Clinical trial results:
A Multicenter Phase 2 Study to Evaluate Subcutaneous Daratumumab in Combination with Standard Multiple Myeloma Treatment Regimens

Summary

EudraCT number	2017-004203-41
Trial protocol	GB DE CZ ES
Global end of trial date	07 December 2020

Results information

Result version number	v1 (current)
This version publication date	24 November 2023
First version publication date	24 November 2023

Trial information

Trial identification

Sponsor protocol code	54767414MMY2040

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03412565
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, 2340
Public contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 December 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 December 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the clinical benefit of subcutaneous (SC) daratumumab administered in combination with standard multiple myeloma (MM) regimens in subjects with MM as measured by overall response rate (ORR) or very good partial response (VGPR) or better rate.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 May 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	Brazil: 5
Country: Number of subjects enrolled	Czechia: 23
Country: Number of subjects enrolled	Germany: 19
Country: Number of subjects enrolled	Spain: 55
Country: Number of subjects enrolled	United Kingdom: 29
Country: Number of subjects enrolled	France: 79
Country: Number of subjects enrolled	Israel: 21
Country: Number of subjects enrolled	Japan: 4
Country: Number of subjects enrolled	United States: 30
Worldwide total number of subjects	265
EEA total number of subjects	176

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	115
From 65 to 84 years	149
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Out of 265 enrolled subjects, 114 subjects completed the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)

Arm description:

Subjects received daratumumab 1800 milligrams (mg) as a subcutaneous (SC) injection on Days 1, 8 and 15 of Cycles 1 to 3 (each cycle of 21 days) and on Day 1 of Cycle 4; bortezomib 1.3 milligrams per square meter (mg/m^2) SC injection on Days 1, 4, 8 and 11 of Cycles 1 to 4; lenalidomide 25 mg orally on Day 1 through Day 14 of Cycles 1 to 4 and dexamethasone 20 mg orally or intravenously (IV) on Days 1, 2 ,8, 9, 15 and 16 of Cycle 1 to 4.

Arm type	Experimental
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	JNJ-54767414
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subject received daratumumab 1800 mg as a SC injection on Days 1, 8 and 15 of Cycles 1 to 3 (each cycle of 21 days) and on Day 1 of Cycle 4.

Investigational medicinal product name	Bortezomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received bortezomib 1.3 mg/m^2 SC injection on Days 1, 4, 8 and 11 of Cycles 1 to 4.

Investigational medicinal product name	Lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received lenalidomide 25 mg orally on Day 1 through Day 14 of Cycles 1 to 4.

Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Infusion
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

Subjects received dexamethasone 20 mg either orally or IV on Days 1, 2 ,8, 9, 15 and 16 of Cycle 1 to 4.

Arm title	D + Bortezomib + Melphalan + Prednisone (D-VMP)

Arm description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15, 22, 29 and 36 of Cycle 1, then on Days 1 and 22 in Cycles 2 to 9, and Day 1 of Cycle 10 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; bortezomib 1.3 mg/m^2 SC injection on Day 1, 4, 8, 11, 22, 25, 29 and 32 of Cycle 1 and on Days 1, 8, 22 and 29 of Cycles 2 to 9; melphalan 9 mg/m^2 orally on Day 1 through Day 4 of Cycles 1 to 9; prednisone 60 mg/m^2 orally on Days 1 to 4 of cycles 1 to 9.

Arm type	Experimental
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	JNJ-54767414
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15, 22, 29 and 36 of Cycle 1, then on Days 1 and 22 in Cycles 2 to 9, and Day 1 of Cycle 10 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Investigational medicinal product name	Bortezomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received bortezomib 1.3 mg/m^2 SC injection on Day 1, 4, 8, 11, 22, 25, 29 and 32 of Cycle 1 and on Days 1, 8, 22 and 29 of Cycles 2 to 9.

Investigational medicinal product name	Melphalan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received melphalan 9 mg/m^2 orally on Day 1 through Day 4 of Cycles 1 to 9.

Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received prednisone 60 mg/m^2 orally on Days 1 to 4 of cycles 1 to 9.

Arm title	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)

Arm description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15 and 22 of Cycles 1 and 2, then on Day 1 and 15 of Cycles 3 to 6, and on Day 1 of Cycle 7 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; lenalidomide 25 mg orally on Day 1 through Day 21 of each cycle until documented progression of disease, unacceptable toxicity, or end of study and dexamethasone 40 mg orally or intravenously weekly until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Arm type	Experimental

Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	JNJ-54767414
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15 and 22 of Cycles 1 and 2, then on Day 1 and 15 of Cycles 3 to 6, and on Day 1 of Cycle 7 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Infusion
Routes of administration	Oral use, Intravenous use

Dosage and administration details:

Subjects received dexamethasone 40 mg either orally or intravenously weekly until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Investigational medicinal product name	Lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received lenalidomide 25 mg orally on Day 1 through Day 21 of each cycle until documented progression of disease, unacceptable toxicity, or end of study.

Arm title	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)

Arm description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15 and 22 of Cycles 1 and 2 (each cycle is of 28 days), then on Day 1 and 15 of Cycles 3 to 6, and on Day 1 of Cycle 7 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; Carfilzomib 20 mg/m^2 IV on Day 1 of Cycle 1 only, then 70 mg/m^2 IV on Days 8 and 15 of Cycle 1 and Days 1, 8 and 15 of Cycle 2 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months and dexamethasone 40 mg orally or IV weekly for Cycles 1-9, then on Days 1, 8, 15 of each cycle for Cycle 10 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Arm type	Experimental
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	JNJ-54767414
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15 and 22 of Cycles 1 and 2 (each cycle is of 28 days), then on Day 1 and 15 of Cycles 3 to 6, and on Day 1 of Cycle 7 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Infusion
Routes of administration	Oral use, Intravenous use

Dosage and administration details:

Subjects received dexamethasone 40 mg either orally or IV weekly for Cycles 1-9, then on Days 1, 8, 15 of each cycle for Cycle 10 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Investigational medicinal product name	Carfilzomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received Carfilzomib 20 mg/m^2 IV on Day 1 of Cycle 1 only, then 70 mg/m^2 IV on Days 8 and 15 of Cycle 1 and Days 1, 8 and 15 of Cycle 2 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months

Number of subjects in period 1	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)
Started	67	67	65
Completed	66	19	14
Not completed	1	48	51
Consent withdrawn by subject	-	4	5
Physician decision	-	-	-
Data collection ended	-	41	41
Death	1	3	4
Lost to follow-up	-	-	1

Number of subjects in period 1	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)
Started	66
Completed	15
Not completed	51
Consent withdrawn by subject	5
Physician decision	1
Data collection ended	40
Death	5
Lost to follow-up	-

Baseline characteristics

Reporting groups	
Reporting group title	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)

Reporting group description:

Subjects received daratumumab 1800 milligrams (mg) as a subcutaneous (SC) injection on Days 1, 8 and 15 of Cycles 1 to 3 (each cycle of 21 days) and on Day 1 of Cycle 4; bortezomib 1.3 milligrams per square meter (mg/m^2) SC injection on Days 1, 4, 8 and 11 of Cycles 1 to 4; lenalidomide 25 mg orally on Day 1 through Day 14 of Cycles 1 to 4 and dexamethasone 20 mg orally or intravenously (IV) on Days 1, 2 ,8, 9, 15 and 16 of Cycle 1 to 4.

Reporting group title	D + Bortezomib + Melphalan + Prednisone (D-VMP)

Reporting group description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15, 22, 29 and 36 of Cycle 1, then on Days 1 and 22 in Cycles 2 to 9, and Day 1 of Cycle 10 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; bortezomib 1.3 mg/m^2 SC injection on Day 1, 4, 8, 11, 22, 25, 29 and 32 of Cycle 1 and on Days 1, 8, 22 and 29 of Cycles 2 to 9; melphalan 9 mg/m^2 orally on Day 1 through Day 4 of Cycles 1 to 9; prednisone 60 mg/m^2 orally on Days 1 to 4 of cycles 1 to 9.

Reporting group title	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)

Reporting group description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15 and 22 of Cycles 1 and 2, then on Day 1 and 15 of Cycles 3 to 6, and on Day 1 of Cycle 7 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; lenalidomide 25 mg orally on Day 1 through Day 21 of each cycle until documented progression of disease, unacceptable toxicity, or end of study and dexamethasone 40 mg orally or intravenously weekly until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Reporting group title	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)

Reporting group description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15 and 22 of Cycles 1 and 2 (each cycle is of 28 days), then on Day 1 and 15 of Cycles 3 to 6, and on Day 1 of Cycle 7 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; Carfilzomib 20 mg/m^2 IV on Day 1 of Cycle 1 only, then 70 mg/m^2 IV on Days 8 and 15 of Cycle 1 and Days 1, 8 and 15 of Cycle 2 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months and dexamethasone 40 mg orally or IV weekly for Cycles 1-9, then on Days 1, 8, 15 of each cycle for Cycle 10 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Reporting group values	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)
Number of subjects	67	67	65
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	54	0	22
From 65 to 84 years	13	66	43
85 years and over	0	1	0
Title for AgeContinuous Units: years			
arithmetic mean	57.3	74.9	66.8
standard deviation	± 9.47	± 4.54	± 9.58

Title for Gender Units: subjects			
Female	19	36	20
Male	48	31	45

Reporting group values	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)	Total	
Number of subjects	66	265	
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	39	115	
From 65 to 84 years	27	149	
85 years and over	0	1	
Title for AgeContinuous Units: years			
arithmetic mean	61		
standard deviation	± 9.77	-	
Title for Gender Units: subjects			
Female	32	107	
Male	34	158	

End points

End points reporting groups

Reporting group title	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)

Reporting group description:

Subjects received daratumumab 1800 milligrams (mg) as a subcutaneous (SC) injection on Days 1, 8 and 15 of Cycles 1 to 3 (each cycle of 21 days) and on Day 1 of Cycle 4; bortezomib 1.3 milligrams per square meter (mg/m^2) SC injection on Days 1, 4, 8 and 11 of Cycles 1 to 4; lenalidomide 25 mg orally on Day 1 through Day 14 of Cycles 1 to 4 and dexamethasone 20 mg orally or intravenously (IV) on Days 1, 2 ,8, 9, 15 and 16 of Cycle 1 to 4.

Reporting group title	D + Bortezomib + Melphalan + Prednisone (D-VMP)

Reporting group description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15, 22, 29 and 36 of Cycle 1, then on Days 1 and 22 in Cycles 2 to 9, and Day 1 of Cycle 10 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; bortezomib 1.3 mg/m^2 SC injection on Day 1, 4, 8, 11, 22, 25, 29 and 32 of Cycle 1 and on Days 1, 8, 22 and 29 of Cycles 2 to 9; melphalan 9 mg/m^2 orally on Day 1 through Day 4 of Cycles 1 to 9; prednisone 60 mg/m^2 orally on Days 1 to 4 of cycles 1 to 9.

Reporting group title	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)

Reporting group description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15 and 22 of Cycles 1 and 2, then on Day 1 and 15 of Cycles 3 to 6, and on Day 1 of Cycle 7 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; lenalidomide 25 mg orally on Day 1 through Day 21 of each cycle until documented progression of disease, unacceptable toxicity, or end of study and dexamethasone 40 mg orally or intravenously weekly until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Reporting group title	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)

Reporting group description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15 and 22 of Cycles 1 and 2 (each cycle is of 28 days), then on Day 1 and 15 of Cycles 3 to 6, and on Day 1 of Cycle 7 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; Carfilzomib 20 mg/m^2 IV on Day 1 of Cycle 1 only, then 70 mg/m^2 IV on Days 8 and 15 of Cycle 1 and Days 1, 8 and 15 of Cycle 2 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months and dexamethasone 40 mg orally or IV weekly for Cycles 1-9, then on Days 1, 8, 15 of each cycle for Cycle 10 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Primary: D-VMP, D-Rd, and D-Kd Cohorts: Overall Response Rate (ORR)

End point title	D-VMP, D-Rd, and D-Kd Cohorts: Overall Response Rate

End point description:

ORR was defined as percentage of subjects who achieved partial response (PR) or better according to international myeloma working group (IMWG) criteria. IMWG criteria for PR: greater than or equal to (>=) 50 percent (%) reduction of serum M-protein and reduction in 24-hour urinary M-protein by >=90% or to less than (<) 200 milligrams (mg) per 24 hours, If serum and urine M-protein are not measurable, a decrease of >=50% in difference between involved and uninvolved free light chain (FLC) levels is required in place of M-protein criteria, If serum and urine M-protein are not measurable, and serum free light assay is also not measurable, >=50% reduction in bone marrow plasma cells (PCs) is required in place of M-protein, provided baseline bone marrow plasma cell percentage was >=30. All treated analysis set included all subjects who received at least 1 dose of study treatment. This primary endpoint was planned to be analysed for D-VMP, D-Rd and D-Kd cohorts only.

End point type	Primary

End point timeframe:

Up to 2 years 3 months

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.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be reported for specified arms only.

End point values	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	65	66	
Units: percentage of subjects				
number (confidence interval 90%)	88.1 (79.5 to 93.9)	90.8 (82.6 to 95.9)	84.8 (75.7 to 91.5)	

Statistical analyses

No statistical analyses for this end point

Primary: D-VRd Cohort: Percentage of Subjects With Very Good Partial Response (VGPR) or Better Response

End point title	D-VRd Cohort: Percentage of Subjects With Very Good Partial Response (VGPR) or Better Response[3][4]

End point description:

VGPR or better rate was defined as the percentage of subjects who achieved VGPR or complete response (CR) (including stringent complete response [sCR]) according to the IMWG criteria during or after the study treatment. VGPR: Serum and urine component detectable by immunofixation but not on electrophoresis, or >= 90% reduction in serum M-protein plus urine M-protein level <100 mg/24 hour; CR: negative immunofixation on the serum and urine, Disappearance of any soft tissue plasmacytomas and <5% PCs in bone marrow; sCR: CR in addition to having a normal FLC ratio and an absence of clonal cells in bone marrow by immunohistochemistry, immunofluorescence, 2-4 color flow cytometry. All treated analysis set included all subjects who received at least 1 dose of study treatment. This primary endpoint was planned to be analysed for D-VRd cohort only.

End point type	Primary

End point timeframe:

Up to 2 years and 3 months

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.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be reported for specified arms only.

End point values	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)			
Subject group type	Reporting group			
Number of subjects analysed	67			

Units: percentage of subjects				
number (confidence interval 90%)	71.6 (61.2 to 80.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Serum Concentration (Cmax) of Daratumumab

End point title	Maximum Observed Serum Concentration (Cmax) of Daratumumab

End point description:

Cmax was defined as maximum serum concentration observed following daratumumab administration. Each cycle for: D-VRd cohort is of 21 days, D-VMP cohort is of 42 days and D-Rd and D-Kd cohorts is of 28 days. Each cohort have a treatment period of 84 days. Pharmacokinetics (PK) analysis set: subjects who received at least 1 dose of daratumumab SC and had at least 1 PK sample value after first dose. 'N' (number of subjects analysed): subjects evaluated for this endpoint; 'n' (number analysed): subjects analysed at specific timepoints. The "0" in the number analysed field indicates that no subject was evaluable for PK at that timepoint. Here, '99999' indicates that no subject was available for analysis.

End point type	Secondary

End point timeframe:

D-VRd: Day 4 of Cycles 1 and 4 and post treatment at Week 8; D-VMP: Day 4 of Cycles 1 and 2 and post treatment at Week 8; D-Rd and D-Kd: Day 4 of Cycles 1 and 3 and post treatment at Week 8

End point values	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	66	56	57
Units: micrograms per milliliter (mcg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 4 (n=60, 66, 56, 57)	100 (± 48.5)	98.6 (± 51.6)	108 (± 49.9)	137 (± 56.7)
Cycle 2 Day 4 (n=0, 55, 0, 0)	99999 (± 99999)	612 (± 256)	99999 (± 99999)	99999 (± 99999)
Cycle 3 Day 4 (n= 0, 0, 50, 45)	99999 (± 99999)	99999 (± 99999)	648 (± 238)	869 (± 274)
Cycle 4 Day 4 (n= 56, 0, 0, 0)	746 (± 275)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Post-treatment Phase Week 8 (n=43, 1, 0, 6)	263 (± 190)	162 (± 99999)	99999 (± 99999)	49.3 (± 106)

Statistical analyses

No statistical analyses for this end point

Secondary: D-VMP, D-Rd, and D-Kd Cohorts: Percentage of Subjects With VGPR or Better Response

End point title	D-VMP, D-Rd, and D-Kd Cohorts: Percentage of Subjects With VGPR or Better Response[5]

End point description:

VGPR or better rate was defined as the percentage of subjects who achieved VGPR or CR (including sCR) according to the IMWG criteria during or after the study treatment. VGPR: Serum and urine component detectable by immunofixation but not on electrophoresis, or >= 90% reduction in serum M-protein plus urine M-protein level <100 mg per 24 hour; CR: negative immunofixation on the serum and urine, Disappearance of any soft tissue plasmacytomas and <5% PCs in bone marrow; sCR: CR in addition to having a normal FLC ratio and an absence of clonal cells in bone marrow by immunohistochemistry, immunofluorescence, 2-4 color flow cytometry. All treated analysis set included all subjects who received at least 1 dose of study treatment. This secondary endpoint was planned to be analysed for D-VMP, D-Rd and D-Kd cohorts only.

End point type	Secondary

End point timeframe:

From baseline up to 2 years 7 months

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be reported for specified arms only.

End point values	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	65	66	
Units: percentage of subjects				
number (confidence interval 90%)	77.6 (67.6 to 85.7)	80.0 (70.1 to 87.7)	77.3 (67.2 to 85.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Infusion-Related Reactions (IRRs)

End point title	Percentage of Subjects with Infusion-Related Reactions (IRRs)

End point description:

Percentage of subjects with IRRs were reported. The administration-related systemic reactions are referred to as IRRs. All treated analysis set included all subjects who received at least 1 dose of study treatment.

End point type	Secondary

End point timeframe:

For D-VRD Arm: Baseline up to 2 years 3 months; For D-VMP, D-Rd and D-Kd Arms: Baseline up to 2 years 7 months

End point values	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	67	65	66
Units: percentage of subjects				
number (confidence interval 90%)	9.0 (4.0 to 16.9)	9.0 (4.0 to 16.9)	4.6 (1.3 to 11.5)	4.5 (1.3 to 11.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With CR or Better Response

End point title	Percentage of Subjects With CR or Better Response

End point description:

CR or better rate was defined as the percentage of subjects with a CR or better response (that is, CR and sCR) as per IMWG criteria. CR: as negative immunofixation on the serum and urine and disappearance of soft tissue plasmacytomas and less than (<) 5 percent plasma cells in bone marrow; sCR: CR plus normal FLC ratio and absence of clonal PCs by immunohistochemistry, immunofluorescence or 2- to 4-color flow cytometry. All treated analysis set included all subjects who received at least 1 dose of study treatment.

End point type	Secondary

End point timeframe:

For D-VRD Arm: Baseline up to 2 years 3 months; For D-VMP, D-Rd and D-Kd Arms: Baseline up to 2 years 7 months

End point values	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	67	65	66
Units: percentage of subjects				
number (confidence interval 90%)	16.4 (9.5 to 25.7)	55.2 (44.5 to 65.6)	50.8 (39.9 to 61.5)	42.4 (32.1 to 53.3)

Statistical analyses

No statistical analyses for this end point

Secondary: D-VRd Cohort: Overall Response Rate (ORR)

End point title	D-VRd Cohort: Overall Response Rate (ORR)[6]

End point description:

ORR was defined as the percentage of subjects who achieved a PR or better, IMWG criteria, during the study or during follow up. IMWG criteria for PR >= 50% reduction of serum M-protein and reduction in 24 hour urinary M-protein by >=90% or to <200 mg/24 hours, if the serum and urine M-protein are not measurable, a decrease of >=50% in the difference between involved and uninvolved FLC levels is required in place of the M-protein criteria, If serum and urine M-protein are not measurable, and serum free light assay is also not measurable, >=50% reduction in bone marrow PCs is required in place of M-protein, provided baseline bone marrow plasma cell percentage was >=30%, in addition to the above criteria, if present at baseline, a >=50% reduction in the size of soft tissue plasmacytomas is also required. All treated analysis set included all subjects who received at least 1 dose of study treatment. This secondary endpoint was planned to be analysed for D-VRd cohort only.

End point type	Secondary

End point timeframe:

Up to 2 years and 3 months

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be reported for specified arms only.

End point values	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)			
Subject group type	Reporting group			
Number of subjects analysed	67			
Units: percentage of subjects				
number (confidence interval 90%)	97.0 (90.9 to 99.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Anti-Daratumumab Antibodies

End point title	Percentage of Subjects with Anti-Daratumumab Antibodies

End point description:

Percentage of subjects with antibodies to daratumumab were reported. Immunogenicity-evaluable analysis set was defined as all subjects who received at least 1 dose administration of daratumumab SC and had at least 1 immunogenicity sample for detection of anti-daratumumab antibodies after the first dose.

End point type	Secondary

End point timeframe:

For D-VRD Arm: Baseline up to 2 years 3 months; For D-VMP, D-Rd and D-Kd Arms: Baseline up to 2 years 7 months

End point values	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	64	62	64
Units: percentage of subjects				
number (not applicable)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: D-VMP, D-Rd and D-Kd Cohorts: Duration of Response (DOR)

End point title	D-VMP, D-Rd and D-Kd Cohorts: Duration of Response (DOR)[7]

End point description:

DOR=time from date of initial documented response (PR or better response) to date of first documented evidence of progressive disease (PD) or death due to PD. PD=increase of 25% from lowest response value in one of following: serum and urine M-component (absolute increase must be >=0.5 gram per deciliter [g/dL] and >=200 mg/24 hours); only in subjects without measurable serum and urine M-protein level difference between involved and uninvolved FLC level (absolute increase must be >10 mg/dL);definite development of new bone lesions or soft tissue plasmacytomas or definite increase in size of existing bone lesions or soft tissue plasmacytomas; development of hypercalcemia (corrected serum calcium >11.5 mg/dL). Analysis population included number of responders (partial response or better) in each cohort. Here, '99999' indicates that median duration of response was not estimable due to less number of events.

End point type	Secondary

End point timeframe:

From baseline up to 2 years 7 months

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be reported for specified arms only.

End point values	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	61	56	
Units: months				
median (full range (min-max))	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Anti-rHuPH20 Antibodies

End point title	Percentage of Subjects with Anti-rHuPH20 Antibodies

End point description:

Percentage of subjects with antibodies to rHuPH20 were reported. Immunogenicity-evaluable analysis set for rHuPH20 is defined as all subjects who received at least one dose of daratumumab SC and had appropriate plasma samples for detection of antibodies to rHuPH20 (at least 1 sample after the start of the first dose of daratumumab SC).

End point type	Secondary

End point timeframe:

For D-VRD Arm: Baseline up to 2 years 3 months; For D-VMP, D-Rd and D-Kd Arms: Baseline up to 2 years 7 months

End point values	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	66	64	62	64
Units: percentage of subjects				
number (not applicable)	6.1	3.1	4.8	4.7

Statistical analyses

No statistical analyses for this end point

Secondary: D-VMP, D-Rd, and D-Kd Cohorts: Percentage of Subjects with Minimal Residual Disease (MRD) Negative Rate

End point title	D-VMP, D-Rd, and D-Kd Cohorts: Percentage of Subjects with Minimal Residual Disease (MRD) Negative Rate[8]

End point description:

MRD negativity rate was defined as the percentage of subjects who were considered MRD negative after MRD testing at any timepoint after the first dose by bone marrow aspirate. MRD negativity rate was assessed by next-generation sequencing at a threshold of <10^5. All treated analysis set included all subjects who have received at least 1 dose of study treatment. This secondary endpoint was planned to be analysed for D-VMP, D-Rd and D-Kd cohorts only.

End point type	Secondary

End point timeframe:

Up to 2 years and 3 months

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was planned to be reported for specified arms only.

End point values	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	65	66	
Units: percentage of subjects				

number (confidence interval 90%)	25.4 (16.9 to 35.6)	21.5 (13.5 to 31.6)	27.3 (18.4 to 37.7)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

From baseline up to 2 years 7 months

Adverse event reporting additional description:

All treated analysis set included all subjects who had received at least 1 dose of study treatment.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1/23.1

Reporting groups

Reporting group title	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)

Reporting group description:

Subjects received daratumumab 1800 milligrams (mg) as a subcutaneous (SC) injection on Days 1, 8 and 15 of Cycles 1 to 3 (each cycle of 21 days) and on Day 1 of Cycle 4; bortezomib 1.3 milligrams per square meter (mg/m^2) SC injection on Days 1, 4, 8 and 11 of Cycles 1 to 4; lenalidomide 25 mg orally on Day 1 through Day 14 of Cycles 1 to 4 and dexamethasone 20 mg orally or intravenously (IV) on Days 1, 2 ,8, 9, 15 and 16 of Cycle 1 to 4.

Reporting group title	D + Bortezomib + Melphalan + Prednisone (D-VMP)

Reporting group description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15, 22, 29 and 36 of Cycle 1, then on Days 1 and 22 in Cycles 2 to 9, and Day 1 of Cycle 10 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; bortezomib 1.3 mg/m^2 SC injection on Day 1, 4, 8, 11, 22, 25, 29 and 32 of Cycle 1 and on Days 1, 8, 22 and 29 of Cycles 2 to 9; melphalan 9 mg/m^2 orally on Day 1 through Day 4 of Cycles 1 to 9; prednisone 60 mg/m^2 orally on Days 1 to 4 of cycles 1 to 9.

Reporting group title	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)

Reporting group description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15 and 22 of Cycles 1 and 2, then on Day 1 and 15 of Cycles 3 to 6, and on Day 1 of Cycle 7 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; lenalidomide 25 mg orally on Day 1 through Day 21 of each cycle until documented progression of disease, unacceptable toxicity, or end of study and dexamethasone 40 mg orally or intravenously weekly until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Reporting group title	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)

Reporting group description:

Subjects received daratumumab 1800 mg by SC injection on Days 1, 8, 15 and 22 of Cycles 1 and 2 (each cycle is of 28 days), then on Day 1 and 15 of Cycles 3 to 6, and on Day 1 of Cycle 7 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months; Carfilzomib 20 mg/m^2 IV on Day 1 of Cycle 1 only, then 70 mg/m^2 IV on Days 8 and 15 of Cycle 1 and Days 1, 8 and 15 of Cycle 2 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months and dexamethasone 40 mg orally or IV weekly for Cycles 1-9, then on Days 1, 8, 15 of each cycle for Cycle 10 and thereafter until documented progression of disease, unacceptable toxicity, or up to 2 years and 7 months.

Serious adverse events	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 67 (28.36%)	30 / 67 (44.78%)	37 / 65 (56.92%)
number of deaths (all causes)	1	3	4

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma Cell Myeloma			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Adenocarcinoma Pancreas			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
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 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Hepatic Neoplasm			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	1 / 67 (1.49%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Cardiac Ablation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
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			
Performance Status Decreased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General Physical Health Deterioration			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	2 / 67 (2.99%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Pyrexia			
subjects affected / exposed	4 / 67 (5.97%)	5 / 67 (7.46%)	3 / 65 (4.62%)
occurrences causally related to treatment / all	4 / 5	3 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Uterine Prolapse			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	2 / 67 (2.99%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Hypoxia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Acute Respiratory Failure			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Respiratory Failure			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary Hypertension			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body Temperature Increased			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Oxygen Saturation Decreased			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Respirovirus Test Positive			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases Increased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Hip Fracture			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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

Limb Injury			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Wrist Fracture			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left Ventricular Dysfunction			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac Failure Congestive			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Atrial Fibrillation			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Flutter			

subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Cardiac Failure			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	3 / 65 (4.62%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			
Cerebellar Haematoma			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Incoherent			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Generalised Tonic-Clonic Seizure			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Encephalopathy			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Small Vessel Ischaemic Disease			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Syncope			

subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Spinal Cord Compression			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Thalamic Infarction			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Vith Nerve Paresis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	3 / 65 (4.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			

subjects affected / exposed	1 / 67 (1.49%)	2 / 67 (2.99%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	2 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 67 (1.49%)	2 / 67 (2.99%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Ophthalmic Vein Thrombosis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	5 / 65 (7.69%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 67 (2.99%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Haemorrhage			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Nausea			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Skin and subcutaneous tissue disorders			

Skin Lesion			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash Maculo-Papular			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash Pruritic			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Hyperhidrosis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Renal and urinary disorders			
Renal Impairment			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Kidney Injury			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	3 / 65 (4.62%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscular Weakness			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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

Hypercreatinaemia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Bone Pain			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (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
Back Pain			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Arthralgia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Spinal Pain			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Osteonecrosis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter Gastroenteritis			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Enterobacter Infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea Infectious			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
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 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
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			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective Exacerbation of Chronic Obstructive Airways Disease			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	3 / 65 (4.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 67 (1.49%)	6 / 67 (8.96%)	9 / 65 (13.85%)
occurrences causally related to treatment / all	1 / 1	1 / 7	4 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Urinary Tract Infection			
subjects affected / exposed	1 / 67 (1.49%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Neutropenic Sepsis			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Lower Respiratory Tract Infection			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	3 / 65 (4.62%)
occurrences causally related to treatment / all	1 / 1	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	4 / 65 (6.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal Sepsis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Urosepsis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Viral Pharyngitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (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
Hypercalcaemia			

subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Hyponatraemia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (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
Diabetic Metabolic Decompensation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)		
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 66 (33.33%)		
number of deaths (all causes)	5		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Plasma Cell Myeloma			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myelodysplastic Syndrome			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma Pancreas			

subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute Myeloid Leukaemia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic Neoplasm			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Cardiac Ablation			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Performance Status Decreased			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

General Physical Health Deterioration				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chills				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Uterine Prolapse				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Pulmonary Embolism				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				

subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic Obstructive Pulmonary Disease				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute Respiratory Failure				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory Failure				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Pulmonary Hypertension				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Alanine Aminotransferase Increased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Body Temperature Increased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oxygen Saturation Decreased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respirovirus Test Positive				

subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transaminases Increased			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hip Fracture			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Limb Injury			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wrist Fracture			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Left Ventricular Dysfunction				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial Infarction				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac Failure Congestive				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial Fibrillation				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial Flutter				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac Failure				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebellar Haematoma				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incoherent				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Generalised Tonic-Clonic Seizure				

subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral Small Vessel Ischaemic Disease				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ischaemic Stroke				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal Cord Compression				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Presyncope				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Loss of Consciousness				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thalamic Infarction				

subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vith Nerve Paresis			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile Neutropenia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Ophthalmic Vein Thrombosis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Vomiting				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal Haemorrhage				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Skin Lesion				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash Maculo-Papular				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash Pruritic				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperhidrosis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				

Renal Impairment				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal Failure				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute Kidney Injury				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Muscular Weakness				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercreatinaemia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone Pain				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Back Pain				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arthralgia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Musculoskeletal Chest Pain				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal Pain				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bronchitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Campylobacter Gastroenteritis				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia Urinary Tract Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterobacter Infection				

subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea Infectious				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Covid-19 Pneumonia				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Covid-19				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Clostridium Difficile Colitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infective Exacerbation of Chronic Obstructive Airways Disease				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper Respiratory Tract Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				

subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Pneumonia				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Pneumocystis Jirovecii Pneumonia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary Tract Infection				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic Sepsis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower Respiratory Tract Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumococcal Sepsis				

subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral Pharyngitis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercalcaemia			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic Metabolic Decompensation			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Daratumumab (D)+Bortezomib+Lenalidomide+Dexamethasone (D-VRd)	D + Bortezomib + Melphalan + Prednisone (D-VMP)	Daratumumab + Lenalidomide + Dexamethasone (D-Rd)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	67 / 67 (100.00%)	67 / 67 (100.00%)	65 / 65 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Seborrhoeic Keratosis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Pituitary Tumour Benign			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Malignant Melanoma			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Lipoma			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Tract Adenoma			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Colon Adenoma			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Basal Cell Carcinoma			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Tumour Pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Aortic Stenosis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1

Venous Thrombosis Limb			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Deep Vein Thrombosis			
subjects affected / exposed	3 / 67 (4.48%)	1 / 67 (1.49%)	4 / 65 (6.15%)
occurrences (all)	3	1	4
Flushing			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Hot Flush			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 67 (1.49%)	10 / 67 (14.93%)	8 / 65 (12.31%)
occurrences (all)	1	19	9
Hypotension			
subjects affected / exposed	3 / 67 (4.48%)	8 / 67 (11.94%)	4 / 65 (6.15%)
occurrences (all)	3	8	5
Orthostatic Hypotension			
subjects affected / exposed	1 / 67 (1.49%)	3 / 67 (4.48%)	0 / 65 (0.00%)
occurrences (all)	1	3	0
Peripheral Coldness			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Phlebitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Thrombophlebitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis Superficial			
subjects affected / exposed	2 / 67 (2.99%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0

Thrombosed Varicose Vein			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Varicose Vein			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Vascular Pain			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Cyanosis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
White Coat Hypertension			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	18 / 67 (26.87%)	10 / 67 (14.93%)	19 / 65 (29.23%)
occurrences (all)	25	20	36
Administration Site Erythema			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Administration Site Pruritus			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Administration Site Swelling			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	10 / 67 (14.93%)	17 / 67 (25.37%)	21 / 65 (32.31%)
occurrences (all)	12	31	38
Catheter Site Erythema			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			

subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Chest Pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	3 / 65 (4.62%)
occurrences (all)	0	0	3
Chills			
subjects affected / exposed	8 / 67 (11.94%)	3 / 67 (4.48%)	4 / 65 (6.15%)
occurrences (all)	10	3	5
Cyst			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Face Oedema			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Facial Pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Feeling Cold			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Injection Site Rash			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Generalised Oedema			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hernia Pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hypothermia			

subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Impaired Healing			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Inflammation			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Influenza Like Illness			
subjects affected / exposed	0 / 67 (0.00%)	3 / 67 (4.48%)	2 / 65 (3.08%)
occurrences (all)	0	3	2
Infusion Site Pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Injection Site Bruising			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Injection Site Eczema			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Injection Site Erythema			
subjects affected / exposed	9 / 67 (13.43%)	5 / 67 (7.46%)	0 / 65 (0.00%)
occurrences (all)	12	13	0
Injection Site Haemorrhage			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Injection Site Induration			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Injection Site Pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Injection Site Pruritus			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	3	0
General Physical Health Deterioration			

subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Localised Oedema			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Injection Site Swelling			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Vaccination Site Erythema			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Temperature Regulation Disorder			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Swelling Face			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Swelling			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Secretion Discharge			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	22 / 67 (32.84%)	22 / 67 (32.84%)	16 / 65 (24.62%)
occurrences (all)	30	32	23
Peripheral Swelling			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	3 / 65 (4.62%)
occurrences (all)	0	0	3
Oedema Peripheral			
subjects affected / exposed	13 / 67 (19.40%)	11 / 67 (16.42%)	15 / 65 (23.08%)
occurrences (all)	14	16	30
Oedema			

subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Injection Site Reaction			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 67 (0.00%)	5 / 67 (7.46%)	1 / 65 (1.54%)
occurrences (all)	0	9	1
Mucosal Inflammation			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	1	1	1
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	3 / 65 (4.62%)
occurrences (all)	1	1	3
Immune system disorders			
Drug Hypersensitivity			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Allergy to Plants			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Breast Haematoma			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Cystocele			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Genital Rash			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Pelvic Discomfort			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Pelvic Floor Muscle Weakness			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Pelvic Pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Scrotal Erythema			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Uterine Prolapse			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Vaginal Haemorrhage			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal Pruritus			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Bronchopneumopathy			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Cough			

subjects affected / exposed	5 / 67 (7.46%)	12 / 67 (17.91%)	10 / 65 (15.38%)
occurrences (all)	5	13	11
Dysphonia			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	5 / 65 (7.69%)
occurrences (all)	0	2	5
Dyspnoea			
subjects affected / exposed	9 / 67 (13.43%)	4 / 67 (5.97%)	16 / 65 (24.62%)
occurrences (all)	11	4	24
Dyspnoea Exertional			
subjects affected / exposed	3 / 67 (4.48%)	2 / 67 (2.99%)	2 / 65 (3.08%)
occurrences (all)	3	2	2
Epistaxis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Haemoptysis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Hiccups			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Orthopnoea			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Lung Disorder			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Nasal Congestion			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Oropharyngeal Pain			
subjects affected / exposed	2 / 67 (2.99%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	2	1	1
Oropharyngeal Spasm			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Wheezing			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Upper-Airway Cough Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Pharyngeal Erythema			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Pleural Effusion			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Pneumothorax			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Productive Cough			
subjects affected / exposed	0 / 67 (0.00%)	5 / 67 (7.46%)	2 / 65 (3.08%)
occurrences (all)	0	5	3
Pulmonary Congestion			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Pulmonary Oedema			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Respiratory Distress			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Respiratory Failure			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Rhinitis Allergic			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Rhinorrhoea			

subjects affected / exposed	0 / 67 (0.00%)	3 / 67 (4.48%)	0 / 65 (0.00%)
occurrences (all)	0	4	0
Sleep Apnoea Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Sneezing			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Congestion			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Aggression			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Mood Swings			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	4
Mood Altered			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Psychiatric Decompensation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Psychotic Disorder			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Restlessness			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Sleep Disorder			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	3 / 65 (4.62%)
occurrences (all)	0	2	4

Anxiety			
subjects affected / exposed	2 / 67 (2.99%)	1 / 67 (1.49%)	4 / 65 (6.15%)
occurrences (all)	3	1	4
Confusional State			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	2	0	2
Depressed Mood			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 67 (0.00%)	4 / 67 (5.97%)	4 / 65 (6.15%)
occurrences (all)	0	4	5
Depressive Symptom			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Emotional Disorder			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Emotional Distress			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Insomnia			
subjects affected / exposed	12 / 67 (17.91%)	16 / 67 (23.88%)	13 / 65 (20.00%)
occurrences (all)	12	25	23
Irritability			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	2 / 65 (3.08%)
occurrences (all)	1	1	2
Libido Decreased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Nervousness			
subjects affected / exposed	1 / 67 (1.49%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	1	2	0

Product issues			
Device Breakage			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Device Dislocation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Investigations			
Alanine Aminotransferase Decreased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Blood Iron Decreased			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Blood Fibrinogen Increased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			
subjects affected / exposed	2 / 67 (2.99%)	7 / 67 (10.45%)	8 / 65 (12.31%)
occurrences (all)	2	11	13
Blood Creatinine Decreased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	1 / 67 (1.49%)	5 / 67 (7.46%)	3 / 65 (4.62%)
occurrences (all)	1	7	3
Aspergillus Test Positive			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0

Aspartate Aminotransferase Increased			
subjects affected / exposed	2 / 67 (2.99%)	4 / 67 (5.97%)	3 / 65 (4.62%)
occurrences (all)	2	6	4
Alanine Aminotransferase Increased			
subjects affected / exposed	3 / 67 (4.48%)	5 / 67 (7.46%)	4 / 65 (6.15%)
occurrences (all)	3	6	6
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Respiratory Rate Increased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Pain Threshold Decreased			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
N-Terminal Prohormone Brain Natriuretic Peptide Increased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Myoglobin Blood Increased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Intra-Abdominal Pressure Increased			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
International Normalised Ratio Increased			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Gamma-Glutamyltransferase Increased			
subjects affected / exposed	1 / 67 (1.49%)	5 / 67 (7.46%)	0 / 65 (0.00%)
occurrences (all)	1	17	0
Ejection Fraction Decreased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Clostridium Test Positive			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Cardiac Murmur			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
C-Reactive Protein Increased			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	1	0	3
Body Temperature Increased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Blood Urea Increased			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Reticulocyte Count Increased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Blood Pressure Increased			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Weight Increased			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	2	1	0
Weight Decreased			
subjects affected / exposed	2 / 67 (2.99%)	7 / 67 (10.45%)	8 / 65 (12.31%)
occurrences (all)	2	10	12
Troponin I Increased			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Meniscus Cyst			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Animal Bite			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Arthropod Bite			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Clavicle Fracture			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	3 / 65 (4.62%)
occurrences (all)	0	0	5
Face Injury			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Ligament Sprain			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Joint Injury			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Joint Dislocation			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Head Injury			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Hand Fracture			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	6 / 65 (9.23%)
occurrences (all)	0	2	10
Muscle Rupture			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Post Procedural Complication			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Rib Fracture			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Skin Abrasion			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Skin Laceration			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Spinal Compression Fracture			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Subcutaneous Haematoma			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Sunburn			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Tendon Rupture			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	2
Thermal Burn			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Tooth Fracture			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Wound Dehiscence			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic			

disorders			
Ichthyosis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Hydrocele			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Limb Malformation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Malformation Venous			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Cardiac Septal Hypertrophy			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Sinus Bradycardia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Sinus Tachycardia			
subjects affected / exposed	2 / 67 (2.99%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	2	1	1
Supraventricular Tachycardia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Tachycardia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	2 / 65 (3.08%)
occurrences (all)	0	1	2
Cardiac Failure Chronic			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Cardiac Failure			

subjects affected / exposed	1 / 67 (1.49%)	3 / 67 (4.48%)	1 / 65 (1.54%)
occurrences (all)	1	4	1
Bundle Branch Block Right			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Bradycardia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Atrial Flutter			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Atrial Fibrillation			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	2 / 65 (3.08%)
occurrences (all)	0	1	3
Ventricular Pre-Excitation			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Angina Pectoris			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	1 / 65 (1.54%)
occurrences (all)	0	2	1
Nervous system disorders			
Ageusia			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	1	1	1
Head Discomfort			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Amnesia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	3 / 65 (4.62%)
occurrences (all)	0	0	3
Aphasia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0

Balance Disorder			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Burning Sensation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Cauda Equina Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Cerebral Small Vessel Ischaemic Disease			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Cervical Radiculopathy			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Cervicobrachial Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Cognitive Disorder			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Depressed Level of Consciousness			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	6 / 67 (8.96%)	8 / 67 (11.94%)	9 / 65 (13.85%)
occurrences (all)	6	9	12
Dysaesthesia			
subjects affected / exposed	2 / 67 (2.99%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	2	1	0
Dysgeusia			
subjects affected / exposed	3 / 67 (4.48%)	2 / 67 (2.99%)	2 / 65 (3.08%)
occurrences (all)	3	2	2
Allodynia			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	7 / 67 (10.45%)	6 / 67 (8.96%)	5 / 65 (7.69%)
occurrences (all)	7	6	7
Piriformis Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 67 (0.00%)	3 / 67 (4.48%)	0 / 65 (0.00%)
occurrences (all)	0	3	0
Hypogeusia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	4
Leukoencephalopathy			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Loss of Consciousness			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Memory Impairment			
subjects affected / exposed	0 / 67 (0.00%)	3 / 67 (4.48%)	1 / 65 (1.54%)
occurrences (all)	0	3	1
Monoparesis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	2 / 67 (2.99%)	2 / 67 (2.99%)	2 / 65 (3.08%)
occurrences (all)	2	2	2
Neuromyopathy			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Neuropathy Peripheral			

subjects affected / exposed	1 / 67 (1.49%)	3 / 67 (4.48%)	1 / 65 (1.54%)
occurrences (all)	1	3	2
Paraesthesia			
subjects affected / exposed	2 / 67 (2.99%)	9 / 67 (13.43%)	5 / 65 (7.69%)
occurrences (all)	2	11	6
Peripheral Motor Neuropathy			
subjects affected / exposed	1 / 67 (1.49%)	4 / 67 (5.97%)	1 / 65 (1.54%)
occurrences (all)	1	10	1
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Peripheral Sensory Neuropathy			
subjects affected / exposed	28 / 67 (41.79%)	26 / 67 (38.81%)	14 / 65 (21.54%)
occurrences (all)	42	56	27
Hyperaesthesia			
subjects affected / exposed	2 / 67 (2.99%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Polyneuropathy			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Psychomotor Hyperactivity			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Resting Tremor			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Restless Legs Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Sciatica			
subjects affected / exposed	2 / 67 (2.99%)	3 / 67 (4.48%)	1 / 65 (1.54%)
occurrences (all)	3	4	1
Seizure			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Sensory Disturbance			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Syncope			
subjects affected / exposed	0 / 67 (0.00%)	4 / 67 (5.97%)	3 / 65 (4.62%)
occurrences (all)	0	5	3
Taste Disorder			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	2 / 65 (3.08%)
occurrences (all)	0	1	2
Tremor			
subjects affected / exposed	4 / 67 (5.97%)	3 / 67 (4.48%)	4 / 65 (6.15%)
occurrences (all)	4	3	7
Trigeminal Neuralgia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Increased Tendency to Bruise			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Febrile Neutropenia			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	1	1	1
Bone Marrow Failure			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0

Leukopenia			
subjects affected / exposed	9 / 67 (13.43%)	8 / 67 (11.94%)	11 / 65 (16.92%)
occurrences (all)	20	49	75
Anaemia Macrocytic			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	25 / 67 (37.31%)	30 / 67 (44.78%)	44 / 65 (67.69%)
occurrences (all)	64	138	226
Lymphopenia			
subjects affected / exposed	13 / 67 (19.40%)	15 / 67 (22.39%)	10 / 65 (15.38%)
occurrences (all)	42	130	64
Lymphadenopathy			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	12 / 67 (17.91%)	30 / 67 (44.78%)	26 / 65 (40.00%)
occurrences (all)	19	86	74
Thrombocytopenic Purpura			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	25 / 67 (37.31%)	38 / 67 (56.72%)	23 / 65 (35.38%)
occurrences (all)	68	179	95
Neutrophilia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo Positional			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	1 / 67 (1.49%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	1	2	0
Tympanic Membrane Perforation			

subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	1	1	1
Meniere's Disease			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Hypoacusis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	2	1
Eustachian Tube Dysfunction			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Ear Pain			
subjects affected / exposed	1 / 67 (1.49%)	2 / 67 (2.99%)	1 / 65 (1.54%)
occurrences (all)	1	2	1
Ear Discomfort			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Deafness Neurosensory			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Deafness			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry Age-Related Macular Degeneration			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Diplopia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Corneal Oedema			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Corneal Disorder			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Conjunctivitis Allergic			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Conjunctival Irritation			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Conjunctival Hyperaemia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Chalazion			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	4	0
Cataract Nuclear			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Cataract Cortical			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Cataract			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	11 / 65 (16.92%)
occurrences (all)	0	1	13
Blepharitis			
subjects affected / exposed	1 / 67 (1.49%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	1	2	0
Keratitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Lens Dislocation			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Macular Degeneration			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Macular Hole			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Ocular Discomfort			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Periorbital Swelling			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Retinal Detachment			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Retinal Vein Occlusion			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Vision Blurred			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	2 / 65 (3.08%)
occurrences (all)	1	1	2
Visual Impairment			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Vitreoretinal Traction Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Dry Eye			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	2 / 65 (3.08%)
occurrences (all)	0	2	2
Eye Discharge			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Eye Pain			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Eyelid Ptosis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Foreign Body Sensation in Eyes			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	1 / 67 (1.49%)	4 / 67 (5.97%)	0 / 65 (0.00%)
occurrences (all)	1	6	0
Abdominal Distension			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Abdominal Hernia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Faecal Vomiting			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Abdominal Pain Upper			
subjects affected / exposed	2 / 67 (2.99%)	4 / 67 (5.97%)	3 / 65 (4.62%)
occurrences (all)	2	4	3
Aerophagia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Anal Fissure			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Aphthous Ulcer			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Bile Acid Malabsorption			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1

Chronic Gastritis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	26 / 67 (38.81%)	30 / 67 (44.78%)	21 / 65 (32.31%)
occurrences (all)	30	39	28
Dental Caries			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	1 / 65 (1.54%)
occurrences (all)	0	2	1
Diarrhoea			
subjects affected / exposed	16 / 67 (23.88%)	23 / 67 (34.33%)	32 / 65 (49.23%)
occurrences (all)	20	37	68
Diarrhoea Haemorrhagic			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Dry Mouth			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	2 / 65 (3.08%)
occurrences (all)	0	2	2
Dyspepsia			
subjects affected / exposed	2 / 67 (2.99%)	4 / 67 (5.97%)	1 / 65 (1.54%)
occurrences (all)	2	4	1
Dysphagia			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Epigastric Discomfort			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Abdominal Pain			
subjects affected / exposed	3 / 67 (4.48%)	9 / 67 (13.43%)	3 / 65 (4.62%)
occurrences (all)	4	9	4
Faeces Discoloured			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Intestinal Obstruction			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0

Food Poisoning			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Gastric Disorder			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	3	0
Gastrointestinal Disorder			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Motility Disorder			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Gingival Bleeding			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Gingival Discomfort			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Gingival Pain			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Gingival Ulceration			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Haemorrhoidal Haemorrhage			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0

Haemorrhoids			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Hypoaesthesia Teeth			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Infrequent Bowel Movements			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Swollen Tongue			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	2 / 67 (2.99%)	4 / 67 (5.97%)	3 / 65 (4.62%)
occurrences (all)	2	5	3
Intra-Abdominal Haematoma			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Irritable Bowel Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Melaena			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Mouth Cyst			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Mouth Haemorrhage			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Mouth Ulceration			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	1	1	0

Nausea			
subjects affected / exposed	12 / 67 (17.91%)	23 / 67 (34.33%)	8 / 65 (12.31%)
occurrences (all)	14	32	11
Noninfective Gingivitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	3 / 67 (4.48%)	2 / 67 (2.99%)	2 / 65 (3.08%)
occurrences (all)	3	2	2
Oesophagitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Oral Dysaesthesia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Oral Pain			
subjects affected / exposed	2 / 67 (2.99%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	2	0	1
Paraesthesia Oral			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Rectal Haemorrhage			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Tooth Disorder			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	2 / 67 (2.99%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	2	0	2
Vomiting			
subjects affected / exposed	6 / 67 (8.96%)	14 / 67 (20.90%)	7 / 65 (10.77%)
occurrences (all)	10	16	9

Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hepatic Function Abnormal			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	7	1
Cholestasis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Liver Disorder			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	3
Hypertransaminasaemia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	1	0	2
Hepatotoxicity			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Hepatocellular Injury			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	4	0	1
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	3	0
Alopecia			

subjects affected / exposed	1 / 67 (1.49%)	3 / 67 (4.48%)	1 / 65 (1.54%)
occurrences (all)	1	3	1
Petechiae			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Dermatitis Diaper			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Dermatitis Exfoliative Generalised			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Drug Eruption			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	4 / 67 (5.97%)	7 / 67 (10.45%)	2 / 65 (3.08%)
occurrences (all)	4	7	2
Haemorrhage Subcutaneous			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Hirsutism			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	2 / 65 (3.08%)
occurrences (all)	1	1	2
Hyperkeratosis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Intertrigo			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	3
Macule			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Pain of Skin			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Dermatitis Allergic			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	4 / 67 (5.97%)	8 / 67 (11.94%)	3 / 65 (4.62%)
occurrences (all)	5	11	3
Urticaria			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Rash			
subjects affected / exposed	9 / 67 (13.43%)	11 / 67 (16.42%)	10 / 65 (15.38%)
occurrences (all)	12	17	12
Rash Erythematous			
subjects affected / exposed	2 / 67 (2.99%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	2	0	1
Rash Generalised			
subjects affected / exposed	4 / 67 (5.97%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	4	0	0
Rash Macular			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Rash Maculo-Papular			
subjects affected / exposed	3 / 67 (4.48%)	4 / 67 (5.97%)	4 / 65 (6.15%)
occurrences (all)	8	8	6
Rash Pruritic			
subjects affected / exposed	3 / 67 (4.48%)	3 / 67 (4.48%)	0 / 65 (0.00%)
occurrences (all)	4	4	0
Rosacea			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Segmented Hyalinising Vasculitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Sensitive Skin			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Skin Lesion			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	2 / 65 (3.08%)
occurrences (all)	0	2	2
Skin Mass			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Skin Reaction			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Skin Ulcer			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	2
Swelling Face			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	2
Toxic Skin Eruption			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Psoriasis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 67 (1.49%)	3 / 67 (4.48%)	4 / 65 (6.15%)
occurrences (all)	1	8	6
Urinary Retention			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	1 / 65 (1.54%)
occurrences (all)	0	2	1

Chronic Kidney Disease			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Cystitis Noninfective			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 67 (0.00%)	3 / 67 (4.48%)	0 / 65 (0.00%)
occurrences (all)	0	4	0
Haematuria			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	1 / 65 (1.54%)
occurrences (all)	0	2	1
Hydronephrosis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Ketonuria			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	1 / 65 (1.54%)
occurrences (all)	0	2	1
Oliguria			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	1 / 67 (1.49%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	1	2	0
Renal Colic			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Renal Failure			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	3 / 65 (4.62%)
occurrences (all)	0	2	5
Renal Impairment			
subjects affected / exposed	1 / 67 (1.49%)	2 / 67 (2.99%)	2 / 65 (3.08%)
occurrences (all)	1	2	3

Urethral Haemorrhage			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Urinary Incontinence			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Bladder Pain			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Urinary Tract Obstruction			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Cushing's Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Thyroid Mass			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Goitre			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Amyotrophy			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Arthralgia			
subjects affected / exposed	1 / 67 (1.49%)	15 / 67 (22.39%)	10 / 65 (15.38%)
occurrences (all)	1	23	21
Arthritis			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Arthropathy			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Back Pain			
subjects affected / exposed	7 / 67 (10.45%)	19 / 67 (28.36%)	14 / 65 (21.54%)
occurrences (all)	8	30	17
Bone Pain			
subjects affected / exposed	0 / 67 (0.00%)	5 / 67 (7.46%)	1 / 65 (1.54%)
occurrences (all)	0	5	1
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Flank Pain			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Foot Deformity			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Fracture Pain			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Groin Pain			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Haematoma Muscle			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	2 / 65 (3.08%)
occurrences (all)	0	1	2
Hypercreatinaemia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Joint Effusion			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Joint Range of Motion Decreased			

subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Joint Stiffness			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Joint Swelling			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Osteonecrosis of Jaw			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	2
Metatarsalgia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Osteitis			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	4	0
Neck Pain			
subjects affected / exposed	2 / 67 (2.99%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	2	1	1
Myopathy			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	2	0	1
Myalgia			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	4 / 65 (6.15%)
occurrences (all)	0	2	6
Musculoskeletal Stiffness			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal Pain			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	1	1	1
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Musculoskeletal Chest Pain			

subjects affected / exposed	1 / 67 (1.49%)	8 / 67 (11.94%)	6 / 65 (9.23%)
occurrences (all)	1	9	8
Muscular Weakness			
subjects affected / exposed	2 / 67 (2.99%)	4 / 67 (5.97%)	3 / 65 (4.62%)
occurrences (all)	3	4	3
Muscle Tightness			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Muscle Spasms			
subjects affected / exposed	4 / 67 (5.97%)	4 / 67 (5.97%)	21 / 65 (32.31%)
occurrences (all)	4	4	36
Muscle Discomfort			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Muscle Contracture			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Muscle Atrophy			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	4
Osteoarthritis			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	1 / 65 (1.54%)
occurrences (all)	0	2	1
Trismus			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Tendonitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Tendon Disorder			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Synovial Cyst			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Spinal Pain			

subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	3 / 65 (4.62%)
occurrences (all)	1	0	3
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Pain in Jaw			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Pain in Extremity			
subjects affected / exposed	6 / 67 (8.96%)	11 / 67 (16.42%)	3 / 65 (4.62%)
occurrences (all)	6	11	6
Osteoporosis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bacterial Infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Acarodermatitis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Balanitis Candida			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	2 / 67 (2.99%)	5 / 67 (7.46%)	4 / 65 (6.15%)
occurrences (all)	2	5	4
Clostridium Difficile Infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Clostridium Difficile Colitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Clostridium Colitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0

Citrobacter Infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Cellulitis Orbital			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	3 / 65 (4.62%)
occurrences (all)	1	0	4
Candida Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Campylobacter Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Campylobacter Gastroenteritis			
subjects affected / exposed	1 / 67 (1.49%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Bronchitis Viral			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	2 / 67 (2.99%)	17 / 67 (25.37%)	10 / 65 (15.38%)
occurrences (all)	2	28	19
Body Tinea			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Covid-19			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Herpes Virus Infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Cytomegalovirus Infection Reactivation			

subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	3	0
Ear Infection			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Herpes Dermatitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hepatitis E			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Genital Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Gastroenteritis Viral			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 67 (1.49%)	7 / 67 (10.45%)	2 / 65 (3.08%)
occurrences (all)	1	7	3
Gastritis Viral			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Eye Infection			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	2
Escherichia Urinary Tract Infection			

subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	3	0
Escherichia Pyelonephritis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Erysipelas			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	3
Hordeolum			
subjects affected / exposed	2 / 67 (2.99%)	3 / 67 (4.48%)	1 / 65 (1.54%)
occurrences (all)	3	5	1
Impetigo			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	3
Infected Skin Ulcer			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	4 / 65 (6.15%)
occurrences (all)	0	0	4
Infection Parasitic			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Infective Exacerbation of Chronic Obstructive Airways Disease			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 67 (1.49%)	3 / 67 (4.48%)	3 / 65 (4.62%)
occurrences (all)	1	3	3
Klebsiella Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0

Lower Respiratory Tract Infection			
subjects affected / exposed	3 / 67 (4.48%)	1 / 67 (1.49%)	2 / 65 (3.08%)
occurrences (all)	3	1	4
Metapneumovirus Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	2 / 67 (2.99%)	16 / 67 (23.88%)	8 / 65 (12.31%)
occurrences (all)	3	21	11
Omphalitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Oral Candidiasis			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	1 / 65 (1.54%)
occurrences (all)	0	2	1
Oral Fungal Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Oral Herpes			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Otitis Externa			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Herpes Zoster			
subjects affected / exposed	0 / 67 (0.00%)	6 / 67 (8.96%)	2 / 65 (3.08%)
occurrences (all)	0	7	2
Respiratory Syncytial Virus Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Pulpitis Dental			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Postoperative Wound Infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1

Pneumonia Bacterial			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	3 / 67 (4.48%)	6 / 67 (8.96%)	9 / 65 (13.85%)
occurrences (all)	3	7	13
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Periodontitis			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	3	0
Paronychia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Otitis Media			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			
subjects affected / exposed	1 / 67 (1.49%)	3 / 67 (4.48%)	2 / 65 (3.08%)
occurrences (all)	1	3	2
Pharyngitis			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	2 / 65 (3.08%)
occurrences (all)	0	2	2
Tooth Infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Tooth Abscess			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Tonsillitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0

Tongue Fungal Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Tinea Infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Skin Infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Sinusitis			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	2 / 65 (3.08%)
occurrences (all)	0	2	2
Sepsis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Rhinovirus Infection			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	7 / 65 (10.77%)
occurrences (all)	0	4	9
Tracheitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Viral Infection			
subjects affected / exposed	3 / 67 (4.48%)	0 / 67 (0.00%)	3 / 65 (4.62%)
occurrences (all)	3	0	3
Urinary Tract Infection Fungal			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Urinary Tract Infection Bacterial			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	3	0
Urinary Tract Infection			
subjects affected / exposed	0 / 67 (0.00%)	9 / 67 (13.43%)	8 / 65 (12.31%)
occurrences (all)	0	11	10

Upper Respiratory Tract Infection Bacterial			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	5 / 67 (7.46%)	19 / 67 (28.36%)	20 / 65 (30.77%)
occurrences (all)	5	34	32
Viral Pharyngitis			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Viral Rhinitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Mycotic Infection			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	3	0
Viral Rash			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Hyperkalaemia			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	3 / 65 (4.62%)
occurrences (all)	0	4	4
Hyperglycaemia			
subjects affected / exposed	1 / 67 (1.49%)	2 / 67 (2.99%)	9 / 65 (13.85%)
occurrences (all)	3	3	31
Hypercreatininaemia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Hypercholesterolaemia			

subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Hyperamylasaemia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 67 (0.00%)	2 / 67 (2.99%)	1 / 65 (1.54%)
occurrences (all)	0	2	1
Fluid Retention			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	1 / 65 (1.54%)
occurrences (all)	0	1	3
Fluid Overload			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Diabetic Metabolic Decompensation			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Diabetes Mellitus			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Decreased Appetite			
subjects affected / exposed	2 / 67 (2.99%)	13 / 67 (19.40%)	4 / 65 (6.15%)
occurrences (all)	2	18	6
Hypernatraemia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Vitamin B12 Deficiency			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			

subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	2 / 65 (3.08%)
occurrences (all)	0	2	2
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Steroid Diabetes			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Malnutrition			
subjects affected / exposed	1 / 67 (1.49%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Iron Deficiency			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Increased Appetite			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 67 (1.49%)	4 / 67 (5.97%)	4 / 65 (6.15%)
occurrences (all)	1	6	20
Hyponatraemia			
subjects affected / exposed	1 / 67 (1.49%)	3 / 67 (4.48%)	0 / 65 (0.00%)
occurrences (all)	1	5	0
Hypomagnesaemia			
subjects affected / exposed	2 / 67 (2.99%)	0 / 67 (0.00%)	5 / 65 (7.69%)
occurrences (all)	2	0	11
Hypokalaemia			
subjects affected / exposed	2 / 67 (2.99%)	7 / 67 (10.45%)	10 / 65 (15.38%)
occurrences (all)	2	8	28
Hypoglycaemia			
subjects affected / exposed	2 / 67 (2.99%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	3	0	6
Hypoferritinaemia			

subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	5 / 67 (7.46%)	6 / 67 (8.96%)	9 / 65 (13.85%)
occurrences (all)	5	11	23
Hypoalbuminaemia			
subjects affected / exposed	2 / 67 (2.99%)	0 / 67 (0.00%)	4 / 65 (6.15%)
occurrences (all)	3	0	4
Hyperphosphataemia			
subjects affected / exposed	0 / 67 (0.00%)	0 / 67 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Vitamin D Deficiency			
subjects affected / exposed	0 / 67 (0.00%)	1 / 67 (1.49%)	0 / 65 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Daratumumab + Carfilzomib + Dexamethasone (D-Kd)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	66 / 66 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Seborrhoeic Keratosis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Pituitary Tumour Benign			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Malignant Melanoma			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Lipoma			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Gastrointestinal Tract Adenoma			

subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Colon Adenoma			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Basal Cell Carcinoma			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Tumour Pain			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Vascular disorders			
Aortic Stenosis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Venous Thrombosis Limb			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Deep Vein Thrombosis			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Flushing			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Haematoma			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Hot Flush			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Hypertension			
subjects affected / exposed	23 / 66 (34.85%)		
occurrences (all)	55		
Hypotension			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		

Orthostatic Hypotension			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Peripheral Coldness			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Phlebitis			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Thrombophlebitis			
subjects affected / exposed	3 / 66 (4.55%)		
occurrences (all)	3		
Thrombophlebitis Superficial			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Thrombosed Varicose Vein			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Varicose Vein			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Vascular Pain			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Cyanosis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
White Coat Hypertension			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	13 / 66 (19.70%)		
occurrences (all)	16		
Administration Site Erythema			

subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	2			
Administration Site Pruritus				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Administration Site Swelling				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Asthenia				
subjects affected / exposed	14 / 66 (21.21%)			
occurrences (all)	18			
Catheter Site Erythema				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Chest Discomfort				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Chest Pain				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Chills				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Cyst				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Discomfort				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Face Oedema				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	7			
Facial Pain				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Feeling Cold				

subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Injection Site Rash				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Generalised Oedema				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	3			
Hernia Pain				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Hyperthermia				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Hypothermia				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Impaired Healing				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Inflammation				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Influenza Like Illness				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Infusion Site Pain				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Injection Site Bruising				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Injection Site Eczema				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Injection Site Erythema				

subjects affected / exposed	5 / 66 (7.58%)			
occurrences (all)	5			
Injection Site Haemorrhage				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Injection Site Induration				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Injection Site Pain				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	4			
Injection Site Pruritus				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
General Physical Health Deterioration				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Localised Oedema				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	3			
Injection Site Swelling				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Vaccination Site Erythema				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Temperature Regulation Disorder				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Swelling Face				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Swelling				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Secretion Discharge				

subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	14 / 66 (21.21%)		
occurrences (all)	22		
Peripheral Swelling			
subjects affected / exposed	3 / 66 (4.55%)		
occurrences (all)	3		
Pain			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Oedema Peripheral			
subjects affected / exposed	12 / 66 (18.18%)		
occurrences (all)	23		
Oedema			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Injection Site Reaction			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Mucosal Inflammation			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Drug Hypersensitivity			

subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Allergy to Plants			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Hypogammaglobulinaemia			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Breast Haematoma			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Cystocele			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Genital Rash			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Pelvic Discomfort			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	2		
Pelvic Floor Muscle Weakness			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Pelvic Pain			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Scrotal Erythema			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Uterine Prolapse			

subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Vaginal Haemorrhage			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Vulvovaginal Pruritus			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Bronchopneumopathy			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	13 / 66 (19.70%)		
occurrences (all)	13		
Dysphonia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	12 / 66 (18.18%)		
occurrences (all)	13		
Dyspnoea Exertional			
subjects affected / exposed	4 / 66 (6.06%)		
occurrences (all)	4		
Epistaxis			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Haemoptysis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Hiccups			

subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Orthopnoea				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Lung Disorder				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Nasal Congestion				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Oropharyngeal Pain				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	3			
Oropharyngeal Spasm				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Hypoxia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Wheezing				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Upper-Airway Cough Syndrome				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Pharyngeal Erythema				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Pleural Effusion				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Pneumothorax				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Productive Cough				

subjects affected / exposed	4 / 66 (6.06%)		
occurrences (all)	5		
Pulmonary Congestion			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Pulmonary Oedema			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Respiratory Distress			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Respiratory Failure			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Rhinitis Allergic			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	5 / 66 (7.58%)		
occurrences (all)	5		
Sleep Apnoea Syndrome			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Sneezing			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Upper Respiratory Tract Congestion			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Agitation			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Aggression			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		

Mood Swings				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Mood Altered				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Psychiatric Decompensation				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Psychotic Disorder				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Restlessness				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Sleep Disorder				
subjects affected / exposed	4 / 66 (6.06%)			
occurrences (all)	5			
Anxiety				
subjects affected / exposed	7 / 66 (10.61%)			
occurrences (all)	8			
Confusional State				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Depressed Mood				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Depression				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Depressive Symptom				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Emotional Disorder				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			

Emotional Distress			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Hallucination			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	23 / 66 (34.85%)		
occurrences (all)	37		
Irritability			
subjects affected / exposed	4 / 66 (6.06%)		
occurrences (all)	5		
Libido Decreased			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Nervousness			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Product issues			
Device Breakage			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Device Dislocation			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Investigations			
Alanine Aminotransferase Decreased			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Blood Iron Decreased			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Blood Fibrinogen Increased			

subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Blood Creatinine Increased				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Blood Creatinine Decreased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Activated Partial Thromboplastin Time Prolonged				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Blood Alkaline Phosphatase Increased				
subjects affected / exposed	5 / 66 (7.58%)			
occurrences (all)	10			
Aspergillus Test Positive				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Aspartate Aminotransferase Increased				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	6			
Alanine Aminotransferase Increased				
subjects affected / exposed	7 / 66 (10.61%)			
occurrences (all)	16			
Blood Creatine Phosphokinase Increased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Respiratory Rate Increased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Pain Threshold Decreased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
N-Terminal Prohormone Brain Natriuretic Peptide Increased				

subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Myoglobin Blood Increased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Intra-Abdominal Pressure Increased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
International Normalised Ratio Increased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Gamma-Glutamyltransferase Increased				
subjects affected / exposed	8 / 66 (12.12%)			
occurrences (all)	19			
Ejection Fraction Decreased				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Clostridium Test Positive				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Cardiac Murmur				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
C-Reactive Protein Increased				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Body Temperature Increased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Blood Urea Increased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Reticulocyte Count Increased				

subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Blood Pressure Increased			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Weight Increased			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Weight Decreased			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Troponin I Increased			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Meniscus Cyst			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Animal Bite			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Arthropod Bite			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Clavicle Fracture			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Face Injury			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Ligament Sprain			

subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Joint Injury				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Joint Dislocation				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Head Injury				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hand Fracture				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Fall				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Muscle Rupture				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Muscle Strain				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Post Procedural Complication				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Rib Fracture				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Skin Abrasion				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Skin Laceration				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Spinal Compression Fracture				

subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0		
Subcutaneous Haematoma subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0		
Sunburn subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0		
Tendon Rupture subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0		
Thermal Burn subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0		
Tooth Fracture subjects affected / exposed occurrences (all)	1 / 66 (1.52%) 1		
Wound Dehiscence subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0		
Congenital, familial and genetic disorders			
Ichthyosis subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0		
Hydrocele subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0		
Limb Malformation subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0		
Malformation Venous subjects affected / exposed occurrences (all)	1 / 66 (1.52%) 2		
Cardiac disorders			

Cardiac Septal Hypertrophy				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Palpitations				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Sinus Bradycardia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Sinus Tachycardia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Supraventricular Tachycardia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Tachycardia				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	5			
Cardiac Failure Chronic				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Cardiac Failure				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Bundle Branch Block Right				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Bradycardia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Atrial Flutter				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Atrial Fibrillation				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			

Ventricular Pre-Excitation			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Angina Pectoris			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Head Discomfort			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Amnesia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Aphasia			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Ataxia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Balance Disorder			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Burning Sensation			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Cauda Equina Syndrome			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Cerebral Small Vessel Ischaemic Disease			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Cervical Radiculopathy			

subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Cervicobrachial Syndrome				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Cognitive Disorder				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Depressed Level of Consciousness				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Dizziness				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	5			
Dysaesthesia				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Dysgeusia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Allodynia				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Headache				
subjects affected / exposed	15 / 66 (22.73%)			
occurrences (all)	23			
Piriformis Syndrome				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hypoaesthesia				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Hypogeusia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Lethargy				

subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Leukoencephalopathy				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Loss of Consciousness				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Memory Impairment				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Monoparesis				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	3			
Neuralgia				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Neuromyopathy				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Neuropathy Peripheral				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Paraesthesia				
subjects affected / exposed	6 / 66 (9.09%)			
occurrences (all)	6			
Peripheral Motor Neuropathy				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Peripheral Sensorimotor Neuropathy				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	5			
Peripheral Sensory Neuropathy				
subjects affected / exposed	7 / 66 (10.61%)			
occurrences (all)	14			
Hyperaesthesia				

subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Polyneuropathy				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Psychomotor Hyperactivity				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Radiculopathy				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Resting Tremor				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Restless Legs Syndrome				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Sciatica				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Seizure				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Sensory Disturbance				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Somnolence				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Syncope				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Taste Disorder				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Tremor				

subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	3		
Trigeminal Neuralgia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Increased Tendency to Bruise			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Febrile Neutropenia			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Bone Marrow Failure			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Leukopenia			
subjects affected / exposed	6 / 66 (9.09%)		
occurrences (all)	38		
Anaemia Macrocytic			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Neutropenia			
subjects affected / exposed	15 / 66 (22.73%)		
occurrences (all)	27		
Lymphopenia			
subjects affected / exposed	12 / 66 (18.18%)		
occurrences (all)	53		
Lymphadenopathy			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		

Anaemia				
subjects affected / exposed	25 / 66 (37.88%)			
occurrences (all)	58			
Thrombocytopenic Purpura				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Thrombocytopenia				
subjects affected / exposed	34 / 66 (51.52%)			
occurrences (all)	175			
Neutrophilia				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	3			
Ear and labyrinth disorders				
Vertigo Positional				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Vertigo				
subjects affected / exposed	6 / 66 (9.09%)			
occurrences (all)	8			
Tympanic Membrane Perforation				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Tinnitus				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	3			
Meniere's Disease				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hypoacusis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Eustachian Tube Dysfunction				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Ear Pain				

subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Ear Discomfort			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Deafness Neurosensory			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Deafness			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Eye disorders			
Dry Age-Related Macular Degeneration			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Diplopia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Corneal Oedema			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Corneal Disorder			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Conjunctivitis Allergic			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Conjunctival Irritation			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Conjunctival Hyperaemia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Conjunctival Haemorrhage			

subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Chalazion				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Cataract Nuclear				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Cataract Cortical				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Cataract				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Blepharitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Keratitis				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Lens Dislocation				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Macular Degeneration				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Macular Hole				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Ocular Discomfort				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Periorbital Swelling				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Retinal Detachment				

subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	3		
Retinal Vein Occlusion			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Vision Blurred			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Visual Impairment			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Vitreoretinal Traction Syndrome			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Dry Eye			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Eye Discharge			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Eye Pain			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Eyelid Ptosis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Foreign Body Sensation in Eyes			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Abdominal Distension			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		

Abdominal Hernia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Faecal Vomiting				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Abdominal Pain Upper				
subjects affected / exposed	4 / 66 (6.06%)			
occurrences (all)	5			
Aerophagia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Anal Fissure				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Aphthous Ulcer				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Bile Acid Malabsorption				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Chronic Gastritis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	6 / 66 (9.09%)			
occurrences (all)	6			
Dental Caries				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Diarrhoea				
subjects affected / exposed	20 / 66 (30.30%)			
occurrences (all)	30			
Diarrhoea Haemorrhagic				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			

Dry Mouth				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Dyspepsia				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Dysphagia				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Epigastric Discomfort				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Abdominal Pain				
subjects affected / exposed	4 / 66 (6.06%)			
occurrences (all)	4			
Faeces Discoloured				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Intestinal Obstruction				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Food Poisoning				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Gastric Disorder				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Gastritis				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Gastrointestinal Disorder				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Gastrointestinal Motility Disorder				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			

Gastrooesophageal Reflux Disease				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	3			
Gingival Bleeding				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Gingival Discomfort				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Gingival Pain				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Gingival Ulceration				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Haematochezia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Haemorrhoidal Haemorrhage				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Haemorrhoids				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Hypoaesthesia Teeth				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Infrequent Bowel Movements				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Flatulence				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Swollen Tongue				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			

Stomatitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Intra-Abdominal Haematoma				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Irritable Bowel Syndrome				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Melaena				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Mouth Cyst				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Mouth Haemorrhage				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Mouth Ulceration				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	17 / 66 (25.76%)			
occurrences (all)	28			
Noninfective Gingivitis				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	2			
Odynophagia				
subjects affected / exposed	4 / 66 (6.06%)			
occurrences (all)	5			
Oesophagitis				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	3			
Oral Dysaesthesia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			

Oral Pain subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0			
Paraesthesia Oral subjects affected / exposed occurrences (all)	1 / 66 (1.52%) 1			
Proctalgia subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0			
Rectal Haemorrhage subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0			
Tooth Disorder subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0			
Toothache subjects affected / exposed occurrences (all)	2 / 66 (3.03%) 2			
Vomiting subjects affected / exposed occurrences (all)	11 / 66 (16.67%) 14			
Upper Gastrointestinal Haemorrhage subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0			
Hepatobiliary disorders Biliary Colic subjects affected / exposed occurrences (all)	1 / 66 (1.52%) 1			
Hepatic Function Abnormal subjects affected / exposed occurrences (all)	2 / 66 (3.03%) 2			
Cholestasis subjects affected / exposed occurrences (all)	1 / 66 (1.52%) 1			
Cholelithiasis				

subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Liver Disorder			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Hypertransaminasaemia			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	6		
Hyperbilirubinaemia			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	3		
Hepatotoxicity			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Hepatocellular Injury			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Alopecia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Dermatitis Diaper			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Dermatitis Exfoliative Generalised			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Drug Eruption			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		

Ecchymosis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Erythema				
subjects affected / exposed	5 / 66 (7.58%)			
occurrences (all)	8			
Haemorrhage Subcutaneous				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hirsutism				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hyperhidrosis				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Hyperkeratosis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Intertrigo				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Macule				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Night Sweats				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Pain of Skin				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Dermatitis Allergic				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Pruritus				
subjects affected / exposed	6 / 66 (9.09%)			
occurrences (all)	8			

Urticaria				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Rash				
subjects affected / exposed	6 / 66 (9.09%)			
occurrences (all)	9			
Rash Erythematous				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Rash Generalised				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Rash Macular				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	2			
Rash Maculo-Papular				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Rash Pruritic				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Rosacea				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Segmented Hyalinising Vasculitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Sensitive Skin				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Skin Lesion				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Skin Mass				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			

Skin Reaction			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Skin Ulcer			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Swelling Face			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Toxic Skin Eruption			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Psoriasis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Urinary Retention			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Chronic Kidney Disease			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Cystitis Noninfective			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	3 / 66 (4.55%)		
occurrences (all)	5		
Haematuria			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Hydronephrosis			

subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Ketonuria			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Nocturia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Oliguria			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Pollakiuria			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Renal Colic			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Renal Failure			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		
Renal Impairment			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Urethral Haemorrhage			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Urinary Incontinence			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Bladder Pain			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Urinary Tract Obstruction			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Endocrine disorders			

Adrenal Insufficiency				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Cushing's Syndrome				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Thyroid Mass				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Goitre				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Musculoskeletal and connective tissue disorders				
Amyotrophy				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Arthralgia				
subjects affected / exposed	13 / 66 (19.70%)			
occurrences (all)	15			
Arthritis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Arthropathy				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Back Pain				
subjects affected / exposed	11 / 66 (16.67%)			
occurrences (all)	14			
Bone Pain				
subjects affected / exposed	7 / 66 (10.61%)			
occurrences (all)	8			
Cervical Spinal Stenosis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Flank Pain				

subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Foot Deformity				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Fracture Pain				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Groin Pain				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Haematoma Muscle				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hypercreatinaemia				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Intervertebral Disc Disorder				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Joint Effusion				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Joint Range of Motion Decreased				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Joint Stiffness				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Joint Swelling				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Osteonecrosis of Jaw				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Metatarsalgia				

subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Osteitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Neck Pain				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Myopathy				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Myalgia				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	4			
Musculoskeletal Stiffness				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Musculoskeletal Pain				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Musculoskeletal Discomfort				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Musculoskeletal Chest Pain				
subjects affected / exposed	7 / 66 (10.61%)			
occurrences (all)	7			
Muscular Weakness				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Muscle Tightness				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Muscle Spasms				
subjects affected / exposed	7 / 66 (10.61%)			
occurrences (all)	9			
Muscle Discomfort				

subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Muscle Contracture				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Muscle Atrophy				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Osteoarthritis				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Trismus				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Tendonitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Tendon Disorder				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Synovial Cyst				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Spinal Pain				
subjects affected / exposed	6 / 66 (9.09%)			
occurrences (all)	6			
Rotator Cuff Syndrome				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Pain in Jaw				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Pain in Extremity				
subjects affected / exposed	4 / 66 (6.06%)			
occurrences (all)	7			
Osteoporosis				

subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Bacterial Infection			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Acarodermatitis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Balanitis Candida			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	3 / 66 (4.55%)		
occurrences (all)	5		
Clostridium Difficile Infection			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Clostridium Difficile Colitis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Clostridium Colitis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Citrobacter Infection			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Cellulitis Orbital			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	2		
Candida Infection			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		

Campylobacter Infection subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0			
Campylobacter Gastroenteritis subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0			
Bronchitis Viral subjects affected / exposed occurrences (all)	1 / 66 (1.52%) 1			
Bronchitis subjects affected / exposed occurrences (all)	7 / 66 (10.61%) 7			
Body Tinea subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0			
Covid-19 subjects affected / exposed occurrences (all)	2 / 66 (3.03%) 2			
Herpes Virus Infection subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0			
Cytomegalovirus Infection Reactivation subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0			
Ear Infection subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0			
Herpes Dermatitis subjects affected / exposed occurrences (all)	1 / 66 (1.52%) 1			
Hepatitis E subjects affected / exposed occurrences (all)	1 / 66 (1.52%) 1			
Gingivitis				

subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Genital Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Gastrointestinal Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Gastroenteritis Viral				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Gastroenteritis				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	3			
Gastritis Viral				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Folliculitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Eye Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Escherichia Urinary Tract Infection				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Escherichia Pyelonephritis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Erysipelas				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Cystitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hordeolum				

subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Impetigo				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Infected Skin Ulcer				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Infection				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	3			
Infection Parasitic				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Infective Exacerbation of Chronic Obstructive Airways Disease				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	3			
Klebsiella Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Lower Respiratory Tract Infection				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	3			
Metapneumovirus Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	17 / 66 (25.76%)			
occurrences (all)	24			
Omphalitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			

Oral Candidiasis				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Oral Fungal Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Oral Herpes				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Otitis Externa				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Herpes Zoster				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Respiratory Syncytial Virus Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Pulpitis Dental				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Postoperative Wound Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Pneumonia Bacterial				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Respiratory Tract Infection Viral				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Periodontitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			

Paronychia				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	2			
Parainfluenzae Virus Infection				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Otitis Media				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Respiratory Tract Infection				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	4			
Pharyngitis				
subjects affected / exposed	3 / 66 (4.55%)			
occurrences (all)	3			
Tooth Infection				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Tooth Abscess				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	2			
Tonsillitis				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Tongue Fungal Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Tinea Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Skin Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			

Sepsis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Rhinovirus Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	5 / 66 (7.58%)			
occurrences (all)	7			
Tracheitis				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Viral Infection				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Urinary Tract Infection Fungal				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Urinary Tract Infection Bacterial				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Urinary Tract Infection				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Upper Respiratory Tract Infection Bacterial				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Upper Respiratory Tract Infection				
subjects affected / exposed	12 / 66 (18.18%)			
occurrences (all)	19			
Viral Pharyngitis				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Viral Rhinitis				

subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	2		
Vulvovaginal Mycotic Infection			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Viral Rash			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Hyperglycaemia			
subjects affected / exposed	7 / 66 (10.61%)		
occurrences (all)	13		
Hypercreatininaemia			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Hypercholesterolaemia			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Hypercalcaemia			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Hyperamylasaemia			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Gout			

subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Fluid Retention				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	2			
Fluid Overload				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Diabetic Metabolic Decompensation				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Diabetes Mellitus Inadequate Control				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Diabetes Mellitus				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Decreased Appetite				
subjects affected / exposed	4 / 66 (6.06%)			
occurrences (all)	6			
Hypernatraemia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Vitamin B12 Deficiency				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hypertriglyceridaemia				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	6			
Hyperuricaemia				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Type 2 Diabetes Mellitus				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Steroid Diabetes				

subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Malnutrition				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Iron Deficiency				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Increased Appetite				
subjects affected / exposed	1 / 66 (1.52%)			
occurrences (all)	1			
Hypophosphataemia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hyponatraemia				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	4			
Hypomagnesaemia				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	2			
Hypokalaemia				
subjects affected / exposed	2 / 66 (3.03%)			
occurrences (all)	4			
Hypoglycaemia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hypoferritinaemia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hypocalcaemia				
subjects affected / exposed	4 / 66 (6.06%)			
occurrences (all)	6			
Hypoalbuminaemia				
subjects affected / exposed	0 / 66 (0.00%)			
occurrences (all)	0			
Hyperphosphataemia				

subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	2		
Vitamin D Deficiency			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 June 2018	The purpose of this amendment-1 was to include address Health Authority requests and to correct administrative errors and inconsistencies in the original protocol.
12 October 2018	The purpose of this amendment-2 was to add a cohort to explore the efficacy and safety of daratumumab subcutaneous (SC) in combination with carfilzomib and dexamethasone (D-Kd).
31 January 2019	The purpose of this amendment-3 was to identification of a new important risk (hepatitis B virus reactivation).
28 January 2020	The purpose of this amendment-4 was to clarify the timing of the primary analysis for the D-Kd cohort and the end of study and to align language for anticipated events and pregnancy/contraception with the daratumumab program standard.
30 September 2020	The purpose of this amendment-5 was to define when the clinical cutoff for the final analysis occurred which marks the end of data collection, to define the end of study, and to clarify access to study drugs for subjects who continued to receive study treatment after data collection has ended.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported