Clinical trial results:
An Open Label Extension (OLE) Study of Voxelotor (GBT440) Administered Orally to Subjects With Sickle Cell Disease who Have Participated in Voxelotor Clinical Trials

Summary

EudraCT number	2017-004045-25
Trial protocol	GB FR NL IT
Global end of trial date	11 November 2024

Results information

Result version number	v1 (current)
This version publication date	15 August 2025
First version publication date	15 August 2025

Trial information

Trial identification

Sponsor protocol code	C5341022

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03573882
WHO universal trial number (UTN)	-
Other trial identifiers	Other study ID: GBT440-034

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	66 Hudson Boulevard East, New York, United States, NY 10001-2192
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 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)	EMEA-002356-PIP02-20
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	19 June 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 November 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The objective of this open-label extension (OLE) study was to assess the long-term safety and treatment effect of voxelotor in subjects who had completed treatment in study GBT440-031 (NCT03036813), using the following parameters: safety based upon adverse events (AEs), clinical laboratory tests, physical examinations (PE) and other clinical measures; frequency of sickle cell disease-related complications and hemolytic anemia as measured by hematological laboratory parameters (example hemoglobin, reticulocytes and unconjugated bilirubin).

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 Council for 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	06 June 2018
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	Canada: 3
Country: Number of subjects enrolled	Egypt: 33
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	United Kingdom: 19
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Kenya: 37
Country: Number of subjects enrolled	Lebanon: 6
Country: Number of subjects enrolled	Netherlands: 7
Country: Number of subjects enrolled	Oman: 8
Country: Number of subjects enrolled	Türkiye: 8
Country: Number of subjects enrolled	United States: 55
Worldwide total number of subjects	178
EEA total number of subjects	9

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	28
Adults (18-64 years)	150
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was an OLE study which included eligible participants from study GBT440-031 (NCT03036813). All participants were administered voxelotor 1500 milligrams (mg) in this study and results were stratified according to previous treatment in GBT440-031 (NCT03036813).

Pre-assignment

Screening details:

A total of 179 participants enrolled, 178 received treatment and 1 did not receive treatment. The study was terminated as emerging clinical data observed in studies other than GBT440-034 indicated that risk profile of voxelotor in people with SCD exceeded benefits observed in previously generated global research and required further assessment.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

NA

Arms

Are arms mutually exclusive?	Yes
Arm title	Prior treatment of placebo in GBT440-031 (NCT03036813)

Arm description:

Participants who received placebo in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.

Arm type	Experimental
Investigational medicinal product name	Voxelotor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received voxelotor 1500 mg orally once daily.

Arm title	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)

Arm description:

Participants who received voxelotor 900 mg in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.

Arm type	Experimental
Investigational medicinal product name	Voxelotor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

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Subjects received voxelotor 1500 mg orally once daily.

Arm title	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)

Arm description:

Participants who received voxelotor 1500 mg in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.

Arm type	Experimental
Investigational medicinal product name	Voxelotor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received voxelotor 1500 mg orally once daily.

Number of subjects in period 1	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)
Started	62	58	58
Completed	16	11	19
Not completed	46	47	39
Consent withdrawn by subject	5	11	7
Physician decision	4	3	2
Adverse event, non-fatal	7	5	6
Pregnancy	1	2	-
Subject was Noncompliant with Study Drug	1	2	1
Unspecified	4	2	2
Study Terminated by Sponsor	22	17	18
Lost to follow-up	2	5	3

Baseline characteristics

Reporting groups	
Reporting group title	Prior treatment of placebo in GBT440-031 (NCT03036813)
Reporting group description:	
Participants who received placebo in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.	
Reporting group title	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)
Reporting group description:	
Participants who received voxelotor 900 mg in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.	
Reporting group title	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)
Reporting group description:	
Participants who received voxelotor 1500 mg in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.	

Reporting group values	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)
Number of subjects	62	58	58
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	28.5	28.5	29.0
standard deviation	± 10.80	± 11.90	± 13.00
Gender categorical Units: Subjects			
Male	34	23	21
Female	28	35	37
Ethnicity Units: Subjects			
Hispanic or Latino	5	3	1
Not Hispanic or Latino	57	55	56
Unknown or Not Reported	0	0	1
Race Units: Subjects			
African	14	8	12
Arab	9	10	9
Asian	0	0	1
Black or African American	26	27	26
Middle Eastern	5	2	2
White	4	5	4
Other	2	2	0
Multiracial	2	4	4

Reporting group values	Total		
Number of subjects	178		
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	- -		
Gender categorical Units: Subjects			
Male	78		
Female	100		
Ethnicity Units: Subjects			
Hispanic or Latino	9		
Not Hispanic or Latino	168		
Unknown or Not Reported	1		
Race Units: Subjects			
African	34		
Arab	28		
Asian	1		
Black or African American	79		
Middle Eastern	9		
White	13		
Other	4		
Multiracial	10		

End points

End points reporting groups

Reporting group title	Prior treatment of placebo in GBT440-031 (NCT03036813)

Reporting group description:

Participants who received placebo in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.

Reporting group title	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)

Reporting group description:

Participants who received voxelotor 900 mg in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.

Reporting group title	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)

Reporting group description:

Participants who received voxelotor 1500 mg in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.

Primary: Number of Participants With Non- SCD-Related TEAEs

End point title	Number of Participants With Non- SCD-Related TEAEs[1]

End point description:

An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. TEAEs were defined as AEs with onset on or after the date of informed consent until 28 days after last dose of study drug. Non-SCD-related TEAEs included all the PTs of TEAEs other than SCD- related TEAEs. The number of participants with any Non-SCD-related TEAEs was reported in this outcome measure.

End point type	Primary

End point timeframe:

From date of informed consent up to 28 days after last dose of study drug (maximum up to 300.7 weeks)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no statistical analysis for this primary endpoint.

End point values	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	58	58	
Units: Participants	59	49	52	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Sickle Cell Disease (SCD)-Related Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Participants With Sickle Cell Disease (SCD)-Related Treatment Emergent Adverse Events (TEAEs)[2]

End point description:

An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. TEAEs were defined as AEs with onset on or after the date of informed consent until 28 days after last dose of study drug. SCD-related TEAEs included preferred terms (PTs) of sickle cell anaemia with crisis, ACS, pneumonia, priapism, and osteonecrosis. The number of participants with any SCD-related TEAEs was reported in this outcome measure.

End point type	Primary

End point timeframe:

From date of informed consent up to 28 days after last dose of study drug (maximum up to 300.7 weeks)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no statistical analysis for this primary endpoint.

End point values	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	58	58	
Units: Participants	47	42	42	

Statistical analyses

No statistical analyses for this end point

Primary: Annualized Incidence Rate of On-Treatment Vaso-occlusive Crisis (VOCs)

End point title	Annualized Incidence Rate of On-Treatment Vaso-occlusive Crisis (VOCs)[3]

End point description:

Annualized incidence rate was defined as total number of VOC events divided by total person years. Total person-years= sum of participant summary period in years where summary period=date of informed consent to last dose of study drug. VOC during the treatment period was defined as composite of acute painful crisis or acute chest syndrome (ACS) and included the following: moderate to severe pain lasting at least 2 hours; no explanation other than VOC; required oral or parenteral opioids, ketorolac, or other analgesics prescribed or directed by a healthcare professional. The 95% CI was based on exact Poisson confidence limits.

End point type	Primary

End point timeframe:

From date of informed consent to last dose of study drug (maximum up to 296.7 weeks)

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: There was no statistical analysis for this primary endpoint.

End point values	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	58	58	
Units: VOC events per person year				
number (confidence interval 95%)	1.038 (0.896 to 1.195)	0.926 (0.778 to 1.095)	0.889 (0.760 to 1.034)	

Statistical analyses

No statistical analyses for this end point

Primary: Annualized Incidence Rate of SCD-Related Complications

End point title	Annualized Incidence Rate of SCD-Related Complications[4]

End point description:

Annualized incidence rate was defined as total number of events (i.e. complications observed for all participants) divided by total person years. Total person-years= sum of participant summary period in years where summary period=date of informed consent until the earlier of 28 days after last dose of study drug and end of study date. SCD related complications included acute chest syndrome, cerebrovascular accident, hepatic sequestration, ocular icterus, osteonecrosis, pneumonia, priapism, pulmonary hypertension, retinopathy, sickle cell anaemia with crisis, skin ulcer and splenic sequestration. The 95% CI was based on exact Poisson confidence limits. Incidence rate all SCD related complication is reported in this outcome measure.

End point type	Primary

End point timeframe:

From date of informed consent up to 28 days after last dose of study drug (maximum up to 300.7 weeks)

Notes:

[4] - 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: There was no statistical analysis for this primary endpoint.

End point values	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	58	58	
Units: Events per person year				
number (confidence interval 95%)	1.181 (1.031 to 1.347)	1.084 (0.924 to 1.264)	1.045 (0.905 to 1.200)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With SCD-Related Treatment Emergent Serious

Adverse Events (TESAEs)

End point title	Number of Participants With SCD-Related Treatment Emergent Serious Adverse Events (TESAEs)[5]

End point description:

An SAE is an AE at any dose, in view of investigator resulted in any of following outcomes: death; life-threatening AE; inpatient hospitalization/prolongation of existing hospitalization; persistent/significant incapacity or disability; a congenital anomaly/birth defect and important medical events (IME) that may not result in death; be immediately life threatening; or require hospitalization may be considered serious when based upon medical judgement, they may jeopardize study participant and may require medical or surgical intervention to prevent one of outcomes listed in definition. TESAEs were defined as SAEs with onset on or after the date of informed consent until 28 days after last dose of study drug. Number of participants with SCD-Related TESAEs was reported in this outcome measure.

End point type	Primary

End point timeframe:

From date of informed consent up to 28 days after last dose of study drug (maximum up to 300.7 weeks)

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: There was no statistical analysis for this primary endpoint.

End point values	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	58	58	
Units: Participants	39	33	22	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Non-SCD-Related TESAEs

End point title	Number of Participants With Non-SCD-Related TESAEs[6]

End point description:

A SAE at any dose, in view of either investigator or Pfizer, results in any of following outcomes: death; life-threatening AE; inpatient hospitalization/prolongation of existing hospitalization; persistent/significant incapacity or disability; a congenital anomaly/birth defect and IME that may not result in death; be immediately life threatening; or require hospitalization may be considered serious when based upon medical judgement, they may jeopardize study participant and may require medical or surgical intervention to prevent one of outcomes listed in definition. A TESAE was defined as an SAE that emerges on or after initiation of study drug (having been absent pretreatment), or an AE that existed pretreatment and worsened on treatment (relative to pretreatment state). Number of participants with Non- SCD-Related TESAEs was reported in this outcome measure.

End point type	Primary

End point timeframe:

From date of informed consent up to 28 days after last dose of study drug (maximum up to 300.7 weeks)

Notes:

[6] - 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: There was no statistical analysis for this primary endpoint.

End point values	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	62	58	58	
Units: Participants	18	14	15	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hemoglobin Level at Week 48

End point title	Change From Baseline in Hemoglobin Level at Week 48

End point description:

Change from baseline in hemoglobin at Week 48 was reported in this endpoint. Baseline value was defined as the last available value (including Week 72, end of treatment [EOT], or end of study [EOS] visits in the parent study GBT440-031 [NCT03036813]) collected on or prior to first dose in GBT440-034. The safety population included all enrolled subjects who received treatment with study drug voxelotor in the current study. Here, 'Subjects Analyzed'= number of subjects evaluable for this endpoint and n= number of subjects evaluable for specified rows.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	57	53	55	
Units: Gram per deciliter (g/dL)				
arithmetic mean (standard deviation)				
Baseline (n=57,53,55)	8.8 (± 1.32)	9.0 (± 1.52)	9.5 (± 1.61)	
Change at Week 48 (n=40,35,39)	1.2 (± 1.50)	0.7 (± 1.48)	0.2 (± 1.15)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Reticulocytes Percentage at Week 48

End point title	Percent Change From Baseline in Reticulocytes Percentage at Week 48

End point description:

Percent change from baseline in reticulocytes percentage at week 48 was reported in this endpoint. Baseline value was defined as the last available value (including Week 72, EOT, or EOS visits in the parent study GBT440-031 [NCT03036813]) collected on or prior to first dose in GBT440-034. The safety population included all enrolled subjects who received treatment with study drug voxelotor in the current study. Here, 'Subjects Analyzed'= number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	38	33	35	
Units: Percent change				
arithmetic mean (standard deviation)	-24.9 (± 58.13)	-15.3 (± 55.82)	-21.0 (± 81.29)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Absolute Reticulocytes at Week 48

End point title	Percent Change From Baseline in Absolute Reticulocytes at Week 48

End point description:

Percent change from baseline in absolute reticulocytes at week 48 was reported in this endpoint. Baseline value was defined as the last available value (including Week 72, EOT, or EOS visits in the parent study GBT440-031 [NCT03036813]) collected on or prior to first dose in GBT440-034. The safety population included all enrolled subjects who received treatment with study drug voxelotor in the current study. Here, 'Subjects Analyzed'= number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	23	31	
Units: Percent change				
arithmetic mean (standard deviation)	111.3 (±	-11.5 (±	-12.2 (±	

721.86)	50.14)	58.18)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Indirect Bilirubin at Week 48

End point title	Percent Change From Baseline in Indirect Bilirubin at Week 48

End point description:

Percent change from baseline in indirect bilirubin at week 48 was reported in this endpoint. Baseline value was defined as the last available value (including Week 72, EOT, or EOS visits in the parent study GBT440-031 [NCT03036813]) collected on or prior to first dose in GBT440-034. The safety population included all enrolled subjects who received treatment with study drug voxelotor in the current study. Here, 'Subjects Analyzed'= number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	32	33	
Units: Percent change				
arithmetic mean (standard deviation)	-39.3 (± 40.70)	3.8 (± 70.47)	1.2 (± 84.21)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From date of informed consent up to 28 days after last dose of study drug (maximum up to 300.7 weeks)

Adverse event reporting additional description:

Safety population included all enrolled participants who received treatment with study drug voxelotor in current study. However, what is presented are distinct events. An event may be categorized as serious in one participant and as non-serious in another, or one participant may have experienced both a serious & non-serious event during the study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	v27.1

Reporting groups

Reporting group title	Prior treatment of placebo in GBT440-031 (NCT03036813)

Reporting group description:

Participants who received placebo in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.

Reporting group title	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)

Reporting group description:

Participants who received voxelotor 1500 mg in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.

Reporting group title	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)

Reporting group description:

Participant who received voxelotor 900 mg in study GBT440-031 (NCT03036813) were administered voxelotor 1500 mg once daily in this study as long as they received clinical benefit and/or until the participant had access to voxelotor from an alternative source.

Serious adverse events	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)
Total subjects affected by serious adverse events			
subjects affected / exposed	42 / 62 (67.74%)	26 / 58 (44.83%)	35 / 58 (60.34%)
number of deaths (all causes)	3	5	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Myelodysplastic syndrome			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			

subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Superficial vein thrombosis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 62 (1.61%)	2 / 58 (3.45%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (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
Pain			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (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
Immune system disorders			
Respiratory tract infection			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Priapism			

subjects affected / exposed[1]	1 / 34 (2.94%)	2 / 21 (9.52%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	4 / 4	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary embolism			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute chest syndrome			
subjects affected / exposed	8 / 62 (12.90%)	4 / 58 (6.90%)	7 / 58 (12.07%)
occurrences causally related to treatment / all	0 / 14	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial hypertension			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (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
Investigations			
White blood cell count increased			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Delayed haemolytic transfusion reaction			

subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Sickle cell anaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nervous system disorders			
Central nervous system lesion			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (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
Cerebral haematoma			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (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
Cerebral infarction			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (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

Migraine			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (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
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	36 / 62 (58.06%)	20 / 58 (34.48%)	32 / 58 (55.17%)
occurrences causally related to treatment / all	0 / 101	0 / 59	2 / 67
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Haemolysis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aplastic anaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	3 / 62 (4.84%)	1 / 58 (1.72%)	5 / 58 (8.62%)
occurrences causally related to treatment / all	0 / 3	0 / 1	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Eye disorders			
Vitreous haemorrhage			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (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 hernia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (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
Acute abdomen			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (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
Hyperchlorhydria			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (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
Peptic ulcer			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (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
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (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
Cholecystitis acute			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (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

Cholelithiasis			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (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
Renal and urinary disorders			
Urinary retention			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteonecrosis			
subjects affected / exposed	0 / 62 (0.00%)	2 / 58 (3.45%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone infarction			
subjects affected / exposed	2 / 62 (3.23%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			

subjects affected / exposed	2 / 62 (3.23%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	4 / 62 (6.45%)	2 / 58 (3.45%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Malaria			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	2 / 58 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	2 / 58 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	2 / 62 (3.23%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 62 (0.00%)	2 / 58 (3.45%)	2 / 58 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Osteomyelitis			
subjects affected / exposed	3 / 62 (4.84%)	2 / 58 (3.45%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parvovirus infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (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
Cellulitis			

subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This PT term was reported for male population only.

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

Non-serious adverse events	Prior treatment of placebo in GBT440-031 (NCT03036813)	Prior treatment of voxelotor 1500mg in GBT440-031(NCT03036813)	Prior treatment of voxelotor 900mg in GBT440-031(NCT03036813)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	60 / 62 (96.77%)	54 / 58 (93.10%)	50 / 58 (86.21%)
Vascular disorders			
Superficial vein thrombosis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	1	1	1
Hypotension			
subjects affected / exposed	4 / 62 (6.45%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	4	0	0
Systolic hypertension			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	12 / 62 (19.35%)	8 / 58 (13.79%)	7 / 58 (12.07%)
occurrences (all)	14	11	13
Asthenia			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	1	1	0

Peripheral swelling			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	2	1	2
Malaise			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	2 / 58 (3.45%)
occurrences (all)	1	1	2
Influenza like illness			
subjects affected / exposed	1 / 62 (1.61%)	3 / 58 (5.17%)	0 / 58 (0.00%)
occurrences (all)	1	3	0
Oedema peripheral			
subjects affected / exposed	2 / 62 (3.23%)	2 / 58 (3.45%)	1 / 58 (1.72%)
occurrences (all)	2	2	1
Non-cardiac chest pain			
subjects affected / exposed	4 / 62 (6.45%)	5 / 58 (8.62%)	6 / 58 (10.34%)
occurrences (all)	9	6	9
Fatigue			
subjects affected / exposed	5 / 62 (8.06%)	5 / 58 (8.62%)	5 / 58 (8.62%)
occurrences (all)	5	6	5
Pyrexia			
subjects affected / exposed	9 / 62 (14.52%)	6 / 58 (10.34%)	6 / 58 (10.34%)
occurrences (all)	11	6	7
Administration site irritation			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Swelling face			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Physical deconditioning			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Hernia pain			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Feeling hot			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	2	0

Facial pain			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Hunger			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	1	1	0
Social circumstances			
Menopause			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Priapism			
subjects affected / exposed[2]	3 / 34 (8.82%)	4 / 21 (19.05%)	3 / 23 (13.04%)
occurrences (all)	3	5	4
Dysmenorrhoea			
subjects affected / exposed	1 / 62 (1.61%)	3 / 58 (5.17%)	1 / 58 (1.72%)
occurrences (all)	1	13	1
Intermenstrual bleeding			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	1	0	1
Menstruation irregular			
subjects affected / exposed	2 / 62 (3.23%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	2	0	0
Abnormal uterine bleeding			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1

Vaginal discharge			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Heavy menstrual bleeding			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Menometrorrhagia			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Menstruation delayed			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	2
Penile pain			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Polycystic ovaries			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Erectile dysfunction			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 62 (3.23%)	10 / 58 (17.24%)	6 / 58 (10.34%)
occurrences (all)	3	10	8
Oropharyngeal pain			
subjects affected / exposed	4 / 62 (6.45%)	2 / 58 (3.45%)	5 / 58 (8.62%)
occurrences (all)	5	9	6
Nasal congestion			
subjects affected / exposed	3 / 62 (4.84%)	2 / 58 (3.45%)	2 / 58 (3.45%)
occurrences (all)	3	2	2
Rhinorrhoea			
subjects affected / exposed	0 / 62 (0.00%)	3 / 58 (5.17%)	2 / 58 (3.45%)
occurrences (all)	0	3	2
Dyspnoea			

subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	1	1	2
Acute chest syndrome			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	2	1	0
Hypoxia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	2	1
Rhinitis allergic			
subjects affected / exposed	0 / 62 (0.00%)	2 / 58 (3.45%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Tonsillar hypertrophy			
subjects affected / exposed	2 / 62 (3.23%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	2	0	0
Atelectasis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Bronchial disorder			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Asthma			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	1	0	2
Lung consolidation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Lung hypoinflation			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	1	0
Nasal septum deviation			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Painful respiration			

subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Pharyngeal swelling			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Throat irritation			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Pulmonary vascular disorder			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Rales			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Respiratory failure			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Sneezing			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Sputum discoloured			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Pulmonary hypertension			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Throat tightness			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			

Depressed mood			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	1	0	1
Depression			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	3
Confusional state			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	3
Delusion			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	4 / 62 (6.45%)	2 / 58 (3.45%)	2 / 58 (3.45%)
occurrences (all)	4	2	2
Initial insomnia			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Paranoia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	5 / 62 (8.06%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	8	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 62 (4.84%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	5	0	0
C-reactive protein increased			

subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	1	1	1
Cardiac murmur			
subjects affected / exposed	2 / 62 (3.23%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	2	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 62 (3.23%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	3	0	0
Blood iron decreased			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Liver function test abnormal			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Helicobacter test positive			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Haemoglobin decreased			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Foetal haemoglobin decreased			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Eosinophil count increased			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Blood potassium increased			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0

Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Blood corticotrophin decreased			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Mean cell volume decreased			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	3	0
Vitamin D decreased			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Staphylococcus test positive			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Pulmonary function test decreased			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			

subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Urine protein/creatinine ratio increased			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Ligament injury			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Joint dislocation			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Immunisation reaction			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Lower limb fracture			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Toxicity to various agents			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	4
Procedural pain			
subjects affected / exposed	2 / 62 (3.23%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	2	0	0
Foot fracture			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	2 / 58 (3.45%)
occurrences (all)	1	1	2
Ankle fracture			

subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Muscle strain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Radius fracture			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Skin wound			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Soft tissue injury			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Thermal burn			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Transfusion reaction			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Wound complication			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	2 / 62 (3.23%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	2	1	1
Tachycardia			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	1	1	1
Cardiomegaly			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	1	1	0
Arrhythmia			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0

Atrial flutter			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Heart failure with reduced ejection fraction			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Silent myocardial infarction			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Sinus bradycardia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	16 / 62 (25.81%)	14 / 58 (24.14%)	10 / 58 (17.24%)
occurrences (all)	23	22	16
Dizziness			
subjects affected / exposed	4 / 62 (6.45%)	7 / 58 (12.07%)	2 / 58 (3.45%)
occurrences (all)	4	8	3
Lethargy			
subjects affected / exposed	2 / 62 (3.23%)	0 / 58 (0.00%)	2 / 58 (3.45%)
occurrences (all)	3	0	2
Hypoaesthesia			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	1	1	1
Burning sensation			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	1	1	0
Cerebral infarction			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	2
Migraine			

subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	1	0	1
Ageusia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Balance disorder			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Facial paralysis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Head discomfort			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Hemiparaesthesia			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Hyperaesthesia			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Tension headache			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Vestibular migraine			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	2 / 62 (3.23%)	3 / 58 (5.17%)	3 / 58 (5.17%)
occurrences (all)	2	3	5
Sickle cell anaemia with crisis			
subjects affected / exposed	28 / 62 (45.16%)	31 / 58 (53.45%)	24 / 58 (41.38%)
occurrences (all)	80	111	70
Thrombocytopenia			
subjects affected / exposed	1 / 62 (1.61%)	2 / 58 (3.45%)	2 / 58 (3.45%)
occurrences (all)	1	3	2
Abdominal lymphadenopathy			
subjects affected / exposed	0 / 62 (0.00%)	2 / 58 (3.45%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Reticulocytopenia			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Thrombocytosis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	2
Microcytosis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Neutrophilia			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	3 / 62 (4.84%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	3	0	0
Leukocytosis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	2 / 58 (3.45%)
occurrences (all)	0	1	2
Haemolysis			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	1	1	1
Ear and labyrinth disorders			
Ear pain			

subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Cerumen impaction			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Astigmatism			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Retinopathy sickle cell			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	1	1	1
Retinal haemorrhage			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	1	1	0
Vision blurred			
subjects affected / exposed	2 / 62 (3.23%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	2	0	0
Vitreous floaters			
subjects affected / exposed	0 / 62 (0.00%)	2 / 58 (3.45%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Vitreous haemorrhage			
subjects affected / exposed	2 / 62 (3.23%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	3	0	0
Blepharitis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Cataract			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Visual impairment			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Visual acuity reduced			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0

Retinopathy proliferative			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Retinopathy			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Retinal neovascularisation			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Retinal detachment			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Glaucoma			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Dry eye			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Conjunctivitis allergic			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	14 / 62 (22.58%)	4 / 58 (6.90%)	11 / 58 (18.97%)
occurrences (all)	20	4	13
Vomiting			
subjects affected / exposed	9 / 62 (14.52%)	6 / 58 (10.34%)	8 / 58 (13.79%)
occurrences (all)	11	6	10
Diarrhoea			
subjects affected / exposed	11 / 62 (17.74%)	4 / 58 (6.90%)	6 / 58 (10.34%)
occurrences (all)	13	5	7
Dyspepsia			

subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	1	1	1
Flatulence			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	2 / 58 (3.45%)
occurrences (all)	0	2	2
Abdominal pain lower			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	1	1	1
Abdominal discomfort			
subjects affected / exposed	2 / 62 (3.23%)	2 / 58 (3.45%)	2 / 58 (3.45%)
occurrences (all)	2	2	3
Gastritis			
subjects affected / exposed	1 / 62 (1.61%)	5 / 58 (8.62%)	2 / 58 (3.45%)
occurrences (all)	1	13	2
Abdominal pain upper			
subjects affected / exposed	4 / 62 (6.45%)	6 / 58 (10.34%)	3 / 58 (5.17%)
occurrences (all)	6	6	7
Abdominal pain			
subjects affected / exposed	8 / 62 (12.90%)	6 / 58 (10.34%)	4 / 58 (6.90%)
occurrences (all)	10	8	5
Constipation			
subjects affected / exposed	5 / 62 (8.06%)	5 / 58 (8.62%)	9 / 58 (15.52%)
occurrences (all)	7	5	12
Umbilical hernia			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	1	0	1
Anal haemorrhage			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	3 / 58 (5.17%)
occurrences (all)	0	0	3
Faecaloma			

subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	2	1	1
Abdominal distension			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Dental caries			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Mouth ulceration			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Rectal haemorrhage			
subjects affected / exposed	1 / 62 (1.61%)	2 / 58 (3.45%)	0 / 58 (0.00%)
occurrences (all)	1	2	0
Gastrointestinal sounds abnormal			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Glossitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Hyperchlorhydria			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Lip disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Oesophagitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Oral pain			

subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Faeces soft			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Gastric ulcer			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Tongue discolouration			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Ocular icterus			
subjects affected / exposed	3 / 62 (4.84%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	3	1	1
Cholelithiasis			
subjects affected / exposed	2 / 62 (3.23%)	0 / 58 (0.00%)	2 / 58 (3.45%)
occurrences (all)	2	0	2
Hepatomegaly			
subjects affected / exposed	0 / 62 (0.00%)	2 / 58 (3.45%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Hepatic cytolysis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Hepatic cyst			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Cholestasis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Cholecystitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Biliary dilatation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	2

Jaundice			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Hypertransaminasaemia			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	4	1	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	2 / 62 (3.23%)	2 / 58 (3.45%)	4 / 58 (6.90%)
occurrences (all)	3	2	5
Rash			
subjects affected / exposed	2 / 62 (3.23%)	2 / 58 (3.45%)	1 / 58 (1.72%)
occurrences (all)	2	2	2
Skin ulcer			
subjects affected / exposed	3 / 62 (4.84%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	4	1	0
Dermatitis allergic			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	1	1	0
Erythema			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Alopecia			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Dermatitis acneiform			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Drug eruption			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Eczema			

subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	2	0	0
Night sweats			
subjects affected / exposed	2 / 62 (3.23%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	2	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Hypertrichosis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	2
Purpura			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Pigmentation disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Neutrophilic dermatosis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Neurodermatitis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Livedo reticularis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Skin plaque			

subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Skin hypopigmentation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Skin hyperpigmentation			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	3 / 58 (5.17%)
occurrences (all)	1	1	4
Acute kidney injury			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	1	1	1
Chronic kidney disease			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	1	0	2
Haematuria			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Renal injury			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Nephropathy			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1

Renal cyst			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Renal hypertrophy			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Microalbuminuria			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	10 / 62 (16.13%)	11 / 58 (18.97%)	6 / 58 (10.34%)
occurrences (all)	18	19	10
Arthralgia			
subjects affected / exposed	14 / 62 (22.58%)	9 / 58 (15.52%)	9 / 58 (15.52%)
occurrences (all)	17	14	13
Pain in extremity			
subjects affected / exposed	10 / 62 (16.13%)	15 / 58 (25.86%)	9 / 58 (15.52%)
occurrences (all)	12	28	21
Bone pain			
subjects affected / exposed	5 / 62 (8.06%)	3 / 58 (5.17%)	3 / 58 (5.17%)
occurrences (all)	13	7	3
Musculoskeletal chest pain			
subjects affected / exposed	3 / 62 (4.84%)	2 / 58 (3.45%)	2 / 58 (3.45%)
occurrences (all)	3	2	3
Bone lesion			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Bone infarction			

subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Arthritis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	2	0	0
Tenosynovitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	2
Spinal pain			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	2	1	0
Sjogren's syndrome			
subjects affected / exposed	0 / 62 (0.00%)	2 / 58 (3.45%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Pain in jaw			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	1	0	1
Muscle spasms			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Neck pain			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	2 / 58 (3.45%)
occurrences (all)	0	1	3
Myalgia			
subjects affected / exposed	0 / 62 (0.00%)	2 / 58 (3.45%)	1 / 58 (1.72%)
occurrences (all)	0	2	1
Osteonecrosis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	3 / 58 (5.17%)
occurrences (all)	0	1	3
Musculoskeletal stiffness			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Osteopenia			

subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Osteosclerosis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Patellofemoral pain syndrome			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Synovitis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	2
Sacral pain			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	12 / 62 (19.35%)	14 / 58 (24.14%)	4 / 58 (6.90%)
occurrences (all)	23	26	10
COVID-19			
subjects affected / exposed	2 / 62 (3.23%)	9 / 58 (15.52%)	4 / 58 (6.90%)
occurrences (all)	3	12	4

Pharyngitis			
subjects affected / exposed	2 / 62 (3.23%)	2 / 58 (3.45%)	1 / 58 (1.72%)
occurrences (all)	2	2	1
Bronchitis			
subjects affected / exposed	1 / 62 (1.61%)	2 / 58 (3.45%)	2 / 58 (3.45%)
occurrences (all)	1	2	2
Lower respiratory tract infection			
subjects affected / exposed	2 / 62 (3.23%)	1 / 58 (1.72%)	3 / 58 (5.17%)
occurrences (all)	3	1	5
Cellulitis			
subjects affected / exposed	1 / 62 (1.61%)	2 / 58 (3.45%)	1 / 58 (1.72%)
occurrences (all)	1	3	1
Malaria			
subjects affected / exposed	2 / 62 (3.23%)	3 / 58 (5.17%)	5 / 58 (8.62%)
occurrences (all)	2	3	16
Gastroenteritis			
subjects affected / exposed	2 / 62 (3.23%)	4 / 58 (6.90%)	5 / 58 (8.62%)
occurrences (all)	3	10	5
Tonsillitis			
subjects affected / exposed	6 / 62 (9.68%)	6 / 58 (10.34%)	1 / 58 (1.72%)
occurrences (all)	9	13	1
Urinary tract infection			
subjects affected / exposed	5 / 62 (8.06%)	3 / 58 (5.17%)	6 / 58 (10.34%)
occurrences (all)	6	4	9
Nasopharyngitis			
subjects affected / exposed	4 / 62 (6.45%)	5 / 58 (8.62%)	5 / 58 (8.62%)
occurrences (all)	4	7	5
Pneumonia			
subjects affected / exposed	3 / 62 (4.84%)	3 / 58 (5.17%)	2 / 58 (3.45%)
occurrences (all)	3	4	2
Infection			
subjects affected / exposed	2 / 62 (3.23%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	2	1	1
Influenza			
subjects affected / exposed	1 / 62 (1.61%)	2 / 58 (3.45%)	1 / 58 (1.72%)
occurrences (all)	1	2	1

Rhinitis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Respiratory tract infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	2
Laryngitis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	2	1
Helicobacter infection			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Gastrointestinal viral infection			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Coronavirus infection			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	1	0	1
Conjunctivitis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Anal abscess			
subjects affected / exposed	0 / 62 (0.00%)	2 / 58 (3.45%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	2 / 58 (3.45%)
occurrences (all)	0	1	2
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	1	1	1
Tooth abscess			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	2 / 58 (3.45%)
occurrences (all)	1	0	2
Abscess limb			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0

Lower respiratory tract infection viral			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Hepatitis C			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Furuncle			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Orchitis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Bronchiolitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Body tinea			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Bacterial infection			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Acarodermatitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0

Otitis media			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Urethritis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Tinea versicolour			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Tinea capitis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Subcutaneous abscess			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Skin infection			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Sepsis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	0	0	1
Pilonidal disease			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Penile infection			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Parotitis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0

Paraspinal abscess			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Urinary tract candidiasis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Wound sepsis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Vulval abscess			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Iron deficiency			
subjects affected / exposed	1 / 62 (1.61%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	2	1	1
Hyperkalaemia			
subjects affected / exposed	3 / 62 (4.84%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	3	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 62 (1.61%)	2 / 58 (3.45%)	1 / 58 (1.72%)
occurrences (all)	1	2	1
Gout			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	1 / 58 (1.72%)
occurrences (all)	0	1	1
Haemochromatosis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Decreased appetite			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Vitamin B12 deficiency			

subjects affected / exposed	0 / 62 (0.00%)	2 / 58 (3.45%)	0 / 58 (0.00%)
occurrences (all)	0	2	0
Hypomagnesaemia			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	1 / 58 (1.72%)
occurrences (all)	1	0	1
Hypokalaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 58 (0.00%)	2 / 58 (3.45%)
occurrences (all)	0	0	2
Hypercalcaemia			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Multi-vitamin deficiency			
subjects affected / exposed	1 / 62 (1.61%)	0 / 58 (0.00%)	0 / 58 (0.00%)
occurrences (all)	1	0	0
Magnesium deficiency			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Iron overload			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 62 (0.00%)	1 / 58 (1.72%)	0 / 58 (0.00%)
occurrences (all)	0	1	0

Notes:

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This PT term was reported for male population only.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 June 2018	The study design was updated to reflect the varying conditions that allow enrollment into the study. Efficacy endpoint was removed (Measures of hemolysis previously captured under "Efficacy endpoints" were moved to "Treatment effects").

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
25 September 2024	Pfizer discontinue voxelotor Study GBT440-034 (C5341022) on 25 September 2024. Emerging clinical data evaluated by Pfizer and shared with regulatory authorities indicated that the risk profile of voxelotor in people with SCD exceeded the benefits observed.	-

Notes:

Limitations and caveats

None reported