



Clinical trial results:

A Phase I/II, randomized, placebo-controlled, observer-blind, multicenter study to evaluate the safety, reactogenicity and immunogenicity of GSK Biologicals' investigational respiratory syncytial virus (RSV) vaccine (adjuvanted with AS01E or AS01B or unadjuvanted) when administered intramuscularly according to a 0, 2 month schedule in adults aged 18 40 or 60-80 years.

Summary

EudraCT number	2018-000849-38
Trial protocol	BE
Global end of trial date	23 February 2021

Results information

Result version number	v2 (current)
This version publication date	10 September 2022
First version publication date	10 March 2022
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	208851
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GSKClinicalSupportHD@gsk.com, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.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	31 March 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 December 2019
Global end of trial reached?	Yes
Global end of trial date	23 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and reactogenicity of 2 doses of the investigational RSV vaccine administered IM according to a 0, 2 month schedule, up to one month after the last dose (Day 91, Visit 6).

Protection of trial subjects:

The subjects were observed closely for at least 60 minutes following the administration of the vaccines, with appropriate medical treatment readily available in case of anaphylaxis.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 January 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 333
Country: Number of subjects enrolled	United States: 720
Worldwide total number of subjects	1053
EEA total number of subjects	333

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)	387
From 65 to 84 years	666
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

1053 participants received the study vaccine or placebo and were included in the Exposed Set.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind ^[1]
Roles blinded	Investigator, Subject, Assessor

Blinding implementation details:

The study was conducted in an observer-blind manner during the vaccination phase. The persistence phase of Part B was considered as single-blind, given that the availability of safety results from the First analysis may have led to unblinding of specific subjects. The subjects remained blinded up to the study end.

Arms

Are arms mutually exclusive?	Yes
Arm title	Low Dose_PLAIN_A Group

Arm description:

Subjects in Part A, aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted low dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Arm type	Experimental
Investigational medicinal product name	RSV Vaccine (GSK3844766A) unadjuvanted low dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm

Arm title	Medium Dose_PLAIN_A Group
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Arm description:

Subjects in Part A aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted medium dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Arm type	Experimental
Investigational medicinal product name	RSV Vaccine (GSK3844766A) unadjuvanted medium dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm

Arm title	High Dose_PLAIN_A Group
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Arm description:

Subjects in Part A aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted high dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Arm type	Experimental
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Investigational medicinal product name	RSV Vaccine (GSK3844766A) unadjuvanted high dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm	
Arm title	Placebo_A Group
Arm description:	
Subjects in Part A aged 18-40 years, receiving 2 doses of placebo (Saline solution) control, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Arm type	Placebo
Investigational medicinal product name	Placebo (Saline solution)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm	
Arm title	Low Dose_PLAIN_B Group
Arm description:	
Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted low dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Arm type	Experimental
Investigational medicinal product name	RSV Vaccine (GSK3844766A) unadjuvanted low dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm	
Arm title	Medium Dose_PLAIN_B Group
Arm description:	
Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted medium dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Arm type	Experimental
Investigational medicinal product name	RSV Vaccine (GSK3844766A) unadjuvanted medium dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm	
Arm title	High Dose_PLAIN_B Group
Arm description:	
Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted high dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Arm type	Experimental

Investigational medicinal product name	RSV Vaccine (GSK3844766A) unadjuvanted high dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm	
Arm title	Low Dose_AS01E_B Group
Arm description:	
Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Arm type	Experimental
Investigational medicinal product name	RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01E
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm	
Arm title	Medium Dose_AS01E_B Group
Arm description:	
Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Arm type	Experimental
Investigational medicinal product name	RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01E
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm	
Arm title	High Dose_AS01E_B Group
Arm description:	
Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Arm type	Experimental
Investigational medicinal product name	RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm	
Arm title	Low Dose_AS01B_B Group
Arm description:	
Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Arm type	Experimental

Investigational medicinal product name	RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm	
Arm title	Medium Dose_AS01B_B Group

Arm description:

Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Arm type	Experimental
Investigational medicinal product name	RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm	
Arm title	High Dose_AS01B_B Group

Arm description:

Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Arm type	Experimental
Investigational medicinal product name	RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm	
Arm title	Placebo_B Group

Arm description:

Subjects in Part B aged 60-80 years, receiving 2 doses of placebo (Saline solution) control, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Arm type	Placebo
Investigational medicinal product name	Placebo (Saline solution)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two doses administered intramuscularly at Days 1 and 61 in the deltoid region of the arm

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.

Justification: The study was conducted in an observer-blind manner during the vaccination phase. The persistence phase of Part B was considered as single-blind, given that the availability of safety results from the First analysis may have led to unblinding of specific subjects. The subjects remained blinded up to the study end.

Number of subjects in period 1	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group
Started	12	12	12
Completed	12	10	11
Not completed	0	2	1
Adverse event, non-fatal	-	-	-
CONSENT WITHDRAWAL,DUE TO COVID-19 BUT NOT TO AEs	-	-	-
MIGRATED / MOVED FROM THE STUDY AREA	-	-	-
Lost to follow-up	-	2	1
UNKNOWN REASON	-	-	-
CONSENT WITHDRAWAL,NOT DUE TO COVID-19 OR TO AN AE	-	-	-

Number of subjects in period 1	Placebo_A Group	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group
Started	12	101	97
Completed	12	100	92
Not completed	0	1	5
Adverse event, non-fatal	-	-	1
CONSENT WITHDRAWAL,DUE TO COVID-19 BUT NOT TO AEs	-	-	-
MIGRATED / MOVED FROM THE STUDY AREA	-	-	-
Lost to follow-up	-	1	1
UNKNOWN REASON	-	-	-
CONSENT WITHDRAWAL,NOT DUE TO COVID-19 OR TO AN AE	-	-	3

Number of subjects in period 1	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group	Medium Dose_AS01E_B Group
Started	100	101	101
Completed	97	95	101
Not completed	3	6	0
Adverse event, non-fatal	1	1	-
CONSENT WITHDRAWAL,DUE TO COVID-19 BUT NOT TO AEs	-	-	-
MIGRATED / MOVED FROM THE STUDY AREA	-	1	-
Lost to follow-up	1	1	-
UNKNOWN REASON	-	1	-
CONSENT WITHDRAWAL,NOT DUE TO COVID-19 OR TO AN AE	1	2	-

Number of subjects in period 1	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Started	100	103	100

Completed	95	100	100
Not completed	5	3	0
Adverse event, non-fatal	-	1	-
CONSENT WITHDRAWAL,DUE TO COVID-19 BUT NOT TO AEs	1	-	-
MIGRATED / MOVED FROM THE STUDY AREA	1	-	-
Lost to follow-up	-	1	-
UNKNOWN REASON	-	-	-
CONSENT WITHDRAWAL,NOT DUE TO COVID-19 OR TO AN AE	3	1	-

Number of subjects in period 1	High Dose_AS01B_B Group	Placebo_B Group
Started	101	101
Completed	97	98
Not completed	4	3
Adverse event, non-fatal	3	-
CONSENT WITHDRAWAL,DUE TO COVID-19 BUT NOT TO AEs	-	-
MIGRATED / MOVED FROM THE STUDY AREA	-	-
Lost to follow-up	-	1
UNKNOWN REASON	-	-
CONSENT WITHDRAWAL,NOT DUE TO COVID-19 OR TO AN AE	1	2

Baseline characteristics

Reporting groups

Reporting group title	Low Dose_PLAIN_A Group
Reporting group description: Subjects in Part A, aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted low dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Medium Dose_PLAIN_A Group
Reporting group description: Subjects in Part A aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted medium dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	High Dose_PLAIN_A Group
Reporting group description: Subjects in Part A aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted high dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Placebo_A Group
Reporting group description: Subjects in Part A aged 18-40 years, receiving 2 doses of placebo (Saline solution) control, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Low Dose_PLAIN_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted low dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Medium Dose_PLAIN_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted medium dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	High Dose_PLAIN_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted high dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Low Dose_AS01E_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Medium Dose_AS01E_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	High Dose_AS01E_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Low Dose_AS01B_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Medium Dose_AS01B_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	High Dose_AS01B_B Group

Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	Placebo_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of placebo (Saline solution) control, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group
Number of subjects	12	12	12
Age categorical			
Units: Subjects			
Adults (18-64 years)	12	12	12
From 65-84 years	0	0	0
Age continuous			
Units: years			
arithmetic mean	31.2	26.5	29.9
standard deviation	± 7.0	± 4.0	± 6.1
Sex: Female, Male			
Units: Participants			
FEMALE	8	7	7
MALE	4	5	5
Race/Ethnicity, Customized			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
ASIAN	0	1	0
BLACK OR AFRICAN AMERICAN	2	1	2
OTHER	0	0	0
WHITE	10	10	10

Reporting group values	Placebo_A Group	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group
Number of subjects	12	101	97
Age categorical			
Units: Subjects			
Adults (18-64 years)	12	38	34
From 65-84 years	0	63	63
Age continuous			
Units: years			
arithmetic mean	31.6	67.3	67.8
standard deviation	± 5.6	± 5.6	± 5.6
Sex: Female, Male			
Units: Participants			
FEMALE	9	58	54
MALE	3	43	43
Race/Ethnicity, Customized			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	0	1	0

ASIAN	0	0	0
BLACK OR AFRICAN AMERICAN	1	5	7
OTHER	0	0	0
WHITE	11	95	90

Reporting group values	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group	Medium Dose_AS01E_B Group
Number of subjects	100	101	101
Age categorical Units: Subjects			
Adults (18-64 years)	26	28	43
From 65-84 years	74	73	58
Age continuous Units: years			
arithmetic mean	67.9	67.8	67.1
standard deviation	± 4.9	± 5.1	± 5.6
Sex: Female, Male Units: Participants			
FEMALE	57	58	57
MALE	43	43	44
Race/Ethnicity, Customized Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
ASIAN	0	1	0
BLACK OR AFRICAN AMERICAN	4	12	7
OTHER	3	0	0
WHITE	93	88	94

Reporting group values	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Number of subjects	100	103	100
Age categorical Units: Subjects			
Adults (18-64 years)	37	33	32
From 65-84 years	63	70	68
Age continuous Units: years			
arithmetic mean	67.6	67.6	67.5
standard deviation	± 5.2	± 4.9	± 4.9
Sex: Female, Male Units: Participants			
FEMALE	57	59	58
MALE	43	44	42
Race/Ethnicity, Customized Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	1	0	0
ASIAN	0	0	0
BLACK OR AFRICAN AMERICAN	5	11	7
OTHER	1	0	0
WHITE	93	92	93

Reporting group values	High Dose_AS01B_B Group	Placebo_B Group	Total
Number of subjects	101	101	1053
Age categorical Units: Subjects			
Adults (18-64 years)	36	32	387
From 65-84 years	65	69	666
Age continuous Units: years			
arithmetic mean	67.5	68.1	
standard deviation	± 4.9	± 5.7	-
Sex: Female, Male Units: Participants			
FEMALE	57	58	604
MALE	44	43	449
Race/Ethnicity, Customized Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	0	0	2
ASIAN	1	0	3
BLACK OR AFRICAN AMERICAN	7	4	75
OTHER	1	0	5
WHITE	92	97	968

End points

End points reporting groups

Reporting group title	Low Dose_PLAIN_A Group
Reporting group description: Subjects in Part A, aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted low dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Medium Dose_PLAIN_A Group
Reporting group description: Subjects in Part A aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted medium dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	High Dose_PLAIN_A Group
Reporting group description: Subjects in Part A aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted high dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Placebo_A Group
Reporting group description: Subjects in Part A aged 18-40 years, receiving 2 doses of placebo (Saline solution) control, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Low Dose_PLAIN_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted low dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Medium Dose_PLAIN_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted medium dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	High Dose_PLAIN_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted high dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Low Dose_AS01E_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Medium Dose_AS01E_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	High Dose_AS01E_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Low Dose_AS01B_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	Medium Dose_AS01B_B Group
Reporting group description: Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.	
Reporting group title	High Dose_AS01B_B Group

Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	Placebo_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of placebo (Saline solution) control, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Primary: Number of subjects with any solicited local symptoms after first vaccination dose

End point title	Number of subjects with any solicited local symptoms after first vaccination dose ^[1]
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End point description:

Assessed solicited local AEs at injection site are pain, erythema and swelling. Any erythema/swelling was scored as injection site erythema/swelling with a diameter larger than (>) 20 millimeters (mm)

End point type	Primary
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End point timeframe:

During a 7-day follow-up period after first vaccination dose (i.e., on the day of vaccination [at Day 1] and 6 subsequent days)

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: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	11	12
Units: Participants				
Erythema	0	1	0	0
Pain	1	7	6	0
Swelling	0	0	0	0

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	96	99	101
Units: Participants				
Erythema	0	1	2	5
Pain	9	5	14	54
Swelling	0	0	2	7

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	100	103	99
Units: Participants				
Erythema	6	9	16	15
Pain	57	56	78	63
Swelling	7	6	10	7

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	98		
Units: Participants				
Erythema	18	1		
Pain	76	4		
Swelling	9	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any solicited local symptoms after second vaccination dose

End point title	Number of subjects with any solicited local symptoms after second vaccination dose ^[2]
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End point description:

Assessed solicited local AEs at injection site are pain, erythema and swelling. Any erythema/swelling was scored as injection site erythema/swelling with a diameter larger than (>) 20 millimeters (mm)

End point type	Primary
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End point timeframe:

During a 7-day follow-up period after second vaccination dose (i.e., on the day of vaccination [at Day 61] and 6 subsequent days)

Notes:

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

Justification: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	11	12
Units: Participants				
Erythema	0	0	0	0
Pain	5	7	8	1
Swelling	0	0	0	0

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	95	91	90	94
Units: Participants				
Erythema	1	0	2	3
Pain	18	18	23	34
Swelling	0	1	2	3

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	95	96	93
Units: Participants				
Erythema	3	7	16	14
Pain	48	47	58	56
Swelling	3	6	10	7

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	97		
Units: Participants				
Erythema	12	0		
Pain	59	4		
Swelling	10	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any solicited general symptom after first vaccination dose

End point title	Number of subjects with any solicited general symptom after first vaccination dose ^[3]
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End point description:

Assessed solicited general symptoms include arthralgia, fatigue, fever [defined as temperature equal to or above 38.0 degrees Celsius (°C)], gastrointestinal symptoms [nausea, vomiting, diarrhea and/or abdominal pain], headache, myalgia and shivering.

End point type	Primary
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End point timeframe:

During a 7-day follow-up period after the first vaccination dose (i.e., on the day of vaccination [at Day 1] and 6 subsequent days)

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: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	11	12
Units: Participants				
Arthralgia	0	0	0	0
Fatigue	4	5	1	6
Fever	0	0	0	0
Gastrointestinal symptoms	1	2	1	1
Headache	2	4	3	2
Myalgia	0	1	1	0
Shivering	0	2	0	1

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	96	99	101
Units: Participants				
Arthralgia	7	4	0	7
Fatigue	22	11	24	26
Fever	1	0	0	1
Gastrointestinal symptoms	8	8	10	8
Headache	8	7	13	20
Myalgia	4	3	1	9
Shivering	1	1	2	6

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	100	103	99
Units: Participants				
Arthralgia	12	6	15	9
Fatigue	28	21	30	29
Fever	3	1	3	3
Gastrointestinal symptoms	8	9	13	7
Headache	12	17	28	27
Myalgia	8	6	19	12

Shivering	5	3	12	8
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End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	98		
Units: Participants				
Arthralgia	17	7		
Fatigue	49	16		
Fever	1	0		
Gastrointestinal symptoms	13	10		
Headache	28	8		
Myalgia	18	5		
Shivering	16	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any solicited general symptom after second vaccination dose

End point title	Number of subjects with any solicited general symptom after second vaccination dose ^[4]
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End point description:

Assessed solicited general symptoms include arthralgia, fatigue, fever [defined as temperature equal to or above 38.0 degrees Celsius (°C)], gastrointestinal symptoms [nausea, vomiting, diarrhea and/or abdominal pain], headache, myalgia and shivering.

End point type	Primary
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End point timeframe:

During a 7-day follow-up period after the second vaccination dose (i.e., on the day of vaccination [at Day 61] and 6 subsequent days)

Notes:

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

Justification: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	11	12
Units: Participants				
Arthralgia	0	0	0	0
Fatigue	3	2	4	5
Fever	0	0	0	0
Gastrointestinal symptoms	1	1	2	2
Headache	2	2	3	3
Myalgia	0	0	0	0

Shivering	0	0	0	0
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End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	95	91	90	94
Units: Participants				
Arthralgia	1	4	2	8
Fatigue	16	11	13	24
Fever	0	0	0	3
Gastrointestinal symptoms	4	2	7	7
Headache	11	9	8	15
Myalgia	0	2	3	6
Shivering	0	0	0	9

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	95	96	93
Units: Participants				
Arthralgia	8	10	21	11
Fatigue	22	24	35	35
Fever	1	1	4	6
Gastrointestinal symptoms	5	7	11	7
Headache	18	10	33	26
Myalgia	9	11	19	12
Shivering	3	4	14	12

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	97		
Units: Participants				
Arthralgia	13	4		
Fatigue	34	16		
Fever	3	0		
Gastrointestinal symptoms	9	6		
Headache	18	9		
Myalgia	18	2		
Shivering	9	2		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any unsolicited adverse events (AEs) after any vaccination dose

End point title	Number of subjects with any unsolicited adverse events (AEs) after any vaccination dose ^[5]
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End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and/or any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any is defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.

End point type	Primary
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End point timeframe:

During a 30-day follow-up period (i.e., on the day of vaccination and 29 subsequent days) after any vaccination dose (across doses)

Notes:

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

Justification: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants	2	4	4	6

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	97	100	101
Units: Participants	34	28	30	40

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	100	103	100
Units: Participants	29	36	39	34

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	101		
Units: Participants	43	33		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects presenting change from baseline in hematology and biochemistry with respect of normal laboratory ranges, after first vaccine dose (Part A groups)

End point title	Number of subjects presenting change from baseline in hematology and biochemistry with respect of normal laboratory ranges, after first vaccine dose (Part A groups) ^{[6][7]}
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End point description:

Assessed hematological laboratory parameters include basophils [BASOs], eosinophils [EOSs], red blood cells [RBCs], hemoglobin [HGB], lymphocytes [LYMs], monocytes [MONOs], neutrophils [NPs], platelets [PLTs], white blood cells [WBCs]. Biochemical laboratory parameters include alanine aminotransferase [ALT], aspartate aminotransferase [AST], creatinine [CR], urea nitrogen [UN] and uric acid [UA]. Categories reported when comparing Day 1 (pre-vaccination dose 1=baseline) and Day 8 hematological and biochemical laboratory results are defined as follows: <parameter>-<range at baseline>-<range at timing> (e.g. ALT-W-W). Ranges level being classified as unknown [U], below [B], within [W] or above [A] the normal ranges.

End point type	Primary
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End point timeframe:

At baseline and at 7 days after the first vaccine dose (Day 8)

Notes:

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

Justification: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

[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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	11	12
Units: Participants				
ALT-W-W (N=12,12,11,12)	12	12	11	12
AST-W-W (N=11,12,11,11)	11	12	11	11
AST-A-W (N=1,0,0,1)	1	0	0	1
BASOs-W-W (N=12,12,11,12)	12	12	11	12
CR-B-B (N=1,2,0,1)	0	0	0	1
CR-B-W (N=1,2,0,1)	1	2	0	0

CR-W-W (N=11,9,11,11)	11	9	11	11
CR-A-A (N=0,1,0,0)	0	1	0	0
EOSs-B-B (N=0,1,1,0)	0	1	0	0
EOSs-B-W (N=0,1,1,0)	0	0	1	0
EOSs-W-W (N=11,10,10,12)	11	10	10	12
EOSs-A-W (N=1,1,0,0)	1	1	0	0
RBCs-B-W (N=1,0,0,1)	1	0	0	1
RBCs-W-W (N=11,11,11,11)	11	11	11	11
RBCs-A-W (N=0,1,0,0)	0	1	0	0
HGB-B-B (N=1,0,0,1)	0	0	0	1
HGB-B-W (N=1,0,0,1)	1	0	0	0
HGB-W-W (N=11,12,11,11)	11	12	11	11
LYMs-B-W (0,1,0,1)	0	1	0	1
LYMs-W-W (N=12,11,11,11)	12	11	11	11
MONOs-B-W (N=0,1,0,0)	0	1	0	0
MONOs-W-W (N=12,11,11,12)	12	11	11	12
NPs-B-B (N=2,1,1,0)	0	0	1	0
NPs-B-W (N=2,1,1,0)	2	1	0	0
NPs-W-W (N=8,11,10, 12)	8	11	10	12
NPs-A-W (N=2,0,0,0)	1	0	0	0
NPs-A-A (N=2,0,0,0)	1	0	0	0
PLTs-W-W (N=12,12,11,12)	12	12	11	12
UN-W-B (N=12,12,11,12)	0	0	0	1
UN-W-W (N=12,12,11,12)	12	12	11	11
UA-B-W (N=1,0,0,0)	1	0	0	0
UA-W-W (N=11,12,11,12)	11	12	11	12
WBCs-B-B (N=2,1,1,1)	0	1	0	0
WBCs-B-W (N=2,1,1,1)	2	0	1	1
WBCs-W-W (N=8,11,10,11)	8	11	10	11
WBCs-A-W (N=2,0,0,0)	1	0	0	0
WBCs-A-A (N=2,0,0,0)	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects presenting change from baseline in hematology and biochemistry with respect of normal laboratory ranges, after first vaccine dose (Part B groups)

End point title	Number of subjects presenting change from baseline in hematology and biochemistry with respect of normal laboratory ranges, after first vaccine dose (Part B groups) ^{[8][9]}
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End point description:

Assessed hematological laboratory parameters include basophils [BASOs], eosinophils [EOSs], red blood cells [RBCs], hemoglobin [HGB], lymphocytes [LYMs], monocytes [MONOs], neutrophils [NPs], platelets [PLTs], white blood cells [WBCs]. Biochemical laboratory parameters include alanine aminotransferase [ALT], aspartate aminotransferase [AST], creatinine [CR], urea nitrogen [UN] and uric acid [UA]. Categories reported when comparing Day 1 (pre-vaccination dose 1=baseline) and Day 8 hematological and biochemical laboratory results are defined as follows: <parameter>-<range at baseline>-<range at timing> (e.g. ALT-W-W). Ranges level being classified as unknown [U], below [B], within [W] or above [A] the normal ranges.

End point type	Primary
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End point timeframe:

At baseline and at 7 days after the first vaccine dose (Day 8)

Notes:

[8] - 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: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

[9] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	97	99	100
Units: Participants				
ALT-W-U (N=100,97,99,98,98,100,100,95,99,100)	0	0	0	1
ALT-W-W (N=100,97,99,98,98,100,100,95,99,100)	99	97	98	97
ALT-W-A (N=100,97,99,98,98,100,100,95,99,100)	1	0	1	0
ALT-A-W (N=1,0,0,2,2,0,3,5,2,1)	0	0	0	0
ALT-A-A (N=1,0,0,2,2,0,3,5,2,1)	1	0	0	2
AST-W-U (N=101,97,99,100,99,99,99,98,100,101)	0	0	0	1
AST-W-W (N=101,97,99,100,99,99,99,98,100,101)	100	97	98	98
AST-W-A (N=101,97,99,100,99,99,99,98,100,101)	1	0	1	1
AST-A-W (N=0,0,0,0,1,1,4,2,1,0)	0	0	0	0
AST-A-A (N=0,0,0,0,1,1,4,2,1,0)	0	0	0	0
BASOs-W-U (N=101,97,99,100,100,100,103,100,101)	0	1	0	1
BASOs-W-W (N=101,97,99,100,100,100,103,100,101)	100	96	99	99
BASOs-W-A (N=101,97,99,100,100,100,103,100,101)	1	0	0	0
CR-B-B (N=1,8,6,3,5,2,4,5,5,1)	0	5	4	3
CR-B-W (N=1,8,6,3,5,2,4,5,5,1)	1	3	2	0
CR-W-U (N=94,85,92,94,95,95,97,92,94,99)	0	0	0	0
CR-W-B (N=94,85,92,94,95,95,97,92,94,99)	1	1	1	1
CR-W-W (N=94,85,92,94,95,95,97,92,94,99)	92	83	89	92
CR-W-A (N=94,85,92,94,95,95,97,92,94,99)	1	1	2	1
CR-A-U (N=6,4,1,3,0,3,2,3,2,1)	0	0	0	1
CR-A-W (N=6,4,1,3,0,3,2,3,2,1)	2	0	0	1
CR-A-A (N=6,4,1,3,0,3,2,3,2,1)	4	4	1	1
EOSs-B-B (N=7,6,5,4,4,7,9,6,5,3)	2	3	4	0
EOSs-B-W (N=7,6,5,4,4,7,9,6,5,3)	5	3	1	3
EOSs-B-A (N=7,6,5,4,4,7,9,6,5,3)	0	0	0	1
EOSs-W-U (N=90,89,90,94,95,92,91,92,94,96)	0	1	0	1

EOSs-W-B (N=90,89,90,94,95,92,91,92,94,96)	3	1	2	2
EOSs-W-W (N=90,89,90,94,95,92,91,92,94,96)	85	86	88	91
EOSs-W-A (N=90,89,90,94,95,92,91,92,94,96)	2	1	0	0
EOSs-A-W (N=4,2,4,2,1,1,3,2,2,2)	2	1	4	1
EOSs-A-A (N=4,2,4,2,1,1,3,2,2,2)	2	1	0	1
RBCs-B-B (N=5,4,1,1,4,4,2,1,3,3)	4	3	0	1
RBCs-B-W (N=5,4,1,1,4,4,2,1,3,3)	1	1	1	0
RBCs-W-U (N=95,91,96,99,95,94,97,98,97,95)	0	1	0	1
RBCs-W-B (N=95,91,96,99,95,94,97,98,97,95)	5	1	0	0
RBCs-W-W (N=95,91,96,99,95,94,97,98,97,95)	89	89	95	98
RBCs-W-A (N=95,91,96,99,95,94,97,98,97,95)	1	0	1	0
RBCs-A-W (N=1,2,2,0,1,2,4,1,1,3)	0	1	1	0
RBCs-A-A (N=1,2,2,0,1,2,4,1,1,3)	1	1	1	0
HGB-B-U (N=10,8,1,5,7,6,4,4,9,2)	0	1	0	0
HGB-B-B (N=10,8,1,5,7,6,4,4,9,2)	9	5	1	4
HGB-B-W (N=10,8,1,5,7,6,4,4,9,2)	1	2	0	1
HGB-W-U (N=91,86,97,93,92, 94,98, 95, 91,98)	0	0	0	1
HGB-W-B (N=91,86,97,93,92, 94,98, 95, 91,98)	4	3	1	1
HGB-W-W (N=91,86,97,93,92, 94,98, 95, 91,98)	87	83	96	91
HGB-W-A (N=91,86,97,93,92, 94,98, 95, 91,98)	0	0	0	0
HGB-A-W (N=0,3,1,2,1,0,1,1,1,1)	0	2	1	1
HGB-A-A (N=0,3,1,2,1,0,1,1,1,1)	0	1	0	1
LYMs-B-B (N=2,2,0,3,3,3,4,2,1,1)	1	0	0	1
LYMs-B-W (N=2,2,0,3,3,3,4,2,1,1)	1	2	0	2
LYMs-W-U (N=99,94,99,97,96,97,99, 98,100,100)	0	1	0	1
LYMs-W-B (N=99,94,99,97,96,97,99, 98,100,100)	0	1	0	1
LYMs-W-W (N=99,94,99,97,96,97,99, 98,100,100)	99	92	99	94
LYMs-W-A (N=99,94,99,97,96,97,99, 98,100,100)	0	0	0	1
LYMs-A-W (N=0,1,0,0,1,0,0,0,0,0)	0	1	0	0
LYMs-A-A (N=0,1,0,0,1,0,0,0,0,0)	0	0	0	0
MONOs-B-U (N=4,2,3,2,1,4,5,6,4,3)	0	0	0	0
MONOs-B-B (N=4,2,3,2,1,4,5,6,4,3)	1	1	0	0
MONOs-B-W (N=4,2,3,2,1,4,5,6,4,3)	3	1	3	2
MONOs-W-U (N=97,95,96,98,99,96,98,94,97,98)	0	1	0	1
MONOs-W-B (N=97,95,96,98,99,96,98,94,97,98)	5	0	2	0
MONOs-W-W (N=97,95,96,98,99,96,98,94,97,98)	91	94	94	97
MONOs-W-A (N=97,95,96,98,99,96,98,94,97,98)	1	0	0	0
NPs-B-B (N=1,1,3,4,1,4,3,1,2,7)	1	0	2	1
NPs-B-W (N=1,1,3,4,1,4,3,1,2,7)	0	1	1	3

NPs-W-U (N=100,96,96,93,99,94,98,98,99,93)	0	1	0	1
NPs-W-B (N=100,96,96,93,99,94,98,98,99,93)	2	1	1	2
NPs-W-W (N=100,96,96,93,99,94,98,98,99,93)	98	94	95	89
NPs-W-A (N=100,96,96,93,99,94,98,98,99,93)	0	0	0	1
NPs-A-W (N=0,0,0,3,0,2,2,1,0,1)	0	0	0	2
NPs-A-A (N=0,0,0,3,0,2,2,1,0,1)	0	0	0	1
PLTs-U-U (N=0,0,1,0,0,0,0,0,0,0)	0	0	1	0
PLTs-B-B (N=3,1,3,1,2,3,2,1,2,2)	3	1	2	1
PLTs-B-W (N=3,1,3,1,2,3,2,1,2,2)	0	0	1	0
PLTs-W-U (N=97,96,95,97,98,96,101,97,98,96)	1	1	0	3
PLTs-W-B (N=97,96,95,97,98,96,101,97,98,96)	0	1	0	1
PLTs-W-W (N=97,96,95,97,98,96,101,97,98,96)	96	94	94	93
PLTs-W-A (N=97,96,95,97,98,96,101,97,98,96)	0	0	1	0
PLTs-A-W (N=1,0,0,2,0,1,0,2,1,3)	0	0	0	1
PLTs-A-A (N=1,0,0,2,0,1,0,2,1,3)	1	0	0	1
UN-B-B (N=0,0,0,1,0,0,1,0,0,0)	0	0	0	1
UN-W-U (N=98,97,98,98,98,93,99,98,100,100)	0	0	0	1
UN-W-B (N=98,97,98,98,98,93,99,98,100,100)	0	0	0	0
UN-W-W (N=98,97,98,98,98,93,99,98,100,100)	97	96	95	95
UN-W-A (N=98,97,98,98,98,93,99,98,100,100)	1	1	3	2
UN-A-W (N=3,0,1,1,2,7,3,2,1,1)	0	0	1	0
UN-A-A (N=3,0,1,1,2,7,3,2,1,1)	3	0	0	1
UA-B-B (N=1,2,0,3,0,2,7,4,2,3)	1	0	0	3
UA-B-W (N=1,2,0,3,0,2,7,4,2,3)	0	2	0	0
UA-W-U (N=95,94,96,96,99,93,93,91,96,94)	0	0	0	1
UA-W-B (N=95,94,96,96,99,93,93,91,96,94)	0	0	0	0
UA-W-W (N=95,94,96,96,99,93,93,91,96,94)	94	91	96	93
UA-W-A (N=95,94,96,96,99,93,93,91,96,94)	1	3	0	2
UA-A-W (N=5,1,3,1,1,5,3,5,3,4)	2	1	1	0
UA-A-A (N=5,1,3,1,1,5,3,5,3,4)	3	0	2	1
WBCs-B-U (N=3,1,4,6,3,5,5,4,5,10)	0	0	0	0
WBCs-B-B (N=3,1,4,6,3,5,5,4,5,10)	1	0	2	2
WBCs-B-W (N=3,1,4,6,3,5,5,4,5,10)	2	1	2	4
WBCs-W-U (N=96,95,95,91,95,93,96,94,95,91)	0	1	0	1
WBCs-W-B (N=96,95,95,91,95,93,96,94,95,91)	2	2	3	2
WBCs-W-W (N=96,95,95,91,95,93,96,94,95,91)	94	91	91	87
WBCs-W-A (N=96,95,95,91,95,93,96,94,95,91)	0	1	1	1
WBCs-A-W (N=2,1,0,3,2,2,2,2,1,0)	1	0	0	1

WBCs-A-A (N=2,1,0,3,2,2,2,1,0)	1	1	0	2
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End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	100	103	100
Units: Participants				
ALT-W-U (N=100,97,99, 98,98,100,100,95,99,100)	0	0	0	0
ALT-W-W (N=100,97,99,98,98,100,100,95,99,100)	98	100	100	94
ALT-W-A (N=100,97,99,98,98,100,100,95,99,100)	0	0	0	1
ALT-A-W (N=1,0,0,2,2,0,3,5,2,1)	2	0	0	2
ALT-A-A (N=1,0,0,2,2,0,3,5,2,1)	0	0	3	3
AST-W-U (N=101,97,99,100,99,99,99,98,100,101)	0	1	2	1
AST-W-W (N=101,97,99,100,99,99,99,98,100,101)	99	98	97	97
AST-W-A (N=101,97,99,100,99,99,99,98,100,101)	0	0	0	0
AST-A-W (N=0,0,0,0,1,1,4,2,1,0)	1	1	1	1
AST-A-A(N=0,0,0,0,1,1,4,2,1,0)	0	0	3	1
BASOs-W- U(N=101,97,99,100,100,100,103,100,101)	4	2	0	0
BASOs-W- W(N=101,97,99,100,100,100,103,100,101)	96	98	103	100
BASOs-W- A(N=101,97,99,100,100,100,103,100,101)	0	0	0	0
CR-B-B (N=1,8,6,3,5,2,4,5,5,1)	4	0	1	3
CR-B-W (N=1,8,6,3,5,2,4,5,5,1)	1	2	3	2
CR-W-U (N=94,85,92,94,95,95,97,92,94,99)	0	0	0	0
CR-W-B (N=94,85,92,94,95,95,97,92,94,99)	1	1	1	1
CR-W-W (N=94,85,92,94,95,95,97,92,94,99)	92	93	93	90
CR-W-A (N=94,85,92,94,95,95,97,92,94,99)	2	1	3	1
CR-A-U (N=6,4,1,3,0,3,2,3,2,1)	0	0	0	0
CR-A-W (N=6,4,1,3,0,3,2,3,2,1)	0	1	0	1
CR-A-A (N=6,4,1,3,0,3,2,3,2,1)	0	2	2	2
EOSs-B-B (N=7,6,5,4,4,7,9,6,5,3)	3	5	3	4
EOSs-B-W (N=7,6,5,4,4,7,9,6,5,3)	1	2	5	2
EOSs-B-A (N=7,6,5,4,4,7,9,6,5,3)	0	0	1	0
EOSs-W-U (N=90,89,90,94,95,92,91,92,94,96)	4	2	0	0
EOSs-W-B (N=90,89,90,94,95,92,91,92,94,96)	1	1	3	5
EOSs-W-W (N=90,89,90,94,95,92,91,92,94,96)	89	88	88	86
EOSs-W-A (N=90,89,90,94,95,92,91,92,94,96)	1	1	0	1
EOSs-A-W (N=4,2,4,2,1,1,3,2,2,2)	0	0	0	0

EOSs-A-A (N=4,2,4,2,1,1,3,2,2,2)	1	1	3	2
RBCs-B-B (N=5,4,1,1,4,4,2,1,3,3)	4	3	2	1
RBCs-B-W (N=5,4,1,1,4,4,2,1,3,3)	0	1	0	0
RBCs-W-U (N=95,91,96,99,95,94,97,98,97,95)	3	2	0	0
RBCs-W-B (N=95,91,96,99,95,94,97,98,97,95)	3	3	2	1
RBCs-W-W (N=95,91,96,99,95,94,97,98,97,95)	88	89	95	96
RBCs-W-A (N=95,91,96,99,95,94,97,98,97,95)	1	0	0	1
RBCs-A-W (N=1,2,2,0,1,2,4,1,1,3)	1	0	2	1
RBCs-A-A (N=1,2,2,0,1,2,4,1,1,3)	0	2	2	0
HGB-B-U (N=10,8,1,5,7,6,4,4,9,2)	0	0	0	0
HGB-B-B (N=10,8,1,5,7,6,4,4,9,2)	7	4	4	3
HGB-B-W (N=10,8,1,5,7,6,4,4,9,2)	0	2	0	1
HGB-W-U (N=91,86,97,93,92, 94,98, 95, 91,98)	3	2	0	0
HGB-W-B (N=91,86,97,93,92, 94,98, 95, 91,98)	1	2	2	3
HGB-W-W (N=91,86,97,93,92, 94,98, 95, 91,98)	88	90	96	90
HGB-W-A (N=91,86,97,93,92, 94,98, 95, 91,98)	0	0	0	2
HGB-A-W (N=0,3,1,2,1,0,1,1,1,1)	0	0	1	0
HGB-A-A (N=0,3,1,2,1,0,1,1,1,1)	1	0	0	1
LYMs-B-B (N=2,2,0,3,3,3,4,2,1,1)	0	1	2	1
LYMs-B-W (N=2,2,0,3,3,3,4,2,1,1)	3	2	2	1
LYMs-W-U (N=99,94,99,97,96,97,99, 98,100,100)	4	2	0	0
LYMs-W-B (N=99,94,99,97,96,97,99, 98,100,100)	1	0	3	0
LYMs-W-W (N=99,94,99,97,96,97,99, 98,100,100)	90	94	96	98
LYMs-W-A (N=99,94,99,97,96,97,99, 98,100,100)	1	1	0	0
LYMs-A-W (N=0,1,0,0,1,0,0,0,0,0)	0	0	0	0
LYMs-A-A (N=0,1,0,0,1,0,0,0,0,0)	1	0	0	0
MONOs-B-U (N=4,2,3,2,1,4,5,6,4,3)	0	1	0	0
MONOs-B-B (N=4,2,3,2,1,4,5,6,4,3)	1	2	0	5
MONOs-B-W (N=4,2,3,2,1,4,5,6,4,3)	0	1	5	1
MONOs-W-U (N=97,95,96,98,99,96,98,94,97,98)	4	1	0	0
MONOs-W-B (N=97,95,96,98,99,96,98,94,97,98)	1	3	2	1
MONOs-W-W (N=97,95,96,98,99,96,98,94,97,98)	92	91	96	92
MONOs-W-A (N=97,95,96,98,99,96,98,94,97,98)	2	1	0	1
NPs-B-B (N=1,1,3,4,1,4,3,1,2,7)	1	1	2	0
NPs-B-W (N=1,1,3,4,1,4,3,1,2,7)	0	3	1	1
NPs-W-U (N=100,96,96,93,99,94,98,98,99,93)	4	2	0	0
NPs-W-B (N=100,96,96,93,99,94,98,98,99,93)	2	2	0	1
NPs-W-W (N=100,96,96,93,99,94,98,98,99,93)	92	88	98	96

NPs-W-A (N=100,96,96,93,99,94,98,98,99,93)	1	2	0	1
NPs-A-W (N=0,0,0,3,0,2,2,1,0,1)	0	2	2	1
NPs-A-A (N=0,0,0,3,0,2,2,1,0,1)	0	0	0	0
PLTs-U-U (N=0,0,1,0,0,0,0,0,0,0)	0	0	0	0
PLTs-B-B (N=3,1,3,1,2,3,2,1,2,2)	1	2	0	1
PLTs-B-W (N=3,1,3,1,2,3,2,1,2,2)	1	1	2	0
PLTs-W-U (N=97,96,95,97,98,96,101,97,98,96)	6	3	2	0
PLTs-W-B (N=97,96,95,97,98,96,101,97,98,96)	1	0	1	0
PLTs-W-W (N=97,96,95,97,98,96,101,97,98,96)	90	93	97	96
PLTs-W-A (N=97,96,95,97,98,96,101,97,98,96)	1	0	1	1
PLTs-A-W (N=1,0,0,2,0,1,0,2,1,3)	0	0	0	1
PLTs-A-A (N=1,0,0,2,0,1,0,2,1,3)	0	1	0	1
UN-B-B (N=0,0,0,1,0,0,1,0,0,0)	0	0	1	0
UN-W-U (N=98,97,98,98,98,93,99,98,100,100)	0	0	0	0
UN-W-B (N=98,97,98,98,98,93,99,98,100,100)	0	0	1	0
UN-W-W (N=98,97,98,98,98,93,99,98,100,100)	97	93	96	96
UN-W-A (N=98,97,98,98,98,93,99,98,100,100)	1	0	2	2
UN-A-W (N=3,0,1,1,2,7,3,2,1,1)	2	5	2	2
UN-A-A (N=3,0,1,1,2,7,3,2,1,1)	0	2	1	0
UA-B-B (N=1,2,0,3,0,2,7,4,2,3)	0	1	5	3
UA-B-W (N=1,2,0,3,0,2,7,4,2,3)	0	1	2	1
UA-W-U (N=95,94,96,96,99,93,93,91,96,94)	0	0	0	0
UA-W-B (N=95,94,96,96,99,93,93,91,96,94)	0	2	1	2
UA-W-W (N=95,94,96,96,99,93,93,91,96,94)	98	90	89	88
UA-W-A (N=95,94,96,96,99,93,93,91,96,94)	1	1	3	1
UA-A-W (N=5,1,3,1,1,5,3,5,3,4)	1	2	2	2
UA-A-A (N=5,1,3,1,1,5,3,5,3,4)	0	3	1	3
WBCs-B-U (N=3,1,4,6,3,5,5,4,5,10)	0	1	0	0
WBCs-B-B (N=3,1,4,6,3,5,5,4,5,10)	2	1	3	0
WBCs-B-W (N=3,1,4,6,3,5,5,4,5,10)	1	3	2	4
WBCs-W-U (N=96,95,95,91,95,93,96,94,95,91)	4	1	0	0
WBCs-W-B (N=96,95,95,91,95,93,96,94,95,91)	1	3	1	1
WBCs-W-W (N=96,95,95,91,95,93,96,94,95,91)	89	87	95	91
WBCs-W-A (N=96,95,95,91,95,93,96,94,95,91)	1	2	0	2
WBCs-A-W (N=2,1,0,3,2,2,2,2,1,0)	1	2	1	2
WBCs-A-A (N=2,1,0,3,2,2,2,2,1,0)	1	0	1	0

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	101		
Units: Participants				
ALT-W-U (N=100,97,99, 98,98,100,100,95,99,100)	1	1		
ALT-W-W (N=100,97,99,98,98,100,100,95,99,100)	98	98		
ALT-W-A (N=100,97,99,98,98,100,100,95,99,100)	0	1		
ALT-A-W (N=1,0,0,2,2,0,3,5,2,1)	0	0		
ALT-A-A (N=1,0,0,2,2,0,3,5,2,1)	2	1		
AST-W-U (N=101,97,99,100,99,99,99,98,100,101)	1	1		
AST-W-W (N=101,97,99,100,99,99,99,98,100,101)	98	99		
AST-W-A (N=101,97,99,100,99,99,99,98,100,101)	1	1		
AST-A-W (N=0,0,0,0,1,1,4,2,1,0)	0	0		
AST-A-A(N=0,0,0,0,1,1,4,2,1,0)	1	0		
BASOs-W- U(N=101,97,99,100,100,100,103,100,1)	0	0		
BASOs-W- W(N=101,97,99,100,100,100,103,100,1)	101	100		
BASOs-W- A(N=101,97,99,100,100,100,103,100,1)	0	1		
CR-B-B (N=1,8,6,3,5,2,4,5,5,1)	2	0		
CR-B-W (N=1,8,6,3,5,2,4,5,5,1)	3	1		
CR-W-U (N=94,85,92,94,95,95,97,92,94,99)	1	1		
CR-W-B (N=94,85,92,94,95,95,97,92,94,99)	5	3		
CR-W-W (N=94,85,92,94,95,95,97,92,94,99)	88	95		
CR-W-A (N=94,85,92,94,95,95,97,92,94,99)	0	0		
CR-A-U (N=6,4,1,3,0,3,2,3,2,1)	0	0		
CR-A-W (N=6,4,1,3,0,3,2,3,2,1)	0	0		
CR-A-A (N=6,4,1,3,0,3,2,3,2,1)	2	1		
EOSs-B-B (N=7,6,5,4,4,7,9,6,5,3)	2	2		
EOSs-B-W (N=7,6,5,4,4,7,9,6,5,3)	3	1		
EOSs-B-A (N=7,6,5,4,4,7,9,6,5,3)	0	0		
EOSs-W-U (N=90,89,90,94,95,92,91,92,94,96)	0	0		
EOSs-W-B (N=90,89,90,94,95,92,91,92,94,96)	3	5		
EOSs-W-W (N=90,89,90,94,95,92,91,92,94,96)	90	90		
EOSs-W-A (N=90,89,90,94,95,92,91,92,94,96)	1	1		
EOSs-A-W (N=4,2,4,2,1,1,3,2,2,2)	0	2		
EOSs-A-A (N=4,2,4,2,1,1,3,2,2,2)	2	0		
RBCs-B-B (N=5,4,1,1,4,4,2,1,3,3)	1	2		
RBCs-B-W (N=5,4,1,1,4,4,2,1,3,3)	2	1		
RBCs-W-U (N=95,91,96,99,95,94,97,98,97,95)	0	0		

RBCs-W-B (N=95,91,96,99,95,94,97,98,97,95)	4	1		
RBCs-W-W (N=95,91,96,99,95,94,97,98,97,95)	93	94		
RBCs-W-A (N=95,91,96,99,95,94,97,98,97,95)	0	0		
RBCs-A-W (N=1,2,2,0,1,2,4,1,1,3)	1	0		
RBCs-A-A (N=1,2,2,0,1,2,4,1,1,3)	0	3		
HGB-B-U (N=10,8,1,5,7,6,4,4,9,2)	0	0		
HGB-B-B (N=10,8,1,5,7,6,4,4,9,2)	5	1		
HGB-B-W (N=10,8,1,5,7,6,4,4,9,2)	4	1		
HGB-W-U (N=91,86,97,93,92, 94,98, 95, 91,98)	0	0		
HGB-W-B (N=91,86,97,93,92, 94,98, 95, 91,98)	5	2		
HGB-W-W (N=91,86,97,93,92, 94,98, 95, 91,98)	86	95		
HGB-W-A (N=91,86,97,93,92, 94,98, 95, 91,98)	0	1		
HGB-A-W (N=0,3,1,2,1,0,1,1,1,1)	1	1		
HGB-A-A (N=0,3,1,2,1,0,1,1,1,1)	0	0		
LYMs-B-B (N=2,2,0,3,3,3,4,2,1,1)	0	1		
LYMs-B-W (N=2,2,0,3,3,3,4,2,1,1)	1	0		
LYMs-W-U (N=99,94,99,97,96,97,99, 98,100,100)	0	0		
LYMs-W-B (N=99,94,99,97,96,97,99, 98,100,100)	0	2		
LYMs-W-W (N=99,94,99,97,96,97,99, 98,100,100)	100	98		
LYMs-W-A (N=99,94,99,97,96,97,99, 98,100,100)	0	0		
LYMs-A-W (N=0,1,0,0,1,0,0,0,0,0)	0	0		
LYMs-A-A (N=0,1,0,0,1,0,0,0,0,0)	0	0		
MONOs-B-U (N=4,2,3,2,1,4,5,6,4,3)	0	0		
MONOs-B-B (N=4,2,3,2,1,4,5,6,4,3)	2	0		
MONOs-B-W (N=4,2,3,2,1,4,5,6,4,3)	2	3		
MONOs-W-U (N=97,95,96,98,99,96,98,94,97,98)	0	0		
MONOs-W-B (N=97,95,96,98,99,96,98,94,97,98)	4	3		
MONOs-W-W (N=97,95,96,98,99,96,98,94,97,98)	93	95		
MONOs-W-A (N=97,95,96,98,99,96,98,94,97,98)	0	0		
NPs-B-B (N=1,1,3,4,1,4,3,1,2,7)	1	5		
NPs-B-W (N=1,1,3,4,1,4,3,1,2,7)	1	2		
NPs-W-U (N=100,96,96,93,99,94,98,98,99,93)	0	0		
NPs-W-B (N=100,96,96,93,99,94,98,98,99,93)	1	0		
NPs-W-W (N=100,96,96,93,99,94,98,98,99,93)	96	93		
NPs-W-A (N=100,96,96,93,99,94,98,98,99,93)	2	0		
NPs-A-W (N=0,0,0,3,0,2,2,1,0,1)	0	1		
NPs-A-A (N=0,0,0,3,0,2,2,1,0,1)	0	0		
PLTs-U-U (N=0,0,1,0,0,0,0,0,0,0)	0	0		
PLTs-B-B (N=3,1,3,1,2,3,2,1,2,2)	1	2		

PLTs-B-W (N=3,1,3,1,2,3,2,1,2,2)	1	0		
PLTs-W-U (N=97,96,95,97,98,96,101,97,98,96)	1	0		
PLTs-W-B (N=97,96,95,97,98,96,101,97,98,96)	0	0		
PLTs-W-W (N=97,96,95,97,98,96,101,97,98,96)	96	96		
PLTs-W-A (N=97,96,95,97,98,96,101,97,98,96)	1	0		
PLTs-A-W (N=1,0,0,2,0,1,0,2,1,3)	0	0		
PLTs-A-A (N=1,0,0,2,0,1,0,2,1,3)	1	3		
UN-B-B (N=0,0,0,1,0,0,1,0,0,0)	0	0		
UN-W-U (N=98,97,98,98,98,93,99,98,100,100)	1	1		
UN-W-B (N=98,97,98,98,98,93,99,98,100,100)	0	0		
UN-W-W (N=98,97,98,98,98,93,99,98,100,100)	98	98		
UN-W-A (N=98,97,98,98,98,93,99,98,100,100)	1	1		
UN-A-W (N=3,0,1,1,2,7,3,2,1,1)	0	1		
UN-A-A (N=3,0,1,1,2,7,3,2,1,1)	1	0		
UA-B-B (N=1,2,0,3,0,2,7,4,2,3)	2	2		
UA-B-W (N=1,2,0,3,0,2,7,4,2,3)	0	1		
UA-W-U (N=95,94,96,96,99,93,93,91,96,94)	1	1		
UA-W-B (N=95,94,96,96,99,93,93,91,96,94)	0	1		
UA-W-W (N=95,94,96,96,99,93,93,91,96,94)	95	89		
UA-W-A (N=95,94,96,96,99,93,93,91,96,94)	0	3		
UA-A-W (N=5,1,3,1,1,5,3,5,3,4)	3	2		
UA-A-A (N=5,1,3,1,1,5,3,5,3,4)	0	2		
WBCs-B-U (N=3,1,4,6,3,5,5,4,5,10)	0	0		
WBCs-B-B (N=3,1,4,6,3,5,5,4,5,10)	1	4		
WBCs-B-W (N=3,1,4,6,3,5,5,4,5,10)	4	6		
WBCs-W-U (N=96,95,95,91,95,93,96,94,95,91)	0	0		
WBCs-W-B (N=96,95,95,91,95,93,96,94,95,91)	0	1		
WBCs-W-W (N=96,95,95,91,95,93,96,94,95,91)	93	90		
WBCs-W-A (N=96,95,95,91,95,93,96,94,95,91)	2	0		
WBCs-A-W (N=2,1,0,3,2,2,2,2,1,0)	1	0		
WBCs-A-A (N=2,1,0,3,2,2,2,2,1,0)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects presenting change from baseline in hematology and biochemistry with respect of normal laboratory ranges, after second vaccine dose (Part A groups)

End point title	Number of subjects presenting change from baseline in hematology and biochemistry with respect of normal laboratory ranges, after second vaccine dose (Part A groups) ^{[10][11]}
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End point description:

Assessed hematological laboratory parameters include basophils [BASOs], eosinophils [EOSs], red blood cells [RBCs], hemoglobin [HGB], lymphocytes [LYMs], monocytes [MONOs], neutrophils [NPs], platelets [PLTs], white blood cells [WBCs]. Biochemical laboratory parameters include alanine aminotransferase [ALT], aspartate aminotransferase [AST], creatinine [CR], urea nitrogen [UN] and uric acid [UA]. Categories reported when comparing Day 61 (pre-vaccination dose 2=baseline) and Day 68 hematological and biochemical laboratory results are defined as follows: <parameter>-<range at baseline>-<range at timing> (e.g. ALT-W-W). Ranges level being classified as unknown [U], below [B], within [W] or above [A] the normal ranges.

End point type	Primary
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End point timeframe:

At baseline and at 7 days after the second vaccine dose (Day 68)

Notes:

[10] - 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: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

[11] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	11	12
Units: Participants				
ALT-W-W (N=12,10,10,12)	11	10	10	12
ALT-W-A (N=12,10,10,12)	1	0	0	0
ALT-A-W (N=0,0,1,0)	0	0	1	0
AST-W-W (N=11,10,11,12)	10	10	11	12
AST-W-A (N=11,10,11,12)	1	0	0	0
AST-A-A (N=1,0,0,0)	1	0	0	0
BASOs-U-W (N=1,0,0,0)	1	0	0	0
BASOs-W-W (N=11,10,11,12)	11	10	11	12
CR-B-B (N=0,0,0,1)	0	0	0	1
CR-W-W (N=12,9,11,10)	12	7	11	10
CR-W-A (N=12,9,11,10)	0	2	0	0
CR-A-W (N=0,1,0,1)	0	0	0	1
CR-A-A (N=0,1,0,1)	0	1	0	0
EOSs-U-W (N=1,0,0,0)	1	0	0	0
EOSs-B-B (N=0,1,1,0)	0	0	1	0
EOSs-B-W (N=0,1,1,0)	0	1	0	0
EOSs-W-B (N=11,9,10,12)	1	0	1	0
EOSs-W-W (N=11,9,10,12)	10	9	8	12
EOSs-W-A (N=11,9,10,12)	0	0	1	0
RBCs-U-B (N=1,0,0,0)	1	0	0	0
RBCs-W-B (N=11,9,11,12)	1	0	0	0
RBCs-W-W (N=11,9,11,12)	10	9	10	12
RBCs-W-A (N=11,9,11,12)	0	0	1	0
RBCs-A-A (N=0,1,0,0)	0	1	0	0
HGB-U-B (N=1,0,0,0)	1	0	0	0

HGB-B-W (N=0,0,1,0)	0	0	1	0
HGB-W-W (N=11,10,10,12)	11	10	9	12
HGB-W-A (N=11,10,10,12)	0	0	1	0
LYMs-U-W (N=1,0,0,0)	1	0	0	0
LYMs-B-W (N=0,0,0,1)	0	0	0	1
LYMs-W-W (N=11,10,11,11)	11	10	11	11
MONOs-U-W (N=1,0,0,0)	1	0	0	0
MONOs-B-W (N=0,0,1,0)	0	0	1	0
MONOs-W-W (N=11,10,10,12)	11	10	10	12
NPs-U-W (N=1,0,0,0)	1	0	0	0
NPs-B-B (N=1,0,1,0)	0	0	1	0
NPs-B-W (N=1,0,1,0)	1	0	0	0
NPs-W-B (N=10,10,10,12)	1	0	0	0
NPs-W-W (N=10,10,10,12)	9	10	10	12
PLTs-U-W (N=1,1,0,0)	1	1	0	0
PLTs-W-W (N=11,8,11,12)	11	8	11	12
PLTs-A-W (N=0,1,0,0)	0	1	0	0
UN-W-W (N=12,10,11,12)	12	10	11	12
UA-B-W (N=1,0,0,0)	1	0	0	0
UA-W-W (N=11,10,11,12)	11	10	11	12
WBCs-U-W (N=1,0,0,0)	1	0	0	0
WBCs-B-B (N=2,0,1,0)	1	0	1	0
WBCs-B-W (N=2,0,1,0)	1	0	0	0
WBCs-W-B (N=8,10,10,12)	1	0	0	0
WBCs-W-W (N=8,10,10,12)	7	10	10	12
WBCs-A-W (N=1,0,0,0)	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects presenting change from baseline in hematology and biochemistry with respect of normal laboratory ranges, after second vaccine dose (Part B groups)

End point title	Number of subjects presenting change from baseline in hematology and biochemistry with respect of normal laboratory ranges, after second vaccine dose (Part B groups) ^{[12][13]}
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End point description:

Assessed hematological laboratory parameters include basophils [BASOs], eosinophils [EOSs], red blood cells [RBCs], hemoglobin [HGB], lymphocytes [LYMs], monocytes [MONOs], neutrophils [NPs], platelets [PLTs], white blood cells [WBCs]. Biochemical laboratory parameters include alanine aminotransferase [ALT], aspartate aminotransferase [AST], creatinine [CR], urea nitrogen [UN] and uric acid [UA]. Categories reported when comparing Day 61 (pre-vaccination dose 2=baseline) and Day 68 hematological and biochemical laboratory results are defined as follows: <parameter>-<range at baseline>-<range at timing> (e.g. ALT-W-W). Ranges level being classified as unknown [U], below [B], within [W] or above [A] the normal ranges.

End point type	Primary
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End point timeframe:

At baseline and at 7 days after the second vaccine dose (Day 68)

Notes:

[12] - 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: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

[13] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	97	94	95	96
Units: Participants				
ALT-U-W (N=1,0,0,1,0,1,1,1,2,0)	1	0	0	1
ALT-W-U (N=95,94,95,93,96,96,95,93,91,97)	0	0	0	0
ALT-W-W (N=95,94,95,93,96,96,95,93,91,97)	93	94	95	93
ALT-W-A (N=95,94,95,93,96,96,95,93,91,97)	2	0	0	0
ALT-A-W (N=1,0,0,2,2,0,2,3,4,2)	1	0	0	1
ALT-A-A (N=1,0,0,2,2,0,2,3,4,2)	0	0	0	1
AST-U-W (N=1,0,0,1,0,1,1,1,2,0)	1	0	0	1
AST-W-U (N=96,93,95,94,97,96,95,95,93,98)	0	0	0	0
AST-W-W (N=96,93,95,94,97,96,95,95,93,98)	94	93	95	93
AST-W-A (N=96,93,95,94,97,96,95,95,93,98)	2	0	0	1
AST-A-W (N=0,1,0,1,1,0,2,1,2,1)	0	1	0	0
AST-A-A (N=0,1,0,1,1,0,2,1,2,1)	0	0	0	1
BASOs-U-W (N=1,0,1,0,2,2,2,1,2,1)	1	0	1	0
BASOs-W-U (N=96,94,94,96,96,95,96,96,95,98)	1	0	0	0
BASOs-W-W (N=96,94,94,96,96,95,96,96,95,98)	95	94	94	96
CR-U-B (N=1,0,0,1,0,1,1,1,2,0)	0	0	0	0
CR-U-W (N=1,0,0,1,0,1,1,1,2,0)	1	0	0	1
CR-U-A (N=1,0,0,1,0,1,1,1,2,0)	0	0	0	0
CR-B-U (N=3,6,3,3,4,1,3,6,7,1)	0	0	0	0
CR-B-B (N=3,6,3,3,4,1,3,6,7,1)	0	4	2	2
CR-B-W (N=3,6,3,3,4,1,3,6,7,1)	3	2	1	1
CR-W-B (N=87,83,90,89,92,94,93,88,87,97)	1	2	2	2
CR-W-W (N=87,83,90,89,92,94,93,88,87,97)	83	81	86	87
CR-W-A (N=87,83,90,89,92,94,93,88,87,97)	3	0	2	0
CR-A-W (N=6,5,2,3,2,1,1,2,1,1)	2	2	0	2
CR-A-A (N=6,5,2,3,2,1,1,2,1,1)	4	3	2	1
EOSs-U-W (N=1,0,1,0,2,2,2,1,2,1)	1	0	1	0
EOSs-U-A (N=1,0,1,0,2,2,2,1,2,1)	0	0	0	0
EOSs-B-U (N=7,5,9,6,8,5,6,8,6,8)	1	0	0	0
EOSs-B-B (N=7,5,9,6,8,5,6,8,6,8)	3	2	4	2

EOSs-B-W (N=7,5,9,6,8,5,6,8,6,8)	3	3	5	4
EOSs-W-U (N=86,87,82,87,84,88,85,87,87,88)	0	0	0	0
EOSs-W-B (N=86,87,82,87,84,88,85,87,87,88)	2	2	4	6
EOSs-W-W (N=86,87,82,87,84,88,85,87,87,88)	82	85	78	79
EOSs-W-A (N=86,87,82,87,84,88,85,87,87,88)	2	0	0	2
EOSs-A-W (N=3,2,3,3,4,2,5,1,2,2)	1	1	2	2
EOSs-A-A (N=3,2,3,3,4,2,5,1,2,2)	2	1	1	1
RBCs-U-B (N=1,0,1,0,2,2,2,1,2,1)	0	0	0	0
RBCs-U-W (N=1,0,1,0,2,2,2,1,2,1)	1	0	1	0
RBCs-U-A (N=1,0,1,0,2,2,2,1,2,1)	0	0	0	0
RBCs-B-B (N=7,2,0,2,3,4,3,0,4,1)	6	2	0	1
RBCs-B-W (N=7,2,0,2,3,4,3,0,4,1)	1	0	0	1
RBCs-W-U (N=87,91,91,93,92,89,90,94,90,96)	1	0	0	0
RBCs-W-B (N=87,91,91,93,92,89,90,94,90,96)	3	3	0	1
RBCs-W-W (N=87,91,91,93,92,89,90,94,90,96)	83	88	91	92
RBCs-W-A (N=87,91,91,93,92,89,90,94,90,96)	0	0	0	0
RBCs-A-W (N=2,1,3,1,1,2,3,2,1,1)	2	1	1	1
RBCs-A-A (N=2,1,3,1,1,2,3,2,1,1)	0	0	2	0
HGB-U-B (N=1,0,1,0,2,2,2,1,2,1)	0	0	0	0
HGB-U-W (N=1,0,1,0,2,2,2,1,2,1)	1	0	1	0
HGB-B-B (N=8,8,3,7,5,9,6,3,9,4)	7	6	2	6
HGB-B-W (N=8,8,3,7,5,9,6,3,9,4)	1	2	1	1
HGB-W-U (N=87,85,90,86,90,84,90,91,85,94)	1	0	0	0
HGB-W-B (N=87,85,90,86,90,84,90,91,85,94)	5	2	0	0
HGB-W-W (N=87,85,90,86,90,84,90,91,85,94)	81	83	89	86
HGB-W-A (N=87,85,90,86,90,84,90,91,85,94)	0	0	1	0
HGB-A-W (N=1,1,1,3,1,2,0,2,1,0)	0	1	1	2
HGB-A-A (N=1,1,1,3,1,2,0,2,1,0)	1	0	0	1
LYMs-U-W (N=1,0,1,0,2,2,2,1,2,1)	1	0	1	0
LYMs-B-B (N=2,1,4,4,4,2,3,1,1,5)	0	0	0	2
LYMs-B-W (N=2,1,4,4,4,2,3,1,1,5)	2	1	4	2
LYMs-W-U (N=93,92,90,91,91,93,93,95,94,93)	1	0	0	0
LYMs-W-B (N=93,92,90,91,91,93,93,95,94,93)	2	0	0	1
LYMs-W-W (N=93,92,90,91,91,93,93,95,94,93)	90	91	89	90
LYMs-W-A (N=93,92,90,91,91,93,93,95,94,93)	0	1	1	0
LYMs-A-W (N=1,1,0,1,1,0,0,0,0,0)	1	1	0	1
LYMs-A-A (N=1,1,0,1,1,0,0,0,0,0)	0	0	0	0
MONOs-U-B (N=1,0,1,0,2,2,2,1,2,1)	0	0	0	0
MONOs-U-W (N=1,0,1,0,2,2,2,1,2,1)	1	0	1	0
MONOs-B-B (N=5,0,4,3,4,6,4,4,5,6)	2	0	0	0
MONOs-B-W (N=5,0,4,3,4,6,4,4,5,6)	3	0	4	3

MONOs-W-U (N=89,94,90,93,92,89,92,91,90,92)	1	0	0	0
MONOs-W-B (N=89,94,90,93,92,89,92,91,90,92)	1	2	3	2
MONOs-W-W (N=89,94,90,93,92,89,92,91,90,92)	87	92	87	91
MONOs-A-W (N=2,0,0,0,0,0,0,1,0,0)	1	0	0	0
MONOs-A-A (N=2,0,0,0,0,0,0,1,0,0)	1	0	0	0
NPs-U-W (N=1,0,1,0,2,2,2,1,2,1)	1	0	1	0
NPs-B-B (N=2,1,1,3,1,3,2,1,1,2)	1	1	0	1
NPs-B-W (N=2,1,1,3,1,3,2,1,1,2)	1	0	1	2
NPs-W-U (N=94,92,93,92,95,92,94,95,93,96)	1	0	0	0
NPs-W-B (N=94,92,93,92,95,92,94,95,93,96)	0	1	3	1
NPs-W-W (N=94,92,93,92,95,92,94,95,93,96)	92	90	90	90
NPs-W-A (N=94,92,93,92,95,92,94,95,93,96)	1	1	0	1
NPs-A-W (N=0,1,0,1,0,0,0,0,1,0)	0	1	0	0
NPs-A-A (N=0,1,0,1,0,0,0,0,1,0)	0	0	0	1
PLTs-U-U (N=3,2,2,0,2,3,5,2,2,1)	1	0	0	0
PLTs-U-W (N=3,2,2,0,2,3,5,2,2,1)	2	2	2	0
PLTs-B-U (N=3,1,3,1,0,2,1,1,1,2)	0	0	1	0
PLTs-B-B (N=3,1,3,1,0,2,1,1,1,2)	3	0	1	1
PLTs-B-W (N=3,1,3,1,0,2,1,1,1,2)	0	1	1	0
PLTs-W-U (N=89,91,89,93,96,90,91,92,92,93)	1	0	0	0
PLTs-W-B (N=89,91,89,93,96,90,91,92,92,93)	0	1	0	0
PLTs-W-W (N=89,91,89,93,96,90,91,92,92,93)	88	89	88	91
PLTs-W-A (N=89,91,89,93,96,90,91,92,92,93)	0	1	1	2
PLTs-A-W (N=2,0,1,2,0,2,1,2,2,3)	1	0	0	0
PLTs-A-A (N=2,0,1,2,0,2,1,2,2,3)	1	0	1	2
UN-U-W (N=1,0,0,1,0,1,1,1,2,0)	1	0	0	1
UN-U-A (N=1,0,0,1,0,1,1,1,2,0)	0	0	0	0
UN-B-B (N=0,0,0,1,0,0,2,1,1,0)	0	0	0	1
UN-B-W (N=0,0,0,1,0,0,2,1,1,0)	0	0	0	0
UN-W-U (N=92,94,93,92,95,94,92,92,92,99)	0	0	0	0
UN-W-W (N=92,94,93,92,95,94,92,92,92,99)	91	94	93	91
UN-W-A (N=92,94,93,92,95,94,92,92,92,99)	1	0	0	1
UN-A-W (N=4,0,2,2,3,2,3,3,2,0)	1	0	2	1
UN-A-A (N=4,0,2,2,3,2,3,3,2,0)	3	0	0	1
UA-U-B (N=1,0,0,1,0,1,1,1,2,0)	0	0	0	0
UA-U-W (N=1,0,0,1,0,1,1,1,2,0)	1	0	0	1
UA-U-A (N=1,0,0,1,0,1,1,1,2,0)	0	0	0	0
UA-B-B (N=2,2,1,3,0,1,4,2,2,3)	1	2	0	3
UA-B-W (N=2,2,1,3,0,1,4,2,2,3)	1	0	1	0
UA-W-U (N=91,87,92,90,98,92,93,91,92,91)	0	0	0	0
UA-W-B (N=91,87,92,90,98,92,93,91,92,91)	0	1	1	0

UA-W-W (N=91,87,92,90,98,92,93,91,92,91)	91	86	87	89
UA-W-A (N=91,87,92,90,98,92,93,91,92,91)	0	0	4	1
UA-A-W (N=3,5,2,2,0,3,0,3,1,5)	1	2	1	2
UA-A-A (N=3,5,2,2,0,3,0,3,1,5)	2	3	1	0
WBCs-U-W (N=1,0,1,0,2,2,2,1,2,1)	1	0	1	0
WBCs-B-B (N=4,0,3,4,5,4,7,4,3,5)	2	0	1	1
WBCs-B-W (N=4,0,3,4,5,4,7,4,3,5)	2	0	2	3
WBCs-W-U (N=91,92,91,90,89,91,89,92,91,93)	1	0	0	0
WBCs-W-B (N=91,92,91,90,89,91,89,92,91,93)	3	0	2	3
WBCs-W-W (N=91,92,91,90,89,91,89,92,91,93)	86	92	89	86
WBCs-W-A (N=91,92,91,90,89,91,89,92,91,93)	1	0	0	1
WBCs-A-W (N=1,2,0,2,2,0,0,0,1,0)	0	1	0	1
WBCs-A-A (N=1,2,0,2,2,0,0,0,1,0)	1	1	0	1

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	97	98	97
Units: Participants				
ALT-U-W (N=1,0,0,1,0,1,1,1,2,0)	0	1	1	1
ALT-W-U (N=95,94,95,93,96,96,95,93,91,97)	0	0	0	0
ALT-W-W (N=95,94,95,93,96,96,95,93,91,97)	94	94	95	91
ALT-W-A (N=95,94,95,93,96,96,95,93,91,97)	2	2	0	2
ALT-A-W (N=1,0,0,2,2,0,2,3,4,2)	1	0	1	2
ALT-A-A (N=1,0,0,2,2,0,2,3,4,2)	1	0	1	1
AST-U-W (N=1,0,0,1,0,1,1,1,2,0)	0	1	1	1
AST-W-U (N=96,93,95,94,97,96,95,95,93,98)	0	0	0	0
AST-W-W (N=96,93,95,94,97,96,95,95,93,98)	97	94	95	93
AST-W-A (N=96,93,95,94,97,96,95,95,93,98)	0	2	0	2
AST-A-W (N=0,1,0,1,1,0,2,1,2,1)	1	0	0	0
AST-A-A (N=0,1,0,1,1,0,2,1,2,1)	0	0	2	1
BASOs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	2	2	1
BASOs-W-U (N=96,94,94,96,96,95,96,96,95,98)	1	1	0	0
BASOs-W-W (N=96,94,94,96,96,95,96,96,95,98)	95	94	96	96
CR-U-B (N=1,0,0,1,0,1,1,1,2,0)	0	0	0	0
CR-U-W (N=1,0,0,1,0,1,1,1,2,0)	0	1	0	1
CR-U-A (N=1,0,0,1,0,1,1,1,2,0)	0	0	1	0
CR-B-U (N=3,6,3,3,4,1,3,6,7,1)	0	0	0	0
CR-B-B (N=3,6,3,3,4,1,3,6,7,1)	4	1	2	3

CR-B-W (N=3,6,3,3,4,1,3,6,7,1)	0	0	1	3
CR-W-B (N=87,83,90,89,92,94,93,88,87,97)	3	3	2	1
CR-W-W (N=87,83,90,89,92,94,93,88,87,97)	88	90	88	86
CR-W-A (N=87,83,90,89,92,94,93,88,87,97)	1	1	3	1
CR-A-W (N=6,5,2,3,2,1,1,2,1,1)	1	0	1	0
CR-A-A (N=6,5,2,3,2,1,1,2,1,1)	1	1	0	2
EOSs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	1	2	1
EOSs-U-A (N=1,0,1,0,2,2,2,1,2,1)	0	1	0	0
EOSs-B-U (N=7,5,9,6,8,5,6,8,6,8)	0	0	0	0
EOSs-B-B (N=7,5,9,6,8,5,6,8,6,8)	3	4	1	1
EOSs-B-W (N=7,5,9,6,8,5,6,8,6,8)	5	1	5	7
EOSs-W-U (N=86,87,82,87,84,88,85,87,87,88)	1	1	0	0
EOSs-W-B (N=86,87,82,87,84,88,85,87,87,88)	3	1	6	1
EOSs-W-W (N=86,87,82,87,84,88,85,87,87,88)	79	83	78	83
EOSs-W-A (N=86,87,82,87,84,88,85,87,87,88)	1	3	1	3
EOSs-A-W (N=3,2,3,3,4,2,5,1,2,2)	0	1	4	1
EOSs-A-A (N=3,2,3,3,4,2,5,1,2,2)	4	1	1	0
RBCs-U-B (N=1,0,1,0,2,2,2,1,2,1)	1	0	0	0
RBCs-U-W (N=1,0,1,0,2,2,2,1,2,1)	1	2	2	1
RBCs-U-A (N=1,0,1,0,2,2,2,1,2,1)	0	0	0	0
RBCs-B-B (N=7,2,0,2,3,4,3,0,4,1)	3	4	2	0
RBCs-B-W (N=7,2,0,2,3,4,3,0,4,1)	0	0	1	0
RBCs-W-U (N=87,91,91,93,92,89,90,94,90,96)	1	1	0	0
RBCs-W-B (N=87,91,91,93,92,89,90,94,90,96)	2	3	1	0
RBCs-W-W (N=87,91,91,93,92,89,90,94,90,96)	89	83	89	94
RBCs-W-A (N=87,91,91,93,92,89,90,94,90,96)	0	2	0	0
RBCs-A-W (N=2,1,3,1,1,2,3,2,1,1)	1	2	1	0
RBCs-A-A (N=2,1,3,1,1,2,3,2,1,1)	0	0	2	2
HGB-U-B (N=1,0,1,0,2,2,2,1,2,1)	2	0	0	0
HGB-U-W (N=1,0,1,0,2,2,2,1,2,1)	0	2	2	1
HGB-B-B (N=8,8,3,7,5,9,6,3,9,4)	3	6	5	3
HGB-B-W (N=8,8,3,7,5,9,6,3,9,4)	2	3	1	0
HGB-W-U (N=87,85,90,86,90,84,90,91,85,94)	1	1	0	0
HGB-W-B (N=87,85,90,86,90,84,90,91,85,94)	3	1	1	1
HGB-W-W (N=87,85,90,86,90,84,90,91,85,94)	86	82	89	90
HGB-W-A (N=87,85,90,86,90,84,90,91,85,94)	0	0	0	0
HGB-A-W (N=1,1,1,3,1,2,0,2,1,0)	0	2	0	1
HGB-A-A (N=1,1,1,3,1,2,0,2,1,0)	1	0	0	1
LYMs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	2	2	1
LYMs-B-B (N=2,1,4,4,4,2,3,1,1,5)	1	1	2	0
LYMs-B-W (N=2,1,4,4,4,2,3,1,1,5)	3	1	1	1

LYMs-W-U (N=93,92,90,91,91,93,93,95,94,93)	1	1	0	0
LYMs-W-B (N=93,92,90,91,91,93,93,95,94,93)	1	0	2	1
LYMs-W-W (N=93,92,90,91,91,93,93,95,94,93)	88	92	91	94
LYMs-W-A (N=93,92,90,91,91,93,93,95,94,93)	1	0	0	0
LYMs-A-W (N=1,1,0,1,1,0,0,0,0,0)	0	0	0	0
LYMs-A-A (N=1,1,0,1,1,0,0,0,0,0)	1	0	0	0
MONOs-U-B (N=1,0,1,0,2,2,2,1,2,1)	0	0	0	0
MONOs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	2	2	1
MONOs-B-B (N=5,0,4,3,4,6,4,4,5,6)	1	1	0	1
MONOs-B-W (N=5,0,4,3,4,6,4,4,5,6)	3	5	4	3
MONOs-W-U (N=89,94,90,93,92,89,92,91,90,92)	1	1	0	0
MONOs-W-B (N=89,94,90,93,92,89,92,91,90,92)	1	6	1	3
MONOs-W-W (N=89,94,90,93,92,89,92,91,90,92)	90	82	91	88
MONOs-A-W (N=2,0,0,0,0,0,0,1,0,0)	0	0	0	0
MONOs-A-A (N=2,0,0,0,0,0,0,1,0,0)	0	0	0	1
NPs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	2	2	1
NPs-B-B (N=2,1,1,3,1,3,2,1,1,2)	0	2	0	0
NPs-B-W (N=2,1,1,3,1,3,2,1,1,2)	1	1	2	1
NPs-W-U (N=94,92,93,92,95,92,94,95,93,96)	1	1	0	0
NPs-W-B (N=94,92,93,92,95,92,94,95,93,96)	1	1	2	0
NPs-W-W (N=94,92,93,92,95,92,94,95,93,96)	91	90	92	95
NPs-W-A (N=94,92,93,92,95,92,94,95,93,96)	2	0	0	0
NPs-A-W (N=0,1,0,1,0,0,0,0,1,0)	0	0	0	0
NPs-A-A (N=0,1,0,1,0,0,0,0,1,0)	0	0	0	0
PLTs-U-U (N=3,2,2,0,2,3,5,2,2,1)	0	1	0	0
PLTs-U-W (N=3,2,2,0,2,3,5,2,2,1)	2	2	5	2
PLTs-B-U (N=3,1,3,1,0,2,1,1,1,2)	0	0	0	0
PLTs-B-B (N=3,1,3,1,0,2,1,1,1,2)	0	1	0	1
PLTs-B-W (N=3,1,3,1,0,2,1,1,1,2)	0	1	1	0
PLTs-W-U (N=89,91,89,93,96,90,91,92,92,93)	1	1	1	1
PLTs-W-B (N=89,91,89,93,96,90,91,92,92,93)	1	1	1	0
PLTs-W-W (N=89,91,89,93,96,90,91,92,92,93)	92	88	87	90
PLTs-W-A (N=89,91,89,93,96,90,91,92,92,93)	2	0	2	1
PLTs-A-W (N=2,0,1,2,0,2,1,2,2,3)	0	1	1	0
PLTs-A-A (N=2,0,1,2,0,2,1,2,2,3)	0	1	0	2
UN-U-W (N=1,0,0,1,0,1,1,1,2,0)	0	1	0	1
UN-U-A (N=1,0,0,1,0,1,1,1,2,0)	0	0	1	0
UN-B-B (N=0,0,0,1,0,0,2,1,1,0)	0	0	1	0
UN-B-W (N=0,0,0,1,0,0,2,1,1,0)	0	0	1	1
UN-W-U (N=92,94,93,92,95,94,92,92,92,99)	0	0	0	0

UN-W-W (N=92,94,93,92,95,94,92,92,92,99)	95	94	91	91
UN-W-A (N=92,94,93,92,95,94,92,92,92,99)	0	0	1	1
UN-A-W (N=4,0,2,2,3,2,3,2,0)	3	1	2	2
UN-A-A (N=4,0,2,2,3,2,3,2,0)	0	1	1	1
UA-U-B (N=1,0,0,1,0,1,1,1,2,0)	0	0	0	0
UA-U-W (N=1,0,0,1,0,1,1,1,2,0)	0	1	0	1
UA-U-A (N=1,0,0,1,0,1,1,1,2,0)	0	0	1	0
UA-B-B (N=2,2,1,3,0,1,4,2,2,3)	0	1	4	2
UA-B-W (N=2,2,1,3,0,1,4,2,2,3)	0	0	0	0
UA-W-U (N=91,87,92,90,98,92,93,91,92,91)	0	0	0	0
UA-W-B (N=91,87,92,90,98,92,93,91,92,91)	0	1	1	1
UA-W-W (N=91,87,92,90,98,92,93,91,92,91)	98	91	92	87
UA-W-A (N=91,87,92,90,98,92,93,91,92,91)	0	0	0	3
UA-A-W (N=3,5,2,2,0,3,0,3,1,5)	0	2	0	2
UA-A-A (N=3,5,2,2,0,3,0,3,1,5)	0	1	0	1
WBCs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	2	2	1
WBCs-B-B (N=4,0,3,4,5,4,7,4,3,5)	1	0	1	2
WBCs-B-W (N=4,0,3,4,5,4,7,4,3,5)	4	4	6	2
WBCs-W-U (N=91,92,91,90,89,91,89,92,91,93)	1	1	0	0
WBCs-W-B (N=91,92,91,90,89,91,89,92,91,93)	3	2	1	0
WBCs-W-W (N=91,92,91,90,89,91,89,92,91,93)	83	88	88	91
WBCs-W-A (N=91,92,91,90,89,91,89,92,91,93)	2	0	0	1
WBCs-A-W (N=1,2,0,2,2,0,0,0,1,0)	2	0	0	0
WBCs-A-A (N=1,2,0,2,2,0,0,0,1,0)	0	0	0	0

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	99		
Units: Participants				
ALT-U-W (N=1,0,0,1,0,1,1,1,2,0)	2	0		
ALT-W-U (N=95,94,95,93,96,96,95,93,91,97)	0	1		
ALT-W-W (N=95,94,95,93,96,96,95,93,91,97)	90	96		
ALT-W-A (N=95,94,95,93,96,96,95,93,91,97)	1	0		
ALT-A-W (N=1,0,0,2,2,0,2,3,4,2)	2	0		
ALT-A-A (N=1,0,0,2,2,0,2,3,4,2)	2	2		
AST-U-W (N=1,0,0,1,0,1,1,1,2,0)	2	0		
AST-W-U (N=96,93,95,94,97,96,95,95,93,98)	0	1		
AST-W-W (N=96,93,95,94,97,96,95,95,93,98)	92	97		

AST-W-A (N=96,93,95,94,97,96,95,95,93,98)	1	0		
AST-A-W (N=0,1,0,1,1,0,2,1,2,1)	1	0		
AST-A-A (N=0,1,0,1,1,0,2,1,2,1)	1	1		
BASOs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	1		
BASOs-W-U (N=96,94,94,96,96,95,96,96,95,98)	0	1		
BASOs-W-W (N=96,94,94,96,96,95,96,96,95,98)	95	97		
CR-U-B (N=1,0,0,1,0,1,1,1,2,0)	1	0		
CR-U-W (N=1,0,0,1,0,1,1,1,2,0)	1	0		
CR-U-A (N=1,0,0,1,0,1,1,1,2,0)	0	0		
CR-B-U (N=3,6,3,3,4,1,3,6,7,1)	0	1		
CR-B-B (N=3,6,3,3,4,1,3,6,7,1)	1	0		
CR-B-W (N=3,6,3,3,4,1,3,6,7,1)	6	0		
CR-W-B (N=87,83,90,89,92,94,93,88,87,97)	1	0		
CR-W-W (N=87,83,90,89,92,94,93,88,87,97)	83	96		
CR-W-A (N=87,83,90,89,92,94,93,88,87,97)	3	1		
CR-A-W (N=6,5,2,3,2,1,1,2,1,1)	0	0		
CR-A-A (N=6,5,2,3,2,1,1,2,1,1)	1	1		
EOSs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	1		
EOSs-U-A (N=1,0,1,0,2,2,2,1,2,1)	0	0		
EOSs-B-U (N=7,5,9,6,8,5,6,8,6,8)	0	0		
EOSs-B-B (N=7,5,9,6,8,5,6,8,6,8)	4	3		
EOSs-B-W (N=7,5,9,6,8,5,6,8,6,8)	2	5		
EOSs-W-U (N=86,87,82,87,84,88,85,87,87,88)	0	1		
EOSs-W-B (N=86,87,82,87,84,88,85,87,87,88)	3	0		
EOSs-W-W (N=86,87,82,87,84,88,85,87,87,88)	83	87		
EOSs-W-A (N=86,87,82,87,84,88,85,87,87,88)	1	0		
EOSs-A-W (N=3,2,3,3,4,2,5,1,2,2)	0	2		
EOSs-A-A (N=3,2,3,3,4,2,5,1,2,2)	2	0		
RBCs-U-B (N=1,0,1,0,2,2,2,1,2,1)	0	0		
RBCs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	0		
RBCs-U-A (N=1,0,1,0,2,2,2,1,2,1)	0	1		
RBCs-B-B (N=7,2,0,2,3,4,3,0,4,1)	2	1		
RBCs-B-W (N=7,2,0,2,3,4,3,0,4,1)	2	0		
RBCs-W-U (N=87,91,91,93,92,89,90,94,90,96)	0	1		
RBCs-W-B (N=87,91,91,93,92,89,90,94,90,96)	1	3		
RBCs-W-W (N=87,91,91,93,92,89,90,94,90,96)	89	92		
RBCs-W-A (N=87,91,91,93,92,89,90,94,90,96)	0	0		
RBCs-A-W (N=2,1,3,1,1,2,3,2,1,1)	0	0		
RBCs-A-A (N=2,1,3,1,1,2,3,2,1,1)	1	1		
HGB-U-B (N=1,0,1,0,2,2,2,1,2,1)	0	0		
HGB-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	1		
HGB-B-B (N=8,8,3,7,5,9,6,3,9,4)	8	3		

HGB-B-W (N=8,8,3,7,5,9,6,3,9,4)	1	1		
HGB-W-U (N=87,85,90,86,90,84,90,91,85,94)	0	1		
HGB-W-B (N=87,85,90,86,90,84,90,91,85,94)	3	2		
HGB-W-W (N=87,85,90,86,90,84,90,91,85,94)	82	91		
HGB-W-A (N=87,85,90,86,90,84,90,91,85,94)	0	0		
HGB-A-W (N=1,1,1,3,1,2,0,2,1,0)	0	0		
HGB-A-A (N=1,1,1,3,1,2,0,2,1,0)	1	0		
LYMs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	1		
LYMs-B-B (N=2,1,4,4,4,2,3,1,1,5)	0	4		
LYMs-B-W (N=2,1,4,4,4,2,3,1,1,5)	1	1		
LYMs-W-U (N=93,92,90,91,91,93,93,95,94,93)	0	1		
LYMs-W-B (N=93,92,90,91,91,93,93,95,94,93)	0	1		
LYMs-W-W (N=93,92,90,91,91,93,93,95,94,93)	94	91		
LYMs-W-A (N=93,92,90,91,91,93,93,95,94,93)	0	0		
LYMs-A-W (N=1,1,0,1,1,0,0,0,0,0)	0	0		
LYMs-A-A (N=1,1,0,1,1,0,0,0,0,0)	0	0		
MONOs-U-B (N=1,0,1,0,2,2,2,1,2,1)	1	0		
MONOs-U-W (N=1,0,1,0,2,2,2,1,2,1)	1	1		
MONOs-B-B (N=5,0,4,3,4,6,4,4,5,6)	1	3		
MONOs-B-W (N=5,0,4,3,4,6,4,4,5,6)	4	3		
MONOs-W-U (N=89,94,90,93,92,89,92,91,90,92)	0	1		
MONOs-W-B (N=89,94,90,93,92,89,92,91,90,92)	1	3		
MONOs-W-W (N=89,94,90,93,92,89,92,91,90,92)	89	88		
MONOs-A-W (N=2,0,0,0,0,0,0,1,0,0)	0	0		
MONOs-A-A (N=2,0,0,0,0,0,0,1,0,0)	0	0		
NPs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	1		
NPs-B-B (N=2,1,1,3,1,3,2,1,1,2)	0	2		
NPs-B-W (N=2,1,1,3,1,3,2,1,1,2)	1	0		
NPs-W-U (N=94,92,93,92,95,92,94,95,93,96)	0	1		
NPs-W-B (N=94,92,93,92,95,92,94,95,93,96)	4	2		
NPs-W-W (N=94,92,93,92,95,92,94,95,93,96)	89	92		
NPs-W-A (N=94,92,93,92,95,92,94,95,93,96)	0	1		
NPs-A-W (N=0,1,0,1,0,0,0,0,1,0)	1	0		
NPs-A-A (N=0,1,0,1,0,0,0,0,1,0)	0	0		
PLTs-U-U (N=3,2,2,0,2,3,5,2,2,1)	0	0		
PLTs-U-W (N=3,2,2,0,2,3,5,2,2,1)	2	1		
PLTs-B-U (N=3,1,3,1,0,2,1,1,1,2)	0	0		
PLTs-B-B (N=3,1,3,1,0,2,1,1,1,2)	0	2		
PLTs-B-W (N=3,1,3,1,0,2,1,1,1,2)	1	0		
PLTs-W-U (N=89,91,89,93,96,90,91,92,92,93)	0	1		

PLTs-W-B (N=89,91,89,93,96,90,91,92,92,93)	0	0		
PLTs-W-W (N=89,91,89,93,96,90,91,92,92,93)	89	91		
PLTs-W-A (N=89,91,89,93,96,90,91,92,92,93)	3	1		
PLTs-A-W (N=2,0,1,2,0,2,1,2,2,3)	1	0		
PLTs-A-A (N=2,0,1,2,0,2,1,2,2,3)	1	3		
UN-U-W (N=1,0,0,1,0,1,1,1,2,0)	2	0		
UN-U-A (N=1,0,0,1,0,1,1,1,2,0)	0	0		
UN-B-B (N=0,0,0,1,0,0,2,1,1,0)	0	0		
UN-B-W (N=0,0,0,1,0,0,2,1,1,0)	1	0		
UN-W-U (N=92,94,93,92,95,94,92,92,92,99)	0	1		
UN-W-W (N=92,94,93,92,95,94,92,92,92,99)	91	97		
UN-W-A (N=92,94,93,92,95,94,92,92,92,99)	1	1		
UN-A-W (N=4,0,2,2,3,2,3,3,2,0)	2	0		
UN-A-A (N=4,0,2,2,3,2,3,3,2,0)	0	0		
UA-U-B (N=1,0,0,1,0,1,1,1,2,0)	1	0		
UA-U-W (N=1,0,0,1,0,1,1,1,2,0)	1	0		
UA-U-A (N=1,0,0,1,0,1,1,1,2,0)	0	0		
UA-B-B (N=2,2,1,3,0,1,4,2,2,3)	2	2		
UA-B-W (N=2,2,1,3,0,1,4,2,2,3)	0	1		
UA-W-U (N=91,87,92,90,98,92,93,91,92,91)	0	1		
UA-W-B (N=91,87,92,90,98,92,93,91,92,91)	0	3		
UA-W-W (N=91,87,92,90,98,92,93,91,92,91)	91	83		
UA-W-A (N=91,87,92,90,98,92,93,91,92,91)	1	4		
UA-A-W (N=3,5,2,2,0,3,0,3,1,5)	1	4		
UA-A-A (N=3,5,2,2,0,3,0,3,1,5)	0	1		
WBCs-U-W (N=1,0,1,0,2,2,2,1,2,1)	2	1		
WBCs-B-B (N=4,0,3,4,5,4,7,4,3,5)	1	4		
WBCs-B-W (N=4,0,3,4,5,4,7,4,3,5)	2	1		
WBCs-W-U (N=91,92,91,90,89,91,89,92,91,93)	0	1		
WBCs-W-B (N=91,92,91,90,89,91,89,92,91,93)	3	1		
WBCs-W-W (N=91,92,91,90,89,91,89,92,91,93)	88	90		
WBCs-W-A (N=91,92,91,90,89,91,89,92,91,93)	0	1		
WBCs-A-W (N=1,2,0,2,2,0,0,0,1,0)	1	0		
WBCs-A-A (N=1,2,0,2,2,0,0,0,1,0)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any Grade 3 non-serious AEs (solicited and

unsolicited) after first dose of vaccination

End point title	Number of subjects with any Grade 3 non-serious AEs (solicited and unsolicited) after first dose of vaccination ^[14]
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End point description:

A Grade 3 AE is any AE assessed as severe, i.e. which prevents normal, everyday activities. In adults, such an AE would, for example, prevent attendance at work and would necessitate the administration of corrective therapy.

End point type	Primary
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End point timeframe:

During a 30-day follow-up period (i.e., on the day of vaccination at Day 1, and 29 subsequent days) after first dose of vaccination

Notes:

[14] - 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: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Any adverse event	1	0	0	0
General adverse event	1	0	0	0
Local adverse event	0	0	0	0

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	97	100	101
Units: Participants				
Any adverse event	1	1	4	3
General adverse event	1	1	3	2
Local adverse event	0	0	2	1

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	100	103	100
Units: Participants				
Any adverse event	7	1	7	6
General adverse event	5	0	2	3
Local adverse event	2	1	6	3

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	101		
Units: Participants				
Any adverse event	8	4		
General adverse event	4	4		
Local adverse event	4	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any Grade 3 non-serious AEs (solicited and unsolicited) after second dose of vaccination

End point title	Number of subjects with any Grade 3 non-serious AEs (solicited and unsolicited) after second dose of vaccination ^[15]
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End point description:

A Grade 3 AE is any AE assessed as severe, i.e. which prevents normal, everyday activities. In adults, such an AE would, for example, prevent attendance at work and would necessitate the administration of corrective therapy.

End point type	Primary
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End point timeframe:

During a 30-day follow-up period (i.e., on the day of vaccination at Day 61, and 29 subsequent days) after second dose of vaccination

Notes:

[15] - 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: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	11	12
Units: Participants				
Any adverse event	1	0	0	0
General adverse event	1	0	0	0
Local adverse event	0	0	0	0

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	95	95	96
Units: Participants				
Any adverse event	1	0	2	5
General adverse event	1	0	2	4
Local adverse event	0	0	0	1

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	97	98	97
Units: Participants				
Any adverse event	3	5	8	7
General adverse event	2	2	5	5
Local adverse event	1	3	4	2

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	99		
Units: Participants				
Any adverse event	3	0		
General adverse event	1	0		
Local adverse event	2	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any Serious Adverse Events (SAEs) up to 30 days after the second vaccination

End point title	Number of subjects with any Serious Adverse Events (SAEs) up to 30 days after the second vaccination ^[16]
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End point description:

A SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization or results in disability/incapacity.

End point type	Primary
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End point timeframe:

From first vaccination (Day 1) up to 30 days post second vaccination (Day 91)

Notes:

[16] - 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: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants	0	0	0	0

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	97	100	101
Units: Participants	6	0	1	4

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	100	103	100
Units: Participants	2	1	1	3

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	101		
Units: Participants	5	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any potential immune-mediated diseases (pIMDs) up to 30 days after the second vaccination (Part B groups)

End point title	Number of subjects with any potential immune-mediated diseases (pIMDs) up to 30 days after the second vaccination (Part B groups) ^{[17][18]}
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End point description:

pIMDs are a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune etiology.

End point type	Primary
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End point timeframe:

From first vaccination (Day 1) up to 30 days post second vaccination (Day 91)

Notes:

[17] - 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: The scope of this endpoint analysis was descriptive, therefore no statistical analyses apply for this endpoint.

[18] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	97	100	101
Units: Participants	0	0	0	0

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	100	103	100
Units: Participants	0	0	0	0

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	101		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any SAEs, up the end of follow-up period (Month 14) - Part B groups

End point title	Number of subjects with any SAEs, up the end of follow-up period (Month 14) - Part B groups ^[19]
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End point description:

A SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization or results in disability/incapacity or is a congenital anomaly/birth defect in the offspring of a study subject.

End point type	Secondary
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End point timeframe:

From Day 1 up to the end of follow-up period (Month 14)

Notes:

[19] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	97	100	101
Units: Participants	13	3	5	8

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	100	103	100
Units: Participants	6	11	9	5

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	101		
Units: Participants	9	9		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting pIMDs up to the end of follow-up period (Month 14) - Part B groups

End point title	Number of subjects reporting pIMDs up to the end of follow-up period (Month 14) - Part B groups ^[20]
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End point description:

pIMDs are a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune etiology.

End point type	Secondary
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End point timeframe:

From Day 1 up to the end of follow-up period (Month 14)

Notes:

[20] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	97	100	101
Units: Participants	1	0	0	0

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	100	103	100
Units: Participants	1	1	0	0

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	101		
Units: Participants	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with at least one RSV-confirmed Respiratory Tract Infection (RTI) episode post-vaccination reported during RTI surveillance - Part B groups

End point title	Number of subjects with at least one RSV-confirmed Respiratory Tract Infection (RTI) episode post-vaccination reported during RTI surveillance - Part B groups ^[21]
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End point description:

The number of subjects with at least one RTI case is provided by group. Reported categories are RSV+ (= RTI episode tested as RSV positive by quantitative reverse transcription polymerase chain reaction (qRT-PCR) on nasal/throat swab) and RSV- (= RTI episode tested as RSV negative by qRT-PCR on nasal/throat swab).

End point type	Secondary
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End point timeframe:

During the RSV seasons (from October 2019 to March 2020)

Notes:

[21] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	97	100	101
Units: Participants				
RSV+	1	2	0	0
RSV-	19	12	20	14

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	100	103	100
Units: Participants				
RSV+	0	0	0	2
RSV-	17	22	20	16

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	101		
Units: Participants				
RSV+	0	3		
RSV-	13	11		

Statistical analyses

No statistical analyses for this end point

Secondary: Humoral immune response with respect to components of the investigational vaccine in terms of neutralizing antibody titers against RSV-serotype A (Part A groups)

End point title	Humoral immune response with respect to components of the investigational vaccine in terms of neutralizing antibody titers against RSV-serotype A (Part A groups) ^[22]
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End point description:

Serological assays for the determination of functional antibodies against RSV-A were performed by neutralization assay. Anti RSV-A neutralizing antibody titers are given as geometric mean titers (GMTs) and expressed as Estimated Dose: serum dilution giving a 60% reduction of the signal compared to a control without serum (ED60).

End point type	Secondary
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End point timeframe:

At pre-vaccination (Day 1), 30 days post-Dose 1 (Day 31), on the day of second vaccination (Day 61) and 30 days post-Dose 2 (Day 91)

Notes:

[22] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	12	12
Units: Titers				
geometric mean (confidence interval 95%)				
D1 (N=11,11,12,12)	1019 (634.6 to 1636.1)	846.2 (481.7 to 1486.4)	673.6 (325.3 to 1394.7)	620.7 (365.1 to 1055.1)
D31 (N=11,8,11,12)	7658.4 (4329.7 to 13546.2)	11741.8 (4883.6 to 28231.5)	8136.9 (5066.1 to 13069.1)	789.1 (518.6 to 1200.9)
D61 (N=11,9,11,12)	4659.8 (2090 to 10389.1)	5895.8 (2791.9 to 12450.5)	4761.5 (2687.7 to 8435.5)	586.5 (333.1 to 1032.7)
D91 (N=11,9,11,12)	6237.8 (3648.1 to 10665.9)	5457.5 (2532.9 to 11758.7)	3651 (1949.6 to 6837.2)	787.9 (495.5 to 1252.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Humoral immune response with respect to components of the investigational vaccine in terms of neutralizing antibody titers against RSV-serotype A (Part B groups)

End point title	Humoral immune response with respect to components of the investigational vaccine in terms of neutralizing antibody titers against RSV-serotype A (Part B groups) ^[23]
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End point description:

Serological assays for the determination of functional antibodies against RSV-A were performed by neutralization assay. Anti RSV-A neutralizing antibody titers are given as geometric mean titers (GMTs) and expressed as Estimated Dose: serum dilution giving a 60% reduction of the signal compared to a control without serum (ED60).

End point type	Secondary
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End point timeframe:

At pre-vaccination (Day 1), 30 days post-Dose 1 (Day 31), on the day of second vaccination (Day 61) and 30 days post-Dose 2 (Day 91)

Notes:

[23] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	96	99	100
Units: Titers				
geometric mean (confidence interval 95%)				
Day 1 (N=101,96,99,100,101,100,102,100,10)	1015.5 (865 to 1192.2)	1146.5 (931.6 to 1411)	976.7 (837.7 to 1138.8)	960.9 (801 to 1152.7)
Day 31 (N=93,90,90,92,97,94,95,95,93,92)	5422.6 (4395 to 6690.5)	7371 (5922.5 to 9173.8)	9403.1 (7471.2 to 11834.4)	5258.5 (4351.8 to 6354.1)
Day 61 (N=95,90,92,93,100,95,94,97,98,96)	5657.9 (4736 to 6759.1)	6490.8 (5190.3 to 8117.1)	7907.4 (6253.9 to 9998.2)	5019.4 (4281.5 to 5884.5)
Day 91 (N=88,84,87,84,91,87,85,93,92,93)	3936.2 (3281.9 to 4720.9)	5632.1 (4559.2 to 6957.5)	5956.1 (4881.4 to 7267.4)	3924.7 (3266 to 4716.2)

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	100	102	100
Units: Titers				
geometric mean (confidence interval 95%)				
Day 1 (N=101,96,99,100,101,100,102,100,10)	966.4 (822.9 to 1134.8)	961.9 (809.5 to 1143)	981.6 (832.7 to 1157.2)	1023 (879.2 to 1190.2)
Day 31 (N=93,90,90,92,97,94,95,95,93,92)	6509.4 (5306.8 to 7984.4)	9350.9 (7606 to 11496.1)	6026.1 (4960.9 to 7320.1)	6899.5 (5767.8 to 8253.2)
Day 61 (N=95,90,92,93,100,95,94,97,98,96)	6201.9 (5106.3 to 7532.6)	6681.7 (5498.4 to 8119.8)	5048.9 (4184.4 to 6092)	5902.1 (5023.4 to 6934.4)
Day 91 (N=88,84,87,84,91,87,85,93,92,93)	4770 (3904.6 to 5827.4)	5175.5 (4273.1 to 6268.5)	4435.9 (3654.7 to 5384.1)	4850.5 (4096.8 to 5742.8)

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	100		
Units: Titers				
geometric mean (confidence interval 95%)				
Day 1 (N=101,96,99,100,101,100,102,100,10)	1035.7 (864.5 to 1240.7)	837.4 (701.3 to 999.9)		
Day 31 (N=93,90,90,92,97,94,95,95,93,92)	8527.7 (7107.9 to 10231)	751.7 (625.2 to 903.9)		

Day 61 (N=95,90,92,93,100,95,94,97,98,96)	7201.4 (6000.4 to 8642.8)	903.4 (750.8 to 1087.1)		
Day 91 (N=88,84,87,84,91,87,85,93,92,93)	5980.6 (4988 to 7170.7)	772.4 (646.2 to 923.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Humoral immune response with respect to components of the investigational vaccine in terms of RSVPreF3-specific Immunoglobulin G (IgG) antibody concentrations (Part A groups)

End point title	Humoral immune response with respect to components of the investigational vaccine in terms of RSVPreF3-specific Immunoglobulin G (IgG) antibody concentrations (Part A groups) ^[24]
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End point description:

The detection and the quantification of total IgG antibodies directed against RSVPreF3 in human serum samples were based on an indirect enzyme-linked immunosorbent assay (ELISA). Anti RSVPreF3 antibody concentration is given in geometric mean concentration (GMC) and is expressed in ELISA Laboratory Units per milliliter (ELU/mL).

End point type	Secondary
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End point timeframe:

At pre-vaccination (Day 1), 30 days post-Dose 1 (Day 31), on the day of second vaccination (Day 61) and 30 days post-Dose 2 (Day 91)

Notes:

[24] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	12	12
Units: Titers				
geometric mean (confidence interval 95%)				
D1 (N=11,11,12,12)	8330.7 (5561.5 to 12478.9)	7699.5 (5326 to 11130.8)	7439.1 (5808.6 to 9527.2)	6524.8 (4828.2 to 8817.6)
D31 (N=11,8,11,12)	69843.3 (38345.8 to 127212.8)	97848.5 (65057.1 to 147168)	96645.4 (62880.7 to 148540.5)	6601 (4888.4 to 8913.6)
D61 (N=11,9,11,12)	50590.1 (27310.9 to 93711.7)	58980.8 (38982.8 to 89237.7)	56380.6 (38602.6 to 82346.1)	6242.4 (4473 to 8711.7)
D91 (N=11,9,11,12)	54900 (33635.4 to 89608.2)	54884.7 (37768.6 to 79757.3)	55444.4 (38128.6 to 80624)	6246 (4375.8 to 8915.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Humoral immune response with respect to components of the investigational vaccine in terms of RSVPreF3-specific Immunoglobulin G (IgG) antibody concentrations (Part B groups)

End point title	Humoral immune response with respect to components of the investigational vaccine in terms of RSVPreF3-specific Immunoglobulin G (IgG) antibody concentrations (Part B groups) ^[25]
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End point description:

The detection and the quantification of total IgG antibodies directed against RSVPreF3 in human serum samples were based on an indirect enzyme-linked immunosorbent assay (ELISA). Anti RSVPreF3 antibody concentration is given in geometric mean concentration (GMC) and is expressed in ELISA Laboratory Units per milliliter (ELU/mL).

End point type	Secondary
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End point timeframe:

At pre-vaccination (Day 1), 30 days post-Dose 1 (Day 31), on the day of second vaccination (Day 61) and 30 days post-Dose 2 (Day 91)

Notes:

[25] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	96	99	100
Units: ELU/mL				
geometric mean (confidence interval 95%)				
Day 1 (N=101,96,99,100,101,100,102,100,101,100)	7500.2 (6582.4 to 8545.9)	7209.7 (6150.9 to 8450.7)	7134.9 (6377.7 to 7982)	6760.5 (5913.7 to 7728.5)
Day 31 (N=93,90,90,92,97,94,95,95,93,92)	53994 (46566.7 to 62605.8)	71618.4 (60729.6 to 84459.5)	90933.2 (79096.2 to 104541.6)	53598.9 (47062.7 to 61043)
Day 61 (N=95,90,93,93,100,95,94,97,98,96)	47594.2 (41241.9 to 54924.8)	56855.4 (47655.2 to 67831.7)	70294.1 (61103.1 to 80867.5)	41543.8 (36864.7 to 46816.8)
Day 91 (N=88,84,87,84,91,87,85,93,92,93)	42523.7 (36905 to 48997.8)	54711.2 (47013.5 to 63669.2)	60955.2 (53029.7 to 70065.1)	42504.6 (38044.3 to 47487.9)

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	101	100	102	100
Units: ELU/mL				
geometric mean (confidence interval 95%)				

Day 1 (N=101,96,99,100,101,100,102,100,101,100)	7438 (6544.6 to 8453.4)	6685.4 (5827 to 7670.4)	7468.5 (6544 to 8523.5)	7245.5 (6265.8 to 8378.3)
Day 31 (N=93,90,90,92,97,94,95,95,93,92)	63823.4 (55601.6 to 73261)	83462.5 (70906.1 to 98242.3)	59026.1 (51236.4 to 68000)	70524 (60825.4 to 81769.1)
Day 61 (N=95,90,93,93,100,95,94,97,98,96)	51209.9 (44850.5 to 58470.9)	62543.2 (52975.1 to 73839.3)	45679.1 (39722.6 to 52528.7)	54342.7 (47099 to 62700.5)
Day 91 (N=88,84,87,84,91,87,85,93,92,93)	52846.4 (47105.8 to 59286.7)	59624.5 (51680 to 68790.2)	53779.9 (47588.5 to 60776.8)	57314.9 (51038.1 to 64363.6)

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101	100		
Units: ELU/mL				
geometric mean (confidence interval 95%)				
Day 1 (N=101,96,99,100,101,100,102,100,101,100)	6655.4 (5862.2 to 7555.9)	6543.8 (5663 to 7561.6)		
Day 31 (N=93,90,90,92,97,94,95,95,93,92)	78831.2 (68382.5 to 90876.4)	6593.4 (5672 to 7664.4)		
Day 61 (N=95,90,93,93,100,95,94,97,98,96)	61577.7 (53431.3 to 70966.1)	6307.9 (5453.8 to 7295.9)		
Day 91 (N=88,84,87,84,91,87,85,93,92,93)	61433.7 (54066.2 to 69805)	6748.7 (5804.1 to 7847.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Descriptive statistics of the frequency of RSVPreF3 specific cluster of differentiation 4+ (CD4+) T cells expressing at least 2 markers (Part A groups)

End point title	Descriptive statistics of the frequency of RSVPreF3 specific cluster of differentiation 4+ (CD4+) T cells expressing at least 2 markers (Part A groups) ^[26]
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End point description:

Among markers expressed were interleukin-2 (IL2), cluster of 40 ligand (CD40L), tumor necrosis factor alpha (TNF α) and interferon gamma (IFN γ), in vitro upon stimulation with RSVPreF3 peptide preparations. Reported statistics at each time point during which blood sample were collected for cell-mediated immunity, are geometric mean and inter-quartile range.

End point type	Secondary
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End point timeframe:

At pre-vaccination (Day 1), 30 days post-Dose 1 (Day 31), on the day of second vaccination (Day 61) and 30 days post-Dose 2 (Day 91)

Notes:

[26] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group	Placebo_A Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	10	12
Units: Cells per million CD4+ T Cells				
median (inter-quartile range (Q1-Q3))				
D1 (N=11,11,10,11)	400.0 (348 to 791)	272.0 (163 to 570)	317.5 (184 to 628)	393.0 (333 to 680)
D31 (N=9,8,10,11)	1649.0 (864 to 2604)	2302.5 (1545 to 2725)	1773.5 (1318 to 2124)	303.0 (90 to 416)
D61 (N=10,8,9,11)	1271.0 (519 to 1679)	1515.0 (1129 to 2159)	1066.0 (764 to 1502)	263.0 (184 to 459)
D91 (N=10,8,9,12)	1006.5 (872 to 1779)	1221.0 (924 to 1518)	1487.0 (1005 to 1664)	374.5 (295 to 588)

Statistical analyses

No statistical analyses for this end point

Secondary: Descriptive statistics of the frequency of RSVPreF3 specific cluster of differentiation 4+ (CD4+) T cells expressing at least 2 markers (Part B groups)

End point title	Descriptive statistics of the frequency of RSVPreF3 specific cluster of differentiation 4+ (CD4+) T cells expressing at least 2 markers (Part B groups) ^[27]
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End point description:

Among markers expressed were interleukin-2 (IL2), cluster of 40 ligand (CD40L), tumor necrosis factor alpha (TNF α) and interferon gamma (IFN γ), in vitro upon stimulation with RSVPreF3 peptide preparations. Reported statistics at each time point during which blood sample were collected for cell-mediated immunity, are geometric mean and inter-quartile range.

End point type	Secondary
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End point timeframe:

At pre-vaccination (Day 1), 30 days post-Dose 1 (Day 31), on the day of second vaccination (Day 61) and 30 days post-Dose 2 (Day 91)

Notes:

[27] - 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 is presented separately for Part A and Part B groups due to character limits in the Category Title field.

End point values	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group	High Dose_PLAIN_B Group	Low Dose_AS01E_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	83	79	84	82
Units: Cells per million CD4+ T Cells				
median (inter-quartile range (Q1-Q3))				

Day 1 (N=82,77,84,82,82,83,80,87,86,84)	208.5 (84 to 351)	166.0 (75 to 291)	225.5 (109 to 327)	209.5 (127 to 338)
Day 31 (N=76,68,76,76,73,75,77,80,76,77)	979.5 (639.5 to 1422.5)	1089.5 (786 to 1812.5)	1052.0 (674.5 to 1798)	1594.0 (916 to 2360)
Day 61 (N=83,79,82,77,81,79,88,86,84,86)	688.0 (430 to 1076)	737.0 (437 to 1309)	770.0 (479 to 1235)	1086.0 (663 to 1621)
Day 91 (N=79,79,82,74,80,78,78,83,80,84)	888.0 (650 to 1318)	1034.0 (670 to 1598)	1081.5 (769 to 1569)	1732.0 (1163 to 2149)

End point values	Medium Dose_AS01E_B Group	High Dose_AS01E_B Group	Low Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	83	88	87
Units: Cells per million CD4+ T Cells				
median (inter-quartile range (Q1-Q3))				
Day 1 (N=82,77,84,82,82,83,80,87,86,84)	188.0 (103 to 326)	192.0 (67 to 381)	187.5 (91 to 325.5)	185.0 (82 to 294)
Day 31 (N=76,68,76,76,73,75,77,80,76,77)	1297.0 (881 to 2321)	1466.0 (787 to 2116)	1952.0 (1353 to 2953)	1690.5 (1162.5 to 2691.5)
Day 61 (N=83,79,82,77,81,79,88,86,84,86)	1020.0 (603 to 1405)	934.0 (598 to 1517)	1228.5 (777.5 to 1832.5)	1315.0 (887 to 1728)
Day 91 (N=79,79,82,74,80,78,78,83,80,84)	1603.5 (1087 to 2284)	1496.0 (1179 to 2072)	1966.0 (1339 to 2700)	1558.0 (1263 to 2353)

End point values	High Dose_AS01B_B Group	Placebo_B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	86	86		
Units: Cells per million CD4+ T Cells				
median (inter-quartile range (Q1-Q3))				
Day 1 (N=82,77,84,82,82,83,80,87,86,84)	206.0 (98 to 351)	178.0 (100.5 to 293.5)		
Day 31 (N=76,68,76,76,73,75,77,80,76,77)	1742.5 (1088 to 2360.5)	176.0 (85 to 297)		
Day 61 (N=83,79,82,77,81,79,88,86,84,86)	1078.0 (781 to 1631)	183.0 (61 to 311)		
Day 91 (N=79,79,82,74,80,78,78,83,80,84)	2096.5 (1441.5 to 2760.5)	190.5 (100.5 to 308)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs: during the 7-day follow-up period after each dose. Unsolicited AEs: during the 30-day follow-up period after any dose. SAEs: during the whole study period, from Day 1 till Day 91 for Part A groups and till Month 14 for Part B groups.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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Reporting groups

Reporting group title	Low Dose_PLAIN_A Group
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Reporting group description:

Subjects in Part A, aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted low dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	Medium Dose_PLAIN_A Group
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Reporting group description:

Subjects in Part A aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted medium dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	High Dose_PLAIN_A Group
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Reporting group description:

Subjects in Part A aged 18-40 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted high dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	Placebo_A Group
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Reporting group description:

Subjects in Part A aged 18-40 years, receiving 2 doses of placebo (Saline solution) control, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	Low Dose_PLAIN_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted low dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	Medium Dose_PLAIN_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted medium dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	High Dose_PLAIN_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of RSV Vaccine (GSK3844766A) unadjuvanted high dose, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	High Dose_AS01E_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	Medium Dose_AS01E_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	Low Dose_AS01E_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01E, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	High Dose_AS01B_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	Medium Dose_AS01B_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	Low Dose_AS01B_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of the RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01B, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Reporting group title	Placebo_B Group
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Reporting group description:

Subjects in Part B aged 60-80 years, receiving 2 doses of placebo (Saline solution) control, on a 0, 2 Months schedule, by IM injection into the deltoid region of the arm.

Serious adverse events	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal cancer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Breast cancer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Hormone receptor positive breast cancer			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Prostate cancer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Sarcoma uterus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Uterine cancer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Vascular disorders			
Aortic aneurysm rupture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Shock haemorrhagic			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Thrombophlebitis superficial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Death			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Rectocele			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Respiratory distress			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Bipolar disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Major depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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			
Acetabulum fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Chest injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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

Femur fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Head injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Jaw fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Meniscus injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Patella fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Rib fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Skin laceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Subdural haematoma			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Upper limb fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Arrhythmia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Atrioventricular block complete			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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 arrest			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cardiomyopathy			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Ventricular extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cervicobrachial syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Encephalitis autoimmune			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Loss of consciousness			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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			
Iron deficiency anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pancreatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Hepatobiliary disorders			
Biliary colic			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cholecystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cholelithiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cervical spinal stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Intervertebral disc protrusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Lumbar spinal stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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

Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Spondylolisthesis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Arthritis bacterial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Arthritis infective			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Device related infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Postoperative wound infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Spinal cord abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Spinal cord infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Staphylococcal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Hyperkalaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo_A Group	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	13 / 101 (12.87%)	3 / 97 (3.09%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal cancer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Breast cancer			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Hormone receptor positive breast cancer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Lung carcinoma cell type unspecified stage IV			

subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Prostate cancer			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Sarcoma uterus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Uterine cancer			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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			
Aortic aneurysm rupture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Shock haemorrhagic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Thrombophlebitis superficial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
General disorders and administration site conditions			

Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Death			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Rectocele			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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			
Asthma			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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 distress			

subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Bipolar disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Major depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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			
Acetabulum fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Chest injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Femur fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Head injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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

Injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Jaw fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Meniscus injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Patella fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Skin laceration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Subdural haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Upper limb fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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 disorders			

Acute myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Arrhythmia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Atrioventricular block complete			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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 arrest			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiomyopathy			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Ventricular extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Ventricular tachycardia			

subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Cervicobrachial syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Encephalitis autoimmune			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Ischaemic stroke			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
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 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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			
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Pancreatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Cholecystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Cholelithiasis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Cervical spinal stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Intervertebral disc protrusion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Lumbar spinal stenosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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
Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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

Spondylolisthesis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Arthritis bacterial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Arthritis infective			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Device related infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Postoperative wound infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Spinal cord abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Spinal cord infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Staphylococcal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (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
Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (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

Serious adverse events	High Dose_PLAIN_B Group	High Dose_AS01E_B Group	Medium Dose_AS01E_B Group
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 100 (5.00%)	11 / 100 (11.00%)	6 / 101 (5.94%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal cancer			

subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Breast cancer			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	2 / 101 (1.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Hormone receptor positive breast cancer			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Prostate cancer			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Sarcoma uterus			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Uterine cancer			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Vascular disorders			
Aortic aneurysm rupture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Shock haemorrhagic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Thrombophlebitis superficial			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Death			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (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
Reproductive system and breast disorders			
Cervical dysplasia			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Rectocele			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Pulmonary embolism			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Respiratory distress			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Bipolar disorder			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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

Major depression			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Femur fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Head injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Jaw fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Meniscus injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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

Patella fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Rib fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Skin laceration			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Subdural haematoma			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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 limb fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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			
Acute myocardial infarction			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (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
Arrhythmia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Atrial fibrillation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Atrioventricular block complete			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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 arrest			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Cardiomyopathy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Ventricular extrasystoles			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Cervicobrachial syndrome			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (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
Encephalitis autoimmune			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Hypoaesthesia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Loss of consciousness			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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			
Iron deficiency anaemia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Pancreatitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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

Small intestinal obstruction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Cholecystitis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Cholelithiasis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (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
Cervical spinal stenosis			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Intervertebral disc protrusion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Lumbar spinal stenosis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Muscular weakness			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Osteoarthritis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Pain in extremity			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Spondylolisthesis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Arthritis infective			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Bacteraemia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Device related infection			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (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
Pneumonia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Spinal cord abscess			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Spinal cord infection			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Staphylococcal infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (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
Hyperkalaemia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Low Dose_AS01E_B Group	High Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 101 (7.92%)	9 / 101 (8.91%)	5 / 100 (5.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal cancer			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Breast cancer			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (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
Clear cell renal cell carcinoma			

subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Hormone receptor positive breast cancer			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Prostate cancer			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	2 / 100 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma uterus			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (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
Uterine cancer			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Vascular disorders			

Aortic aneurysm rupture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Shock haemorrhagic			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Thrombophlebitis superficial			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Death			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Rectocele			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			

subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Pulmonary embolism			
subjects affected / exposed	2 / 101 (1.98%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (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
Major depression			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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			
Acetabulum fracture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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

Chest injury			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Femur fracture			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Head injury			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Jaw fracture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Meniscus injury			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (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
Patella fracture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Rib fracture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Skin laceration			

subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Subdural haematoma			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Upper limb fracture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Arrhythmia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Atrial fibrillation			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Atrioventricular block complete			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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 arrest			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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 / 1
Cardio-respiratory arrest			

subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Cardiomyopathy			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Ventricular extrasystoles			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (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
Cervicobrachial syndrome			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Encephalitis autoimmune			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Hypoaesthesia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Loss of consciousness			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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			
Iron deficiency anaemia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Pancreatitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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

Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (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
Cholecystitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Cholelithiasis			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Cervical spinal stenosis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (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
Intervertebral disc protrusion			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Lumbar spinal stenosis			

subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Muscular weakness			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Osteoarthritis			
subjects affected / exposed	1 / 101 (0.99%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Spondylolisthesis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Arthritis infective			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Bacteraemia			

subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Device related infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Pneumonia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Postoperative wound infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Spinal cord abscess			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Spinal cord infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Staphylococcal infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes mellitus			

subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (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
Hyperkalaemia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Low Dose_AS01B_B Group	Placebo_B Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 103 (8.74%)	9 / 101 (8.91%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal cancer			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hormone receptor positive breast cancer			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoma uterus			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm rupture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			

subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Head injury			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial syndrome			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis autoimmune			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			

Iron deficiency anaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 103 (1.94%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Osteoarthritis			
subjects affected / exposed	1 / 103 (0.97%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord abscess			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Low Dose_PLAIN_A Group	Medium Dose_PLAIN_A Group	High Dose_PLAIN_A Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 12 (75.00%)	10 / 12 (83.33%)	9 / 12 (75.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Monoclonal gammopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Basal cell carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Benign anorectal neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Large intestine benign neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Injection site pain			
subjects affected / exposed	6 / 12 (50.00%)	9 / 12 (75.00%)	8 / 12 (66.67%)
occurrences (all)	6	14	14
Fatigue			
subjects affected / exposed	5 / 12 (41.67%)	5 / 12 (41.67%)	4 / 12 (33.33%)
occurrences (all)	7	7	5
Chills			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Injection site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hangover			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site warmth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injection site haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Injection site bruising			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Impaired healing subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Injection site induration subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Injection site movement impairment subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Injection site paraesthesia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Immune system disorders Allergy to arthropod bite subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Reaction to preservatives subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Erectile dysfunction			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal discharge discolouration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract congestion			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pulmonary mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Basophil count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Heart rate irregular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Back injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Patella fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Post procedural inflammation			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Thermal burn subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Tooth fracture subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Upper limb fracture subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Congenital, familial and genetic disorders Dermoid cyst subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	3 / 12 (25.00%) 4	5 / 12 (41.67%) 6	5 / 12 (41.67%) 6
Dizziness subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Sciatica			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Nerve compression subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Sinus headache subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Blood and lymphatic system disorders			
Leukopenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 2	0 / 12 (0.00%) 0
Lymphocytosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Ear and labyrinth disorders			
Ear pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
External ear pain			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Deafness			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Ear discomfort			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Ear disorder			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Eye disorders			
Blepharitis			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Conjunctivitis allergic			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Gastrointestinal disorder			
subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 2	2 / 12 (16.67%) 3	2 / 12 (16.67%) 3
Diarrhoea			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Constipation			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Gastritis			
subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Toothache			

subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Faeces soft			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palatal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eructation			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastric disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pancreatic cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cold sweat			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Night sweats subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Rash pruritic subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	1 / 12 (8.33%) 1
Back pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Pain in extremity			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fibromyalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1

Tooth abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Paronychia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sialoadenitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Pulpitis dental			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vulvovaginitis streptococcal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis norovirus subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Gastroenteritis viral subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Gingivitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Herpes simplex subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Oral herpes subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Pharyngitis streptococcal subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Tracheitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Bacterial infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Furuncle subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Otitis media subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0	0 / 12 (0.00%) 0
Metabolism and nutrition disorders Hyperlipidaemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoferritinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo_A Group	Low Dose_PLAIN_B Group	Medium Dose_PLAIN_B Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 12 (83.33%)	62 / 101 (61.39%)	54 / 97 (55.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Monoclonal gammopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Basal cell carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Benign anorectal neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Large intestine benign neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Lipoma			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Squamous cell carcinoma subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Vascular disorders			
Hypertension subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 101 (0.99%) 1	0 / 97 (0.00%) 0
Haematoma subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Phlebitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
General disorders and administration site conditions			
Injection site pain subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	23 / 101 (22.77%) 27	19 / 97 (19.59%) 23
Fatigue subjects affected / exposed occurrences (all)	7 / 12 (58.33%) 11	29 / 101 (28.71%) 39	20 / 97 (20.62%) 22
Chills subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	2 / 101 (1.98%) 2	1 / 97 (1.03%) 1
Injection site swelling subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	1 / 97 (1.03%) 1
Hangover subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 101 (0.99%) 1	1 / 97 (1.03%) 1
Influenza like illness			

subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Injection site warmth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Injection site haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Inflammation			

subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Impaired healing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Injection site movement impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Injection site paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0

Reaction to preservatives subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Reproductive system and breast disorders			
Dysmenorrhoea subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 101 (0.99%) 1	2 / 97 (2.06%) 2
Cough subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	2 / 97 (2.06%) 2
Nasal congestion subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Chronic obstructive pulmonary			

disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Nasal discharge discolouration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Sneezing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Pulmonary mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0

Asthma subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	2 / 101 (1.98%) 2	0 / 97 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 101 (0.99%) 1	0 / 97 (0.00%) 0
Cardiac murmur subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Haemoglobin decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Basophil count increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Heart rate irregular			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	2 / 101 (1.98%)	1 / 97 (1.03%)
occurrences (all)	0	2	1
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Foot fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Back injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Limb injury			

subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Patella fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Post procedural inflammation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Upper limb fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Dermoid cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Palpitations			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 12 (41.67%)	16 / 101 (15.84%)	14 / 97 (14.43%)
occurrences (all)	7	19	18
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	2 / 101 (1.98%)	0 / 97 (0.00%)
occurrences (all)	0	2	0
Dysgeusia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Nerve compression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Lymphocytosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Ear and labyrinth disorders			
Ear pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
External ear pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Deafness subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Ear discomfort subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Ear disorder subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Eye disorders			
Blepharitis subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 101 (0.00%) 0	0 / 97 (0.00%) 0
Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 101 (0.00%) 0	1 / 97 (1.03%) 1
Gastrointestinal disorders			

Enteritis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	3 / 12 (25.00%)	11 / 101 (10.89%)	9 / 97 (9.28%)
occurrences (all)	3	13	10
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	2 / 97 (2.06%)
occurrences (all)	0	0	2
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	2 / 97 (2.06%)
occurrences (all)	0	0	2
Gastritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Faeces soft			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0

Palatal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Cheilitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Eruption			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Gastric disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Pancreatic cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	1 / 97 (1.03%)
occurrences (all)	0	1	1
Rash			
subjects affected / exposed	0 / 12 (0.00%)	3 / 101 (2.97%)	0 / 97 (0.00%)
occurrences (all)	0	3	0
Urticaria			
subjects affected / exposed	1 / 12 (8.33%)	2 / 101 (1.98%)	0 / 97 (0.00%)
occurrences (all)	1	2	0
Dermatitis contact			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Eczema			

subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Intertrigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Cold sweat			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	9 / 101 (8.91%)	8 / 97 (8.25%)
occurrences (all)	0	10	10
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	5 / 101 (4.95%)	6 / 97 (6.19%)
occurrences (all)	0	5	7
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	1 / 97 (1.03%)
occurrences (all)	0	1	1
Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			

subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Groin pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Muscle discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Fibromyalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 12 (25.00%)	3 / 101 (2.97%)	3 / 97 (3.09%)
occurrences (all)	3	3	3
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	2 / 97 (2.06%)
occurrences (all)	0	0	2
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	4 / 97 (4.12%)
occurrences (all)	0	0	4
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	2 / 101 (1.98%)	0 / 97 (0.00%)
occurrences (all)	0	2	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1

Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Sialoadenitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	1 / 97 (1.03%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0

Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Vulvovaginitis streptococcal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 12 (0.00%)	1 / 101 (0.99%)	0 / 97 (0.00%)
occurrences (all)	0	1	0

Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperlipidaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Hypoferritinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 101 (0.00%)	0 / 97 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	High Dose_PLAIN_B Group	High Dose_AS01E_B Group	Medium Dose_AS01E_B Group
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Total subjects affected by non-serious adverse events			
subjects affected / exposed	61 / 100 (61.00%)	83 / 100 (83.00%)	80 / 101 (79.21%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Monoclonal gammopathy			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Basal cell carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Benign anorectal neoplasm			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Large intestine benign neoplasm			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Lipoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Phlebitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	31 / 100 (31.00%)	65 / 100 (65.00%)	63 / 101 (62.38%)
occurrences (all)	37	103	105
Fatigue			

subjects affected / exposed	29 / 100 (29.00%)	36 / 100 (36.00%)	39 / 101 (38.61%)
occurrences (all)	37	46	51
Chills			
subjects affected / exposed	2 / 100 (2.00%)	6 / 100 (6.00%)	7 / 101 (6.93%)
occurrences (all)	2	7	8
Injection site swelling			
subjects affected / exposed	4 / 100 (4.00%)	11 / 100 (11.00%)	9 / 101 (8.91%)
occurrences (all)	4	12	10
Hangover			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 100 (0.00%)	2 / 100 (2.00%)	4 / 101 (3.96%)
occurrences (all)	0	2	4
Influenza like illness			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	1	0	1
Injection site pruritus			
subjects affected / exposed	3 / 100 (3.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	3	0	1
Injection site warmth			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 100 (0.00%)	2 / 100 (2.00%)	0 / 101 (0.00%)
occurrences (all)	0	2	0
Feeling hot			
subjects affected / exposed	0 / 100 (0.00%)	2 / 100 (2.00%)	1 / 101 (0.99%)
occurrences (all)	0	2	1
Injection site haemorrhage			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Swelling			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Impaired healing			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Injection site induration			

subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Injection site movement impairment subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Injection site paraesthesia subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Immune system disorders Allergy to arthropod bite subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Reaction to preservatives subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Pelvic pain			

subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	1 / 100 (1.00%)	3 / 100 (3.00%)	1 / 101 (0.99%)
occurrences (all)	1	3	1
Cough			
subjects affected / exposed	2 / 100 (2.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	2	1	0
Nasal congestion			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	2	0	0
Dysphonia			
subjects affected / exposed	2 / 100 (2.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	2	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	1 / 101 (0.99%)
occurrences (all)	0	1	1
Rhinorrhoea			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Nasal discharge discolouration			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract congestion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus hypersecretion			

subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Pulmonary mass subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Respiratory disorder subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Rhonchi subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Sinus congestion subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Asthma subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Basophil count increased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Heart rate irregular			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	1	1	0
Contusion			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Muscle strain			

subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Foot fracture			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	1 / 101 (0.99%)
occurrences (all)	0	1	1
Skin laceration			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Back injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Tendon rupture			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Arthropod sting			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Bone contusion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Patella fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Post procedural inflammation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Thermal burn			

subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Tooth fracture subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Upper limb fracture subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Congenital, familial and genetic disorders Dermoid cyst subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	17 / 100 (17.00%) 21	24 / 100 (24.00%) 29	25 / 101 (24.75%) 32
Dizziness subjects affected / exposed occurrences (all)	1 / 100 (1.00%) 1	1 / 100 (1.00%) 2	2 / 101 (1.98%) 2
Dysgeusia subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Paraesthesia subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	1 / 100 (1.00%) 1	0 / 101 (0.00%) 0
Sciatica subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	1 / 100 (1.00%) 1	0 / 101 (0.00%) 0
Nerve compression			

subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Sinus headache subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Blood and lymphatic system disorders			
Leukopenia subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	1 / 100 (1.00%) 1	0 / 101 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	1 / 100 (1.00%) 1	0 / 101 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Lymphocytosis subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Ear and labyrinth disorders			
Ear pain subjects affected / exposed occurrences (all)	3 / 100 (3.00%) 3	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	1 / 100 (1.00%) 1	1 / 100 (1.00%) 1	0 / 101 (0.00%) 0
External ear pain subjects affected / exposed occurrences (all)	1 / 100 (1.00%) 1	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Deafness			

subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Ear discomfort subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Ear disorder subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Eye disorders Blepharitis subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Gastrointestinal disorders Enteritis subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Gastrointestinal disorder subjects affected / exposed occurrences (all)	14 / 100 (14.00%) 17	15 / 100 (15.00%) 16	11 / 101 (10.89%) 13
Diarrhoea subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	2 / 101 (1.98%) 2
Toothache subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	2 / 100 (2.00%) 2	0 / 101 (0.00%) 0
Faeces soft			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Palatal disorder			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Aphthous ulcer			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Gastric disorder			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Pancreatic cyst			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	4 / 100 (4.00%)	14 / 100 (14.00%)	9 / 101 (8.91%)
occurrences (all)	4	16	9
Rash			
subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	1 / 101 (0.99%)
occurrences (all)	2	1	1
Urticaria			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			

subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	1	0	1
Pruritus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Blister			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Night sweats			

subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Rash pruritic subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	1 / 101 (0.99%) 1
Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	4 / 100 (4.00%) 4	18 / 100 (18.00%) 19	19 / 101 (18.81%) 23
Myalgia subjects affected / exposed occurrences (all)	5 / 100 (5.00%) 6	15 / 100 (15.00%) 17	12 / 101 (11.88%) 17
Back pain subjects affected / exposed occurrences (all)	2 / 100 (2.00%) 3	1 / 100 (1.00%) 1	1 / 101 (0.99%) 1
Neck pain subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0	2 / 100 (2.00%) 2	0 / 101 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	1 / 100 (1.00%) 1	0 / 100 (0.00%) 0	0 / 101 (0.00%) 0
Tendonitis			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	1 / 101 (0.99%)
occurrences (all)	0	1	1
Bursitis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	1	0	1
Arthritis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Osteoporosis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Rotator cuff syndrome			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Joint range of motion decreased			

subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Muscle discomfort			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Fibromyalgia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Tonsillitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 100 (4.00%)	3 / 100 (3.00%)	4 / 101 (3.96%)
occurrences (all)	4	3	5
Urinary tract infection			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	2	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 100 (0.00%)	2 / 100 (2.00%)	1 / 101 (0.99%)
occurrences (all)	0	2	1
Bronchitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0

Gastroenteritis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	1 / 100 (1.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	1	1	0
Herpes zoster			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0

Sialoadenitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Fungal skin infection			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Hordeolum			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Pulpitis dental			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Vulvovaginitis streptococcal			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Body tinea			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis viral			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	2
Oral herpes			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Tracheitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperlipidaemia			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Hypoferritinaemia			

subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 100 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1

Non-serious adverse events	Low Dose_AS01E_B Group	High Dose_AS01B_B Group	Medium Dose_AS01B_B Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	77 / 101 (76.24%)	93 / 101 (92.08%)	88 / 100 (88.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Monoclonal gammopathy			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Basal cell carcinoma			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Benign anorectal neoplasm			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Large intestine benign neoplasm			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Lipoma			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			

subjects affected / exposed occurrences (all)	1 / 101 (0.99%) 1	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	60 / 101 (59.41%)	82 / 101 (81.19%)	78 / 100 (78.00%)
occurrences (all)	89	137	120
Fatigue			
subjects affected / exposed	41 / 101 (40.59%)	53 / 101 (52.48%)	47 / 100 (47.00%)
occurrences (all)	51	83	64
Chills			
subjects affected / exposed	11 / 101 (10.89%)	19 / 101 (18.81%)	19 / 100 (19.00%)
occurrences (all)	15	25	20
Injection site swelling			
subjects affected / exposed	8 / 101 (7.92%)	14 / 101 (13.86%)	9 / 100 (9.00%)
occurrences (all)	10	19	14
Hangover			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 101 (2.97%)	6 / 101 (5.94%)	8 / 100 (8.00%)
occurrences (all)	4	6	9
Influenza like illness			
subjects affected / exposed	2 / 101 (1.98%)	3 / 101 (2.97%)	2 / 100 (2.00%)
occurrences (all)	2	3	2
Injection site pruritus			

subjects affected / exposed	1 / 101 (0.99%)	3 / 101 (2.97%)	0 / 100 (0.00%)
occurrences (all)	1	3	0
Injection site warmth			
subjects affected / exposed	3 / 101 (2.97%)	2 / 101 (1.98%)	1 / 100 (1.00%)
occurrences (all)	3	2	2
Malaise			
subjects affected / exposed	1 / 101 (0.99%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	1	1	1
Feeling hot			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	1 / 101 (0.99%)	2 / 101 (1.98%)	1 / 100 (1.00%)
occurrences (all)	1	2	2
Injection site bruising			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Feeling cold			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
Oedema peripheral			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Swelling			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Inflammation			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			

subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Axillary pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Impaired healing			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Injection site induration			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Injection site movement impairment			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Injection site paraesthesia			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Reaction to preservatives			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0

Seasonal allergy subjects affected / exposed occurrences (all)	1 / 101 (0.99%) 1	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Reproductive system and breast disorders			
Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	1 / 100 (1.00%) 1
Breast pain subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	1 / 100 (1.00%) 1
Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	1 / 101 (0.99%) 1	0 / 100 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	1 / 101 (0.99%) 1	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	3 / 101 (2.97%) 3	1 / 100 (1.00%) 1
Cough subjects affected / exposed occurrences (all)	2 / 101 (1.98%) 2	1 / 101 (0.99%) 1	1 / 100 (1.00%) 1
Nasal congestion subjects affected / exposed occurrences (all)	1 / 101 (0.99%) 1	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0

Rhinorrhoea			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Nasal discharge discolouration			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract congestion			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Paranasal sinus hypersecretion			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Pulmonary mass			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Asthma			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0

Epistaxis subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	1 / 100 (1.00%) 1
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	1 / 101 (0.99%) 1	0 / 100 (0.00%) 0
Cardiac murmur subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	1 / 100 (1.00%) 1
Haemoglobin decreased subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Neutrophil count decreased subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Basophil count increased subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Heart rate irregular subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Injury, poisoning and procedural complications			

Joint dislocation			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 101 (0.00%)	2 / 101 (1.98%)	0 / 100 (0.00%)
occurrences (all)	0	2	0
Muscle strain			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Foot fracture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Back injury			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Hand fracture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0

Arthropod sting subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Bone contusion subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Patella fracture subjects affected / exposed occurrences (all)	1 / 101 (0.99%) 1	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Post procedural inflammation subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Thermal burn subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Tooth fracture subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	1 / 101 (0.99%) 1	0 / 100 (0.00%) 0
Upper limb fracture subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Congenital, familial and genetic disorders Dermoid cyst subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	1 / 100 (1.00%) 2
Palpitations subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	28 / 101 (27.72%) 36	38 / 101 (37.62%) 48	38 / 100 (38.00%) 54

Dizziness			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	2 / 100 (2.00%)
occurrences (all)	0	0	2
Dysgeusia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Nerve compression			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Lymphocytosis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			

subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 101 (0.00%)	2 / 101 (1.98%)	0 / 100 (0.00%)
occurrences (all)	0	2	0
Vertigo			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
External ear pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Ear discomfort			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Ear disorder			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	13 / 101 (12.87%)	19 / 101 (18.81%)	12 / 100 (12.00%)
occurrences (all)	15	22	15
Diarrhoea			

subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	2 / 101 (1.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	3	0	0
Gastritis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Faeces soft			
subjects affected / exposed	2 / 101 (1.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Vomiting			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	2	0
Flatulence			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Palatal disorder			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Eruption			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Gastric disorder			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Large intestine polyp			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Lip swelling			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Pancreatic cyst			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Erythema			

subjects affected / exposed	7 / 101 (6.93%)	24 / 101 (23.76%)	20 / 100 (20.00%)
occurrences (all)	8	30	29
Rash			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Urticaria			
subjects affected / exposed	0 / 101 (0.00%)	3 / 101 (2.97%)	0 / 100 (0.00%)
occurrences (all)	0	3	0
Dermatitis contact			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Ecchymosis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 101 (1.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Hidradenitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			

subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	14 / 101 (13.86%)	24 / 101 (23.76%)	19 / 100 (19.00%)
occurrences (all)	17	31	23
Myalgia			

subjects affected / exposed	14 / 101 (13.86%)	32 / 101 (31.68%)	22 / 100 (22.00%)
occurrences (all)	17	36	24
Back pain			
subjects affected / exposed	2 / 101 (1.98%)	4 / 101 (3.96%)	3 / 100 (3.00%)
occurrences (all)	2	4	3
Neck pain			
subjects affected / exposed	0 / 101 (0.00%)	2 / 101 (1.98%)	1 / 100 (1.00%)
occurrences (all)	0	2	2
Pain in extremity			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Arthritis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Pain in jaw			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Joint effusion			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			

subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Muscle discomfort			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Fibromyalgia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Tonsillitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 101 (2.97%)	6 / 101 (5.94%)	2 / 100 (2.00%)
occurrences (all)	3	6	2
Urinary tract infection			
subjects affected / exposed	1 / 101 (0.99%)	2 / 101 (1.98%)	1 / 100 (1.00%)
occurrences (all)	1	2	1

Nasopharyngitis			
subjects affected / exposed	2 / 101 (1.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Bronchitis			
subjects affected / exposed	2 / 101 (1.98%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Rhinitis			
subjects affected / exposed	2 / 101 (1.98%)	0 / 101 (0.00%)	2 / 100 (2.00%)
occurrences (all)	2	0	2
Tooth abscess			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	2 / 100 (2.00%)
occurrences (all)	0	0	2
Gastroenteritis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	1 / 101 (0.99%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	2
Laryngitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1

Otitis externa			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 101 (0.99%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Wound infection			
subjects affected / exposed	0 / 101 (0.00%)	1 / 101 (0.99%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Sialoadenitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Chronic sinusitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Dermatophytosis of nail			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0

Vulvovaginitis streptococcal subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Body tinea subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Folliculitis subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Gastroenteritis norovirus subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	1 / 101 (0.99%) 1	0 / 100 (0.00%) 0
Gastroenteritis viral subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Gingivitis subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	1 / 101 (0.99%) 1	0 / 100 (0.00%) 0
Herpes simplex subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Oral herpes subjects affected / exposed occurrences (all)	1 / 101 (0.99%) 1	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Pharyngitis streptococcal subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Tracheitis subjects affected / exposed occurrences (all)	1 / 101 (0.99%) 1	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0
Bacterial infection subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 101 (0.00%) 0	0 / 100 (0.00%) 0

Furuncle			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperlipidaemia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Hypoferritinaemia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 101 (0.00%)	0 / 101 (0.00%)	0 / 100 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Low Dose_AS01B_B Group	Placebo_B Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	91 / 103 (88.35%)	54 / 101 (53.47%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Monoclonal gammopathy			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Basal cell carcinoma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	

Benign anorectal neoplasm subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Large intestine benign neoplasm subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Lipoma subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	1 / 101 (0.99%) 1	
Squamous cell carcinoma subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	2 / 103 (1.94%) 2	1 / 101 (0.99%) 1	
Haematoma subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Phlebitis subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
General disorders and administration site conditions Injection site pain subjects affected / exposed occurrences (all)	81 / 103 (78.64%) 136	8 / 101 (7.92%) 8	
Fatigue subjects affected / exposed occurrences (all)	45 / 103 (43.69%) 66	24 / 101 (23.76%) 32	
Chills subjects affected / exposed occurrences (all)	21 / 103 (20.39%) 26	3 / 101 (2.97%) 3	
Injection site swelling subjects affected / exposed occurrences (all)	17 / 103 (16.50%) 20	0 / 101 (0.00%) 0	
Hangover			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Pyrexia		
subjects affected / exposed	6 / 103 (5.83%)	1 / 101 (0.99%)
occurrences (all)	7	1
Influenza like illness		
subjects affected / exposed	2 / 103 (1.94%)	0 / 101 (0.00%)
occurrences (all)	2	0
Injection site pruritus		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Injection site warmth		
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)
occurrences (all)	1	0
Malaise		
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)
occurrences (all)	1	0
Feeling hot		
subjects affected / exposed	2 / 103 (1.94%)	0 / 101 (0.00%)
occurrences (all)	2	0
Injection site haemorrhage		
subjects affected / exposed	0 / 103 (0.00%)	2 / 101 (1.98%)
occurrences (all)	0	2
Injection site bruising		
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	1
Peripheral swelling		
subjects affected / exposed	1 / 103 (0.97%)	1 / 101 (0.99%)
occurrences (all)	1	1
Chest discomfort		
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	1
Feeling cold		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Oedema peripheral		

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Swelling			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Inflammation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Pain			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences (all)	0	1	
Asthenia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Axillary pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences (all)	0	1	
Impaired healing			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Injection site induration			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Injection site movement impairment			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Injection site paraesthesia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			

Allergy to arthropod bite subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Reaction to preservatives subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	1 / 101 (0.99%) 1	
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Reproductive system and breast disorders			
Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Breast pain subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Pelvic pain subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain subjects affected / exposed occurrences (all)	4 / 103 (3.88%) 4	1 / 101 (0.99%) 1	
Cough subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Nasal congestion			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Dysphonia		
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)
occurrences (all)	1	0
Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Rhinorrhoea		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Nasal discharge discolouration		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Sneezing		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Productive cough		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Lower respiratory tract congestion		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Paranasal sinus hypersecretion		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Pulmonary mass		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Respiratory disorder		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Rhinitis allergic		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0

Rhonchi			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Sinus congestion			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Asthma			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Epistaxis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Cardiac murmur			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Haemoglobin decreased			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Neutrophil count decreased			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
White blood cell count decreased			

subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Basophil count increased subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	1 / 101 (0.99%) 1	
Heart rate irregular subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 101 (0.00%) 0	
Injury, poisoning and procedural complications			
Joint dislocation subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Arthropod bite subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	2 / 101 (1.98%) 2	
Procedural pain subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	2 / 101 (1.98%) 2	
Contusion subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Muscle strain subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Foot fracture subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Skin laceration subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Ligament sprain subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 101 (0.00%) 0	
Back injury			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Hand fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Limb injury			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Tendon rupture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Arthropod sting			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Bone contusion			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences (all)	0	1	
Patella fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Post procedural inflammation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Thermal burn			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Tooth fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Upper limb fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Congenital, familial and genetic disorders			
Dermoid cyst			

subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	1 / 101 (0.99%) 1	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	1 / 101 (0.99%) 1	
Palpitations			
subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 101 (0.00%) 0	
Nervous system disorders			
Headache			
subjects affected / exposed occurrences (all)	45 / 103 (43.69%) 61	13 / 101 (12.87%) 17	
Dizziness			
subjects affected / exposed occurrences (all)	2 / 103 (1.94%) 2	1 / 101 (0.99%) 1	
Dysgeusia			
subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Paraesthesia			
subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Sciatica			
subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Nerve compression			
subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Sinus headache			
subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Neutropenia			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Leukocytosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Lymphadenopathy			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Lymphocytosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
External ear pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Deafness			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Ear discomfort			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Ear disorder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Blepharitis			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis allergic			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorder			
subjects affected / exposed	18 / 103 (17.48%)	13 / 101 (12.87%)	
occurrences (all)	24	16	
Diarrhoea			
subjects affected / exposed	0 / 103 (0.00%)	3 / 101 (2.97%)	
occurrences (all)	0	3	
Constipation			
subjects affected / exposed	1 / 103 (0.97%)	1 / 101 (0.99%)	
occurrences (all)	1	1	
Gastritis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Faeces soft			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Flatulence			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	

Dry mouth		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Nausea		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Palatal disorder		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Abdominal discomfort		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Abdominal pain		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Aphthous ulcer		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Cheilitis		
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	1
Eructation		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Gastric disorder		
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	1
Gastroesophageal reflux disease		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Large intestine polyp		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Lip swelling		
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	1

Pancreatic cyst subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 101 (0.00%) 0	
Hepatobiliary disorders Cholelithiasis subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Skin and subcutaneous tissue disorders Erythema subjects affected / exposed occurrences (all)	24 / 103 (23.30%) 33	1 / 101 (0.99%) 1	
Rash subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Urticaria subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Dermatitis contact subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 101 (0.00%) 0	
Ecchymosis subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Pruritus subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Hidradenitis subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Blister			

subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences (all)	0	1	
Dermatitis allergic			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Eczema			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Intertrigo			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences (all)	0	1	
Photosensitivity reaction			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences (all)	0	1	
Skin hyperpigmentation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Skin lesion			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Cold sweat			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Night sweats			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Rash pruritic			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Nephrolithiasis			
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)	
occurrences (all)	0	1	

Dysuria subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 101 (0.00%) 0	
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	28 / 103 (27.18%) 37	11 / 101 (10.89%) 14	
Myalgia subjects affected / exposed occurrences (all)	28 / 103 (27.18%) 39	9 / 101 (8.91%) 9	
Back pain subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	3 / 101 (2.97%) 4	
Neck pain subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 101 (0.00%) 0	
Pain in extremity subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	1 / 101 (0.99%) 1	
Tendonitis subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	1 / 101 (0.99%) 1	
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Bursitis subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Arthritis subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	1 / 101 (0.99%) 1	
Muscular weakness			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Pain in jaw		
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	1
Joint effusion		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Groin pain		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Musculoskeletal chest pain		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Musculoskeletal pain		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Osteoporosis		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Rotator cuff syndrome		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Joint range of motion decreased		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Joint swelling		
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	1
Muscle discomfort		
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	1
Muscle spasms		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Fibromyalgia		

subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 101 (0.00%) 0	
Infections and infestations			
Tonsillitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	4 / 103 (3.88%)	2 / 101 (1.98%)	
occurrences (all)	5	2	
Urinary tract infection			
subjects affected / exposed	2 / 103 (1.94%)	1 / 101 (0.99%)	
occurrences (all)	2	1	
Nasopharyngitis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Bronchitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Tooth abscess			
subjects affected / exposed	0 / 103 (0.00%)	2 / 101 (1.98%)	
occurrences (all)	0	2	
Gastroenteritis			
subjects affected / exposed	0 / 103 (0.00%)	2 / 101 (1.98%)	
occurrences (all)	0	2	
Respiratory tract infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
subjects affected / exposed	2 / 103 (1.94%)	0 / 101 (0.00%)	
occurrences (all)	2	0	
Viral infection			
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	

Tooth infection		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Conjunctivitis		
subjects affected / exposed	1 / 103 (0.97%)	1 / 101 (0.99%)
occurrences (all)	1	1
Cystitis		
subjects affected / exposed	1 / 103 (0.97%)	0 / 101 (0.00%)
occurrences (all)	2	0
Laryngitis		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Otitis externa		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Herpes zoster		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Wound infection		
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	1
Paronychia		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Sialoadenitis		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Cellulitis		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Chronic sinusitis		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Dermatophytosis of nail		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0

Fungal skin infection		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Hordeolum		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Pharyngitis		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Pulpitis dental		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Vulvovaginitis streptococcal		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Body tinea		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Folliculitis		
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	1
Gastroenteritis norovirus		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Gastroenteritis viral		
subjects affected / exposed	0 / 103 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	1
Gingivitis		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Herpes simplex		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0
Oral herpes		
subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0

Pharyngitis streptococcal subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Pneumonia subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Tracheitis subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Bacterial infection subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 101 (0.00%) 0	
Furuncle subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 101 (0.00%) 0	
Otitis media subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1	0 / 101 (0.00%) 0	
Metabolism and nutrition disorders			
Hyperlipidaemia subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Hypoferritinaemia subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Dehydration subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0	0 / 101 (0.00%) 0	
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 103 (0.00%)	0 / 101 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 May 2020	This Protocol Amendment 1 outlines measures that may be applicable during special circumstances (e.g., Coronavirus disease 2019 [COVID-19] pandemic). The purpose of the amendment is to protect subject's welfare and safety, and as far as possible ensure the potential benefit to the subject and promote data integrity. A new section has been added (Section 5.10) to provide guidance on adapting study procedures during special circumstances, such as COVID-19 pandemic.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported