) 2	
Graft complication alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 40 (2.50%) 1	
Laceration alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 40 (0.00%) 0	
Joint injury alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 40 (0.00%) 0	
Overdose alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 40 (2.50%) 1	
Scratch alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 40 (0.00%) 0	
Suture related complication alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 40 (2.50%) 1	
Congenital, familial and genetic disorders			

Factor VII deficiency alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 40 (2.50%) 1	
Cardiac disorders			
Atrioventricular block first degree alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 40 (0.00%) 0	
Bradycardia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	2 / 40 (5.00%) 2	
Dilatation ventricular alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 40 (0.00%) 0	
Left ventricular hypertrophy alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 40 (0.00%) 0	
Sinus tachycardia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 40 (2.50%) 1	
Tachycardia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	3 / 40 (7.50%) 3	
Ventricular extrasystoles alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 40 (0.00%) 0	
Nervous system disorders			

Burning sensation alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 40 (2.50%) 1	
Dizziness alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 40 (0.00%) 0	
Lethargy alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	0 / 40 (0.00%) 0	
Headache alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	3 / 34 (8.82%) 3	4 / 40 (10.00%) 4	
Somnolence alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	1 / 40 (2.50%) 1	
Tremor alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 40 (2.50%) 1	
Blood and lymphatic system disorders Anaemia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 40 (2.50%) 1	
Haemolysis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 40 (2.50%) 1	
Leukocytosis alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Neutropenia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	3 / 40 (7.50%)	
occurrences (all)	1	3	
Pancytopenia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	2 / 40 (5.00%)	
occurrences (all)	1	2	
Splenomegaly			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Thrombocytopenia			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 34 (11.76%)	4 / 40 (10.00%)	
occurrences (all)	4	5	
Ear and labyrinth disorders			
Ear pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	2 / 40 (5.00%)	
occurrences (all)	0	2	
Eye disorders			
Astigmatism			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Blindness			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Conjunctival haemorrhage			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Colour blindness acquired		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Eye pain		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Eye irritation		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Dry eye		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	3 / 40 (7.50%)
occurrences (all)	1	3
Eye pruritus		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Lacrimation decreased		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Myopia		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Periorbital oedema		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1

Vision blurred alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 40 (2.50%) 1	
Visual acuity reduced alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	0 / 40 (0.00%) 0	
Gastrointestinal disorders			
Abdominal discomfort alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 40 (0.00%) 0	
Abdominal distension alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	3 / 40 (7.50%) 3	
Anorectal discomfort alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 40 (2.50%) 1	
Abdominal pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	9 / 34 (26.47%) 10	9 / 40 (22.50%) 10	
Abdominal pain upper alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	2 / 40 (5.00%) 2	
Ascites alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 40 (2.50%) 1	
Constipation alternative assessment type: Non-systematic			

subjects affected / exposed	7 / 34 (20.59%)	5 / 40 (12.50%)
occurrences (all)	7	5
Gastric haemorrhage		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Diarrhoea		
alternative assessment type: Non-systematic		
subjects affected / exposed	6 / 34 (17.65%)	6 / 40 (15.00%)
occurrences (all)	6	7
Dysphagia		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Gastritis		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	1 / 40 (2.50%)
occurrences (all)	2	1
Gastroesophageal reflux disease		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	2
Gingival bleeding		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Haematochezia		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Haematemesis		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	2 / 40 (5.00%)
occurrences (all)	2	2

Gingival hypertrophy		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Lip ulceration		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Lip dry		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Mouth haemorrhage		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	2 / 40 (5.00%)
occurrences (all)	1	2
Nausea		
alternative assessment type: Non-systematic		
subjects affected / exposed	6 / 34 (17.65%)	3 / 40 (7.50%)
occurrences (all)	6	4
Oral disorder		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Oral pain		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	2 / 40 (5.00%)
occurrences (all)	2	2
Proctalgia		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Stomatitis		
alternative assessment type: Non-systematic		

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vomiting</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 34 (2.94%)</p> <p>1</p> <p>4 / 34 (11.76%)</p> <p>5</p>	<p>3 / 40 (7.50%)</p> <p>3</p> <p>4 / 40 (10.00%)</p> <p>4</p>	
<p>Hepatobiliary disorders</p> <p>Hepatomegaly</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hepatosplenomegaly</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hyperbilirubinaemia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 34 (2.94%)</p> <p>1</p> <p>1 / 34 (2.94%)</p> <p>1</p> <p>4 / 34 (11.76%)</p> <p>4</p>	<p>3 / 40 (7.50%)</p> <p>5</p> <p>2 / 40 (5.00%)</p> <p>2</p> <p>5 / 40 (12.50%)</p> <p>6</p>	
<p>Skin and subcutaneous tissue disorders</p> <p>Alopecia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dermatitis contact</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dry skin</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Erythema</p> <p>alternative assessment type: Non-systematic</p>	<p>7 / 34 (20.59%)</p> <p>7</p> <p>1 / 34 (2.94%)</p> <p>1</p> <p>1 / 34 (2.94%)</p> <p>1</p>	<p>6 / 40 (15.00%)</p> <p>6</p> <p>1 / 40 (2.50%)</p> <p>1</p> <p>2 / 40 (5.00%)</p> <p>2</p>	

subjects affected / exposed	2 / 34 (5.88%)	1 / 40 (2.50%)
occurrences (all)	2	1
Papule		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Pruritus		
alternative assessment type: Non-systematic		
subjects affected / exposed	10 / 34 (29.41%)	12 / 40 (30.00%)
occurrences (all)	10	12
Rash		
alternative assessment type: Non-systematic		
subjects affected / exposed	9 / 34 (26.47%)	8 / 40 (20.00%)
occurrences (all)	10	8
Rash erythematous		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Rash macular		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	2 / 40 (5.00%)
occurrences (all)	1	2
Rash pruritic		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Rash maculo-papular		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	3 / 40 (7.50%)
occurrences (all)	3	3
Skin disorder		
alternative assessment type: Non-systematic		
subjects affected / exposed	3 / 34 (8.82%)	3 / 40 (7.50%)
occurrences (all)	3	3

<p>Skin discolouration</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 34 (2.94%)</p> <p>1</p>	<p>0 / 40 (0.00%)</p> <p>0</p>	
<p>Skin exfoliation</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 34 (2.94%)</p> <p>1</p>	<p>0 / 40 (0.00%)</p> <p>0</p>	
<p>Skin lesion</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 34 (2.94%)</p> <p>1</p>	<p>0 / 40 (0.00%)</p> <p>0</p>	
<p>Skin hyperpigmentation</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 34 (2.94%)</p> <p>1</p>	<p>0 / 40 (0.00%)</p> <p>0</p>	
<p>Swelling face</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 34 (2.94%)</p> <p>1</p>	<p>0 / 40 (0.00%)</p> <p>0</p>	
<p>Urticaria</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 34 (0.00%)</p> <p>0</p>	<p>1 / 40 (2.50%)</p> <p>1</p>	
<p>Renal and urinary disorders</p> <p>Bladder spasm</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Cystitis haemorrhagic</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dysuria</p> <p>alternative assessment type: Non-systematic</p>	<p>1 / 34 (2.94%)</p> <p>1</p> <p>2 / 34 (5.88%)</p> <p>2</p>	<p>1 / 40 (2.50%)</p> <p>1</p> <p>2 / 40 (5.00%)</p> <p>2</p>	

subjects affected / exposed	6 / 34 (17.65%)	4 / 40 (10.00%)	
occurrences (all)	6	4	
Glycosuria			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)	
occurrences (all)	1	1	
Haematuria			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 34 (11.76%)	3 / 40 (7.50%)	
occurrences (all)	4	3	
Oliguria			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 34 (5.88%)	1 / 40 (2.50%)	
occurrences (all)	2	1	
Pyelocaliectasis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Renal impairment			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Urethral pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			
Cushingoid			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	2 / 40 (5.00%)	
occurrences (all)	1	2	
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)	
occurrences (all)	2	1	
Back pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 34 (5.88%)	0 / 40 (0.00%)	
occurrences (all)	2	0	
Bone pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 34 (5.88%)	0 / 40 (0.00%)	
occurrences (all)	2	0	
Musculoskeletal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Groin pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Pain in extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 34 (8.82%)	2 / 40 (5.00%)	
occurrences (all)	4	2	
Infections and infestations			
Alpha haemolytic streptococcal infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Bacteraemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)	
occurrences (all)	1	1	
Bacterial infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 34 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	2
Bacterial sepsis		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	0 / 40 (0.00%)
occurrences (all)	2	0
Clostridium difficile infection		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	1 / 40 (2.50%)
occurrences (all)	2	1
Candida infection		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Conjunctivitis		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	1 / 40 (2.50%)
occurrences (all)	2	1
Cystitis		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Cytomegalovirus infection		
alternative assessment type: Non-systematic		
subjects affected / exposed	3 / 34 (8.82%)	2 / 40 (5.00%)
occurrences (all)	3	2
Cytomegalovirus viraemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	3 / 34 (8.82%)	1 / 40 (2.50%)
occurrences (all)	3	1
Enterococcal infection		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	0 / 40 (0.00%)
occurrences (all)	2	0

Enterococcal bacteraemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Escherichia bacteraemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Herpes virus infection		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Gastroenteritis adenovirus		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	2 / 40 (5.00%)
occurrences (all)	2	2
Human herpesvirus 6 infection		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Oral candidiasis		
alternative assessment type: Non-systematic		
subjects affected / exposed	4 / 34 (11.76%)	0 / 40 (0.00%)
occurrences (all)	4	0
Paronychia		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Pneumonia cytomegaloviral		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Rhinovirus infection		
alternative assessment type: Non-systematic		

subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Sinusitis		
alternative assessment type: Non-systematic		
subjects affected / exposed	4 / 34 (11.76%)	3 / 40 (7.50%)
occurrences (all)	4	3
Staphylococcal bacteraemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Urinary tract infection staphylococcal		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Streptococcal bacteraemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Urinary tract infection viral		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Viraemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)
occurrences (all)	1	0
Viral rhinitis		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Viral upper respiratory tract infection		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1

Metabolism and nutrition disorders			
Decreased appetite			
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 34 (17.65%)	5 / 40 (12.50%)	
occurrences (all)	6	6	
Fluid overload			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Fluid retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 34 (14.71%)	8 / 40 (20.00%)	
occurrences (all)	5	8	
Hyperamylasaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	3	0	
Hypercalcaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Hyperglycaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 34 (14.71%)	7 / 40 (17.50%)	
occurrences (all)	9	8	
Hyperkalaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 34 (2.94%)	4 / 40 (10.00%)	
occurrences (all)	1	4	
Hypermagnesaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Hypertriglyceridaemia			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	4	1
Hyperuricaemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Hypoalbuminaemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	3 / 40 (7.50%)
occurrences (all)	4	3
Hypocalcaemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	0 / 34 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	1
Hypomagnesaemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	4 / 34 (11.76%)	3 / 40 (7.50%)
occurrences (all)	4	3
Hypokalaemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	3 / 34 (8.82%)	7 / 40 (17.50%)
occurrences (all)	4	8
Hyponatraemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	2 / 34 (5.88%)	2 / 40 (5.00%)
occurrences (all)	2	2
Hypophagia		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	1 / 40 (2.50%)
occurrences (all)	1	1
Hypophosphataemia		
alternative assessment type: Non-systematic		
subjects affected / exposed	1 / 34 (2.94%)	2 / 40 (5.00%)
occurrences (all)	1	2

Malnutrition alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	2 / 40 (5.00%) 2	
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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported