Clinical trial results:
Phase 2b multi center, randomised, partial blind parallel cohort study to assess the efficacy and safety of treatment with bepirovirsen in participants with chronic hepatitis B virus (B Clear)

Summary

EudraCT number	2020-001083-29
Trial protocol	PL GB BG IT RO
Global end of trial date	18 March 2022

Results information

Result version number	v2 (current)
This version publication date	07 May 2023
First version publication date	17 March 2023
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	209668

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS
Public contact	GlaxoSmithKline, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 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	05 May 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 March 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of the three dosing regimens of bepirovirsen in participants with chronic Hepatitis B Virus (HBV).

Protection of trial subjects:

None.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 July 2020
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	Argentina: 12
Country: Number of subjects enrolled	Bulgaria: 24
Country: Number of subjects enrolled	Canada: 30
Country: Number of subjects enrolled	France: 18
Country: Number of subjects enrolled	Germany: 8
Country: Number of subjects enrolled	Hong Kong: 3
Country: Number of subjects enrolled	Italy: 15
Country: Number of subjects enrolled	Japan: 74
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 46
Country: Number of subjects enrolled	Malaysia: 5
Country: Number of subjects enrolled	Poland: 29
Country: Number of subjects enrolled	Romania: 38
Country: Number of subjects enrolled	Russian Federation: 41
Country: Number of subjects enrolled	Singapore: 37
Country: Number of subjects enrolled	Spain: 14
Country: Number of subjects enrolled	Thailand: 18
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	United States: 11
Country: Number of subjects enrolled	China: 16
Country: Number of subjects enrolled	Philippines: 3
Country: Number of subjects enrolled	South Africa: 6
Country: Number of subjects enrolled	Taiwan: 3

Worldwide total number of subjects	457
EEA total number of subjects	146

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)	432
From 65 to 84 years	25
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 457 participants were randomized in the study. These 457 participants were from 2 different set of populations (referred here after as on nucleos(t)ide [NA] and not on NA therapy). Participants from these subpopulations were randomized in a ratio of 3:3:3:1 into 4 treatment arms for each population (total of 8 arms).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK3228836 for 24 weeks (WK) (on NA therapy)

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).

Arm type	Experimental
Investigational medicinal product name	GSK3228836 and NA therapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3228836 300mg once a week for 24 weeks, plus a loading dose of GSK3228836 300mg on Day 4 and 11).

Arm title	GSK3228836 for 12+12 WK (on NA therapy)

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	GSK3228836 and NA therapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3228836 300mg once a week for 12 weeks, plus a loading dose of GSK3228836 300mg on Day 4 and 11). Followed by a step down in dose of 150mg (plus placebo to match to maintain blinding) GSK3228836 once a week for 12 weeks.

Arm title	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by a placebo once/week for 12 weeks.

Arm type	Experimental and Placebo

Investigational medicinal product name	GSK3228836 followed by placebo and NA therapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks.

Arm title	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)

Arm description:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks

Arm type	Placebo
Investigational medicinal product name	Placebo followed by GSK3228836 and NA therapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks

Arm title	GSK3228836 for 24 WK (not on NA therapy)

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).

Arm type	Experimental
Investigational medicinal product name	GSK3228836
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3228836 300mg once a week for 24 weeks, plus a loading dose of GSK3228836 300mg on Day 4 and 11).

Arm title	GSK3228836 for 12+12 WK (not on NA therapy)

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	GSK3228836
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

GSK3228836 300mg once a week for 12 weeks, plus a loading dose of GSK3228836 300mg on Day 4 and 11). Followed by a step down in dose of 150mg (plus placebo to match to maintain blinding) GSK3228836 once a week for 12 weeks.

Arm title	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)

Arm description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by placebo once/week for 12 weeks.

Arm type	Experimental and Placebo

Investigational medicinal product name	GSK3228836 followed by placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks.

Arm title	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)

Arm description:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks

Arm type	Placebo and Experimental
Investigational medicinal product name	Placebo followed by GSK3228836
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks.

Number of subjects in period 1	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)
Started	68	68	68
Completed	65	65	66
Not completed	3	3	2
Consent withdrawn by subject	3	-	1
Physician decision	-	-	-
Adverse event, non-fatal	-	1	1
Lost to follow-up	-	1	-
Protocol deviation	-	1	-

Number of subjects in period 1	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)
Started	23	70	68
Completed	22	64	66
Not completed	1	6	2
Consent withdrawn by subject	1	5	1
Physician decision	-	-	1
Adverse event, non-fatal	-	1	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Started	68	24
Completed	63	24
Not completed	5	0
Consent withdrawn by subject	4	-
Physician decision	-	-
Adverse event, non-fatal	1	-
Lost to follow-up	-	-
Protocol deviation	-	-

Baseline characteristics

Reporting groups	
Reporting group title	GSK3228836 for 24 weeks (WK) (on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).	
Reporting group title	GSK3228836 for 12+12 WK (on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.	
Reporting group title	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by a placebo once/week for 12 weeks.	
Reporting group title	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Reporting group description:	
All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks	
Reporting group title	GSK3228836 for 24 WK (not on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).	
Reporting group title	GSK3228836 for 12+12 WK (not on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.	
Reporting group title	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by placebo once/week for 12 weeks.	
Reporting group title	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Reporting group description:	
All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks	

Reporting group values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)
Number of subjects	68	68	68
Age categorical Units: Subjects			
From less than 50 years	37	42	40
50 years and over	31	26	28
Age continuous Units: years			
arithmetic mean	49.0	46.1	47.4
standard deviation	± 11.54	± 12.60	± 11.18

Sex: Female, Male Units: Participants			
Female	20	19	17
Male	48	49	51
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	36	35	36
Black or African American	2	1	4
Mixed Race	0	0	1
White	30	32	26

Reporting group values	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)
Number of subjects	23	70	68
Age categorical Units: Subjects			
From less than 50 years	11	46	49
50 years and over	12	24	19
Age continuous Units: years			
arithmetic mean	49.8	44.5	43.8
standard deviation	± 11.21	± 11.10	± 9.92
Sex: Female, Male Units: Participants			
Female	6	37	27
Male	17	33	41
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	12	37	44
Black or African American	0	9	4
Mixed Race	0	0	0
White	11	24	20

Reporting group values	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)	Total
Number of subjects	68	24	457
Age categorical Units: Subjects			
From less than 50 years	54	17	296
50 years and over	14	7	161
Age continuous Units: years			
arithmetic mean	40.7	42.4	
standard deviation	± 11.10	± 12.02	-
Sex: Female, Male Units: Participants			
Female	29	13	168
Male	39	11	289

Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	38	12	250
Black or African American	6	1	27
Mixed Race	0	0	1
White	24	11	178

Subject analysis sets

Subject analysis set title	GSK3228836 dose level 300mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Represents Pharmacokinetic (PK) set of participants who received GSK3228836 at a dose level of 300 mg once a week. Baseline analysis was not performed for sub group population.

Subject analysis set title	GSK3228836 dose level 150mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Represents PK set of participants who received GSK3228836 at a dose level of 150 mg once a week. Baseline analysis was not performed for sub group population.

Subject analysis set title	Tenofovir disoproxil fumarate
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who received Tenofovir disoproxil fumarate 245 or 300mg once daily. Baseline analysis was not performed for subgroup population.

Subject analysis set title	Tenofovir alafenamide
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who received Tenofovir alafenamide 25 mg once daily or every 2 days. Baseline analysis was not performed for subgroup population.

Subject analysis set title	Entecavir
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who received Entecavir 0.5 mg once daily. Baseline analysis was not performed for subgroup population.

Reporting group values	GSK3228836 dose level 300mg	GSK3228836 dose level 150mg	Tenofovir disoproxil fumarate
Number of subjects	12	12	7
Age categorical Units: Subjects			
From less than 50 years	0	0	0
50 years and over	0	0	0
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units: Participants			
Female			
Male			

Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black or African American	0	0	0
Mixed Race	0	0	0
White	0	0	0

Reporting group values	Tenofovir alafenamide	Entecavir	
Number of subjects	5	16	
Age categorical Units: Subjects			
From less than 50 years	0	0	
50 years and over	0	0	
Age continuous Units: years arithmetic mean standard deviation	±	±	
Sex: Female, Male Units: Participants			
Female			
Male			
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Black or African American	0	0	
Mixed Race	0	0	
White	0	0	

End points

End points reporting groups

Reporting group title	GSK3228836 for 24 weeks (WK) (on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).	
Reporting group title	GSK3228836 for 12+12 WK (on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.	
Reporting group title	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by a placebo once/week for 12 weeks.	
Reporting group title	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Reporting group description:	
All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks	
Reporting group title	GSK3228836 for 24 WK (not on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).	
Reporting group title	GSK3228836 for 12+12 WK (not on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.	
Reporting group title	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)
Reporting group description:	
All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by placebo once/week for 12 weeks.	
Reporting group title	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Reporting group description:	
All participants of this arm received Placebo once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11) followed by 300 mg GSK3228836 once/week for 12 weeks	
Subject analysis set title	GSK3228836 dose level 300mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Represents Pharmacokinetic (PK) set of participants who received GSK3228836 at a dose level of 300 mg once a week. Baseline analysis was not performed for sub group population.	
Subject analysis set title	GSK3228836 dose level 150mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Represents PK set of participants who received GSK3228836 at a dose level of 150 mg once a week. Baseline analysis was not performed for sub group population.	
Subject analysis set title	Tenofovir disoproxil fumarate
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants who received Tenofovir disoproxil fumarate 245 or 300mg once daily. Baseline analysis was not performed for subgroup population.	
Subject analysis set title	Tenofovir alafenamide
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who received Tenofovir alafenamide 25 mg once daily or every 2 days. Baseline analysis was not performed for subgroup population.

Subject analysis set title	Entecavir
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants who received Entecavir 0.5 mg once daily. Baseline analysis was not performed for subgroup population.

Primary: Number of participants achieving sustained virologic response (SVR)

End point title	Number of participants achieving sustained virologic response (SVR)[1]

End point description:

The SVR was a composite endpoint defined as Hepatitis B surface antigen (HBsAg) and Hepatitis B virus (HBV) Deoxyribonucleic acid (DNA) levels were less than (<) Lower limit of quantitation (LLOQ) at the planned end of GSK3228836 treatment which is sustained for 24 weeks post-GSK3228836 treatment in the absence of rescue medication.

End point type	Primary

End point timeframe:

Up to Week 48

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: No hypothesis was tested using statistical analysis

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	68	67	68	23
Units: Participants				
Number of participants.	6	6	2	0

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	68	68	24
Units: Participants				
Number of participants.	7	4	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with categorical changes from baseline in HBsAg values

End point title	Number of participants with categorical changes from baseline in HBsAg values

End point description:

Participants who achieved a decline in HBsAg values from baseline were reported. Participants were categorized in the following categorical HBsAg decline of <0.5, greater than or equal to (>=) 0.5, >=1, >=1.5, and >=3 log10 international units per milliliter (IU/mL).

End point type	Secondary

End point timeframe:

At Baseline and Week 24

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	68	67	68	23
Units: Participants				
HBsAg decline <0.5 log10 IU/mL	12	21	37	4
HBsAg decline >=0.5 log10 IU/mL	52	42	20	17
HBsAg decline >=1 log10 IU/mL	48	38	14	17
HBsAg decline >=1.5 log10 IU/mL	42	32	12	15
HBsAg decline >=3 log10 IU/mL	34	16	5	10

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	68	68	24
Units: Participants				
HBsAg decline <0.5 log10 IU/mL	8	14	29	8
HBsAg decline >=0.5 log10 IU/mL	55	48	22	15
HBsAg decline >=1 log10 IU/mL	51	36	18	15
HBsAg decline >=1.5 log10 IU/mL	48	30	9	12
HBsAg decline >=3 log10 IU/mL	35	13	4	9

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants achieving HBsAg and HBV DNA<LLOQ

End point title	Number of participants achieving HBsAg and HBV DNA<LLOQ

End point description:

Participants achieving HBsAg and HBV DNA levels <LLOQ at the end of treatment (EOT) were reported.

End point type	Secondary

End point timeframe:

Up to Week 24

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	66	66	66	22
Units: Participants	16	9	8	4

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	66	66	24
Units: Participants	17	10	6	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with categorical changes from baseline in HBV DNA values

End point title	Number of participants with categorical changes from baseline in HBV DNA values

End point description:

Participants who achieved a decline in HBV DNA values from baseline were reported. Participants were categorized in the following categorical HBV DNA decline of <1, >=1, >=2, and >=3 log IU/mL.

End point type	Secondary

End point timeframe:

At Baseline and Week 24

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	68	67	68	23
Units: Participants				
HBV DNA decline <1 log10 IU/mL	2	0	0	0

HBV DNA decline >=1 log10 IU/mL	11	4	13	3
HBV DNA decline >=2 log10 IU/mL	0	0	0	0
HBV DNA decline >=3 log10 IU/mL	0	0	0	0

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	67	68	24
Units: Participants				
HBV DNA decline <1 log10 IU/mL	3	12	21	3
HBV DNA decline >=1 log10 IU/mL	51	44	30	18
HBV DNA decline >=2 log10 IU/mL	40	23	19	14
HBV DNA decline >=3 log10 IU/mL	27	19	11	9

Statistical analyses

No statistical analyses for this end point

Secondary: Median time to ALT normalization

End point title	Median time to ALT normalization

End point description:

Time to ALT normalization (ALT≤ULN) in the absence of rescue medication in participants with baseline ALT>ULN. The numbers of participants analyzed at Week 24 are as follows for NA therapy population: n=6 in GSK3228836 for 24 WK, n= 7 in GSK3228836 for 12WK+12WK, n=6 in GSK3228836 for 12WK + Placebo for 12WK, n=2 in Placebo for 12WK + GSK3228836 for 12WK, respectively. The numbers of participants analyzed are as follows for the not on NA therapy population: n=20 GSK3228836 for 24WK, n=20 in GSK3228836 for 12WK +12WK, n=21 in GSK3228836 for 12WK + Placebo for 12WK, n=9 in Placebo for 12 WK + GSK3228836 12 WK arm, respectively.
Note that the upper confidence limit for the GSK3228836 300mg for 24WK (on NA), Placebo for 12WK + GSK3228836 300mg for 12WK (on NA), and GSK3228836 300 mg for 24WK (not on NA) were not estimable but set to 48 weeks (maximum follow up) here.

End point type	Secondary

End point timeframe:

Baseline and up to Week 48

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	6	2
Units: Weeks				
median (confidence interval 95%)	16.6 (1.1 to 48)	4.1 (1.0 to 11.9)	1 (1.0 to 8.1)	7 (1.1 to 48)

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	9	24
Units: Weeks				
median (confidence interval 95%)	13.4 (2.1 to 48)	15.1 (4.3 to 18.1)	10.7 (5.1 to 21.1)	18.1 (1 to 32.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with alanine aminotransferase (ALT) normalization

End point title	Number of participants with alanine aminotransferase (ALT) normalization

End point description:

The ALT normalization (ALT≤ upper limit of normal [ULN]) over time in absence of rescue medication in participants with baseline ALT>ULN. Participants who achieved ALT normalization were reported.

End point type	Secondary

End point timeframe:

Baseline and Up to Week 24

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	6	2
Units: Participants				
Participants with ALT > ULN, At Baseline	6	7	6	2
Participants with ALT normalization, At Week 24	3	6	5	0

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	21	9

Units: Participants				
Participants with ALT > ULN, At Baseline	20	20	21	9
Participants with ALT normalization, At Week 24	10	11	8	5

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with positive Hepatitis B virus e-antibody (HBeAb)

End point title	Number of participants with positive Hepatitis B virus e-antibody (HBeAb)

End point description:

Blood samples were collected to assess HBeAb level and participants with positive HBeAb were reported.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	19	24	7
Units: Participants	3	4	5	2

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	11	7
Units: Participants	6	4	6	3

Statistical analyses

No statistical analyses for this end point

Secondary: Mean HBsAg and HBV DNA levels

End point title	Mean HBsAg and HBV DNA levels

End point description:

Blood samples were collected from participants to assess HBsAg and HBV DNA levels at indicated time points.

End point type	Secondary

End point timeframe:

At Baseline, Week 12, and 24

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	65	65	22
Units: Log10 (IU/mL)				
arithmetic mean (standard deviation)				
HBsAg, At Week 12	1.20 (± 1.878)	1.04 (± 1.858)	1.76 (± 1.706)	3.36 (± 0.431)
HBsAg, At Week 24	0.65 (± 1.939)	1.45 (± 1.809)	2.51 (± 1.536)	0.83 (± 1.801)
HBV DNA, At Week 12	0.74 (± 0.654)	0.86 (± 0.700)	0.67 (± 0.785)	0.61 (± 0.682)
HBV DNA, At Week 24	0.55 (± 0.654)	0.56 (± 0.649)	0.56 (± 0.714)	0.79 (± 0.667)

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	63	61	24
Units: Log10 (IU/mL)				
arithmetic mean (standard deviation)				
HBsAg, At Week 12	1.39 (± 1.965)	1.27 (± 2.000)	1.57 (± 1.808)	3.68 (± 0.798)
HBsAg, At Week 24	0.77 (± 2.016)	1.88 (± 1.915)	2.88 (± 1.511)	1.64 (± 2.171)
HBV DNA, At Week 12	3.00 (± 2.242)	2.92 (± 2.142)	2.68 (± 1.996)	4.96 (± 2.074)
HBV DNA, At Week 24	2.37 (± 2.137)	2.93 (± 2.317)	3.07 (± 1.938)	3.04 (± 2.224)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean values of Hepatitis B virus e antigen (HBeAg) level

End point title	Mean values of Hepatitis B virus e antigen (HBeAg) level

End point description:

Blood samples were collected from participants to assess HBeAg levels at indicated time points. Note: The units are on the log10 scale so negative values are expected (e.g. 0.933 U/mL = -0.03 log10 U/mL).

End point type	Secondary

End point timeframe:

At Baseline, Week 12, and 24

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	24	7
Units: Log10 unit per milliliter (U/mL)				
arithmetic mean (standard deviation)				
HBeAg, at Baseline	0.49 (± 1.014)	0.12 (± 0.756)	0.36 (± 1.053)	0.63 (± 1.323)
HBeAg, at Week 12	0.06 (± 1.027)	-0.21 (± 0.732)	0.19 (± 1.089)	0.60 (± 1.310)
HBeAg, at Week 24	-0.41 (± 0.635)	-0.48 (± 0.752)	-0.19 (± 1.071)	0.08 (± 1.497)

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	16	16	7
Units: Log10 unit per milliliter (U/mL)				
arithmetic mean (standard deviation)				
HBeAg, at Baseline	2.13 (± 1.564)	2.52 (± 0.919)	1.77 (± 1.612)	2.84 (± 0.743)
HBeAg, at Week 12	1.84 (± 1.805)	1.52 (± 1.831)	1.07 (± 1.551)	2.79 (± 0.725)
HBeAg, at Week 24	1.18 (± 2.064)	1.34 (± 1.936)	0.89 (± 1.667)	1.06 (± 2.165)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in HBsAg and HBV DNA levels

End point title	Mean change from Baseline in HBsAg and HBV DNA levels

End point description:

Blood samples were collected from participants to assess HBsAg and HBV DNA levels at indicated time points. Note: The units are on the log10 scale so negative values are expected (e.g. 0.933 IU/mL = -0.03 log10 IU/mL).

End point type	Secondary

End point timeframe:

At Baseline, Week 12, and 24

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	65	65	22
Units: log IU/mL				
arithmetic mean (standard deviation)				
HBsAg, Week 12	-2.09 (± 1.649)	-2.23 (± 1.597)	-1.59 (± 1.474)	-0.03 (± 0.089)
HBsAg, Week 24	-2.62 (± 1.653)	-1.81 (± 1.488)	-0.83 (± 1.248)	-2.57 (± 1.671)
HBV DNA, Week 12	0.24 (± 0.793)	0.47 (± 0.773)	0.16 (± 0.942)	0.19 (± 0.727)
HBV DNA, Week 24	0.06 (± 0.831)	0.17 (± 0.661)	0.09 (± 0.928)	0.33 (± 0.928)

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	63	61	24
Units: log IU/mL				
arithmetic mean (standard deviation)				
HBsAg, Week 12	-2.37 (± 1.585)	-2.41 (± 1.562)	-2.06 (± 1.638)	-0.08 (± 0.292)
HBsAg, Week 24	-2.96 (± 1.656)	-1.77 (± 1.489)	-0.77 (± 1.108)	-2.09 (± 1.764)
HBV DNA, Week 12	-1.96 (± 1.365)	-2.22 (± 1.592)	-1.92 (± 1.349)	-0.54 (± 1.421)
HBV DNA, Week 24	-2.66 (± 1.646)	-2.2 (± 1.68)	-1.52 (± 1.637)	-2.6 (± 2.001)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from Baseline in HBeAg level

End point title	Mean change from Baseline in HBeAg level

End point description:

Blood samples were collected from participants to assess HBAg levels at indicated time points. Note: The units are on the log10 scale so negative values are expected (e.g. 0.933 U/mL = -0.03 log10 U/mL).

End point type	Secondary

End point timeframe:

At Baseline, Week 12, and 24

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	20	24	7
Units: Log u/mL				
arithmetic mean (standard deviation)				
HBeAg, at Baseline	0.49 (± 1.014)	0.12 (± 0.756)	0.36 (± 1.053)	0.63 (± 1.323)
HBeAg, at Week 12	-0.52 (± 0.874)	-0.42 (± 0.480)	-0.33 (± 0.343)	-0.17 (± 0.453)
HBeAg, at WeeK 24	-0.85 (± 1.071)	-0.56 (± 0.811)	-0.46 (± 0.595)	-0.56 (± 0.598)

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	16	16	7
Units: Log u/mL				
arithmetic mean (standard deviation)				
HBeAg, at Baseline	2.13 (± 1.564)	2.52 (± 0.919)	1.77 (± 1.612)	2.84 (± 0.743)
HBeAg, at Week 12	-0.65 (± 0.919)	-1.25 (± 1.522)	-0.94 (± 1.618)	-0.14 (± 0.313)
HBeAg, at WeeK 24	-1.01 (± 1.426)	-1.18 (± 1.532)	-0.70 (± 1.673)	-1.78 (± 2.057)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Hepatitis B virus surface antigen antibody (anti-HBsAg) level

End point title	Mean Hepatitis B virus surface antigen antibody (anti-HBsAg) level

End point description:

Blood samples were collected to assess anti-HBsAg level at indicated timepoints.

End point type	Secondary

End point timeframe:

Up to Week 48

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	65	66	22
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
At Week 36	0.94 (± 0.534)	0.83 (± 0.401)	0.74 (± 0.333)	0.79 (± 0.368)
At Week 48	0.88 (± 0.471)	0.77 (± 0.368)	0.70 (± 0.277)	0.75 (± 0.326)

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	66	63	24
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
At Week 36	1.01 (± 0.660)	0.82 (± 0.385)	0.74 (± 0.347)	0.90 (± 0.437)
At Week 48	0.91 (± 0.567)	0.79 (± 0.369)	0.71 (± 0.296)	0.83 (± 0.356)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in anti-HBsAg level

End point title	Change from Baseline in anti-HBsAg level
End point description:	
Blood samples were collected to assess anti-HBsAg levels at indicated timepoints.	
End point type	Secondary
End point timeframe:	
Up to Week 24	

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 12WK + Placebo for 12WK (on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	65	65	22
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
At Week 12	0.28 (± 0.481)	0.18 (± 0.343)	0.11 (± 0.319)	0.13 (± 0.250)
At Week 24	0.22 (± 0.429)	0.12 (± 0.335)	0.07 (± 0.267)	0.09 (± 0.239)

End point values	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)	GSK3228836 12WK + Placebo for 12WK (not on NA therapy)	Placebo for 12WK + GSK3228836 for 12WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	66	62	24
Units: Log10 IU/mL				
arithmetic mean (standard deviation)				
At Week 12	0.37 (± 0.615)	0.13 (± 0.353)	0.12 (± 0.221)	0.16 (± 0.355)
At Week 24	0.26 (± 0.507)	0.10 (± 0.319)	0.09 (± 0.203)	0.09 (± 0.203)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean area under the concentration-time curve from time 0 up to 24 hours (AUC0-24h) of GSK3228836

End point title	Mean area under the concentration-time curve from time 0 up to 24 hours (AUC0-24h) of GSK3228836

End point description:

Intensive pharmacokinetic (PK) sampling was done in a subset of participants on stable NA therapy to analyze AUC0-24h for GSK3228836. Participants received GSK3228836 weekly.

End point type	Secondary

End point timeframe:

Up to Week 24

End point values	GSK3228836 dose level 300mg	GSK3228836 dose level 150mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: h*ug/mL (hour*micrograms per milliliter)				
arithmetic mean (standard deviation)	140.312 (± 37.3548)	55.214 (± 22.9901)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean maximum observed concentration (Cmax) of GSK3228836

End point title	Mean maximum observed concentration (Cmax) of GSK3228836

End point description:

Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze AUC0-24h for GSK3228836. Participants received GSK3228836 weekly

End point type	Secondary

End point timeframe:

Up to Week 24

End point values	GSK3228836 dose level 300mg	GSK3228836 dose level 150mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: ug/mL				
arithmetic mean (standard deviation)	14.956 (± 5.6592)	6.112 (± 2.8112)		

Statistical analyses

No statistical analyses for this end point

Secondary: Median time of maximum observed concentration (tmax) of GSK3228836

End point title	Median time of maximum observed concentration (tmax) of GSK3228836

End point description:

Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze AUC0-24h for GSK3228836. Participants received GSK3228836 weekly.

End point type	Secondary

End point timeframe:

Up to Week 24

End point values	GSK3228836 dose level 300mg	GSK3228836 dose level 150mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: h (hour)				
median (full range (min-max))	3.017 (2.00 to 5.00)	3.008 (2.00 to 4.02)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Cmax of NA therapies

End point title	Mean Cmax of NA therapies

End point description:

Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze Cmax. Participants on NA therapy were stratified as per the following NA therapy Tenofovir disoproxil fumarate 245 or 300 mg once daily, Tenofovir alafenamide 25 mg once a daily or every 2 days, and Entecavir 0.5 mg once daily.

End point type	Secondary

End point timeframe:

Up to Week 24

End point values	Tenofovir disoproxil fumarate	Tenofovir alafenamide	Entecavir	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	5	16	
Units: ng/mL				
arithmetic mean (standard deviation)	318.857 (± 95.94)	19.36 (± 5.85)	6.526 (± 2.27)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Ctau of NA therapies

End point title	Mean Ctau of NA therapies

End point description:

Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze Ctau. Participants on NA therapy were stratified as per the following NA therapy Tenofovir disoproxil fumarate 245 or 300 mg once daily, Tenofovir alafenamide 25 mg once daily or every 2 days, and Entecavir 0.5 mg once daily.

End point type	Secondary

End point timeframe:

Up to Week 24

End point values	Tenofovir disoproxil fumarate	Tenofovir alafenamide	Entecavir	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	5	4	12	
Units: ng/mL				
arithmetic mean (standard deviation)	57.04 (± 17.0787)	10.31 (± 3.4802)	0.478 (± 0.1055)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean AUC0-24h of NA therapies

End point title	Mean AUC0-24h of NA therapies

End point description:

Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze AUC0-24h. Participants on NA therapy were stratified as per the following NA therapy Tenofovir disoproxil fumarate 245 or 300 mg once daily, Tenofovir alafenamide 25 mg once daily or every 2 days, and Entecavir 0.5 mg once daily.

End point type	Secondary

End point timeframe:

Up to week 24

End point values	Tenofovir disoproxil fumarate	Tenofovir alafenamide	Entecavir	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	5	4	12	
Units: h*nanograms per milliliter (h*ng/mL)				
arithmetic mean (standard deviation)	2753.908 (± 661.3392)	308.167 (± 104.8297)	24.43 (± 6.761)	

Statistical analyses

No statistical analyses for this end point

Secondary: Median terminal half-life (t1/2) of GSK3228836

End point title	Median terminal half-life (t1/2) of GSK3228836[2]

End point description:

Blood samples were collected from all participants for t1/2 analysis of GSK3228836. Note: for this endpoint data for more comparable arms GSK3228836 for 24WK and 12 WK from both on NA and not on NA therapy were presented.

End point type	Secondary

End point timeframe:

Up to Week 48

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: For Median terminal half-life endpoint, only GSK3228836 300mg 24 weeks and 12 +12 weeks were compared. Since both arms are more comparable.

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	63	62	64
Units: Day				
median (full range (min-max))	28.897 (7.52 to 191.98)	24.918 (8.84 to 161.83)	27.846 (10.19 to 149.74)	38.205 (6.87 to 161.83)

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Ctau of GSK3228836

End point title	Mean Ctau of GSK3228836[3]

End point description:

Blood samples were collected from all participants for Ctau analysis of GSK3228836. Note: for this endpoint data for more comparable arms GSK3228836 for 24WK and 12 WK from both on NA and not on NA therapy were presented.

End point type	Secondary

End point timeframe:

Up to Week 24

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: For Mean Ctau endpoint, only GSK3228836 300mg 24 weeks and 12 +12 weeks were compared. Since both arms are more comparable.

End point values	GSK3228836 for 24 weeks (WK) (on NA therapy)	GSK3228836 for 12+12 WK (on NA therapy)	GSK3228836 for 24 WK (not on NA therapy)	GSK3228836 for 12+12 WK (not on NA therapy)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	68	68	70	68
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 8 n=62, 62, 67, and 65, respectively	21.009 (± 9.6214)	47.039 (± 198.1345)	21.663 (± 14.4479)	23.46 (± 16.6498)
Week 12 n= 66, 64, 63, and, 65, respectively	23.162 (± 11.8963)	23.234 (± 11.6993)	21.777 (± 9.9248)	22.789 (± 11.7361)
Week 24 n=64, 61, 63 and 64, respectively	31.102 (± 28.7535)	18.95 (± 14.6513)	28.158 (± 17.0606)	20.138 (± 19.023)

Statistical analyses

No statistical analyses for this end point

Secondary: Median tmax of NA therapies

End point title	Median tmax of NA therapies

End point description:

Intensive PK sampling was done in a subset of participants on stable NA therapy to analyze tmax. Participants on NA therapy were stratified as per the following NA therapy Tenofovir disoproxil fumarate 245 or 300 mg once daily, Tenofovir alafenamide 25 mg once a daily or every 2 days, and Entecavir 0.5 mg once daily.

End point type	Secondary

End point timeframe:

Up to Week 24

End point values	Tenofovir disoproxil fumarate	Tenofovir alafenamide	Entecavir	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	5	16	
Units: hour				
median (full range (min-max))	1.000 (0.52 to 1.47)	1.417 (0.93 to 1.55)	0.983 (0.48 to 2.02)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All adverse events (AEs) and serious adverse events (SAEs) were collected from the signing of the informed consent until the final follow-up visit, up to 48 weeks.

Adverse event reporting additional description:

The safety population (N=455) included participants who received at least one dose of study treatment. 2 participants from arms GSK3228836 300mg for 12 weeks in both on NA and not on NA therapy population, did not receive study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	GSK3228836 for 24WK (on NA)

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).

Reporting group title	GSK3228836 for 12 WK (on NA)

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.

Reporting group title	GSK3228836+Placebo for 12 WK (on NA therapy)

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by placebo once/week for 12 weeks.

Reporting group title	Placebo+GSK3228836 for 12WK each (not on NA)

Reporting group description:

All participants of this arm received Placebo once/week for 12 weeks followed by 300 mg GSK3228836 once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11).

Reporting group title	GSK3228836 for 24Wk (not on NA)

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 24 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11).

Reporting group title	GSK3228836 for 12WK (not on NA)

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by step-down in dose of 150 mg (plus placebo to match to maintain participant blinding) GSK3228836 once/week for 12 weeks.

Reporting group title	GSK3228836+Placebo for 12WK (not on NA)

Reporting group description:

All participants of this arm received 300 mg GSK3228836 once/week for 12 weeks (plus a loading dose of 300 mg GSK3228836 on Day 4 and 11) followed by placebo once/week for 12 weeks.

Reporting group title	Placebo+GSK3228836 300mg for 12WK each (on NA)

Reporting group description:

All participants of this arm received Placebo once/week for 12 weeks followed by 300 mg GSK3228836 once/week for 12 weeks (plus placebo loading doses to match on Day 4 and 11).

Serious adverse events	GSK3228836 for 24WK (on NA)	GSK3228836 for 12 WK (on NA)	GSK3228836+Placebo for 12 WK (on NA therapy)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 68 (1.47%)	1 / 67 (1.49%)	4 / 68 (5.88%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bile duct cancer			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
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 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
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			
Concussion			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle injury			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column injury			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
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			
Cryoglobulinaemia			

subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (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
Hypotension			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral infarction			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
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 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
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			
Haemorrhoids			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Cervical dysplasia			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
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			
Hepatic function abnormal			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
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			
Interstitial lung disease			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Hepatitis B			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
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 pneumonia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
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+GSK3228836 for 12WK each (not on NA)	GSK3228836 for 24Wk (not on NA)	GSK3228836 for 12WK (not on NA)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	6 / 70 (8.57%)	2 / 67 (2.99%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bile duct cancer			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (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
Hepatocellular carcinoma			

subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
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 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
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			
Concussion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
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 column injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Cryoglobulinaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
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			
Cerebral infarction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
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			
Lymphadenopathy			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (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 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (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
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (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			
Haemorrhoids			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
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 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
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			
Hepatic function abnormal			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (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			
Interstitial lung disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
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			
Hepatitis B			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GSK3228836+Placebo for 12WK (not on NA)	Placebo+GSK3228836 300mg for 12WK each (on NA)	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 68 (4.41%)	0 / 23 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bile duct cancer			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle injury			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column injury			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Cryoglobulinaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (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			
Cerebral infarction			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (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			
Lymphadenopathy			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (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 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Haemorrhoids			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (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			
Interstitial lung disease			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (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			
Hepatitis B			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (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	GSK3228836 for 24WK (on NA)	GSK3228836 for 12 WK (on NA)	GSK3228836+Placebo for 12 WK (on NA therapy)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	56 / 68 (82.35%)	59 / 67 (88.06%)	53 / 68 (77.94%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Neoplasm skin			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Leiomyoma			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Haemangioma of liver			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Cervix carcinoma			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	1	0	1
Vasculitis			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Varicose vein			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Vascular pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Energy increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	5 / 68 (7.35%)	1 / 67 (1.49%)	1 / 68 (1.47%)
occurrences (all)	6	3	1
Chest discomfort			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 68 (1.47%)	4 / 67 (5.97%)	1 / 68 (1.47%)
occurrences (all)	1	6	2
Injection site erosion			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			
subjects affected / exposed	36 / 68 (52.94%)	37 / 67 (55.22%)	34 / 68 (50.00%)
occurrences (all)	216	175	194
Injection site haematoma			

subjects affected / exposed	5 / 68 (7.35%)	3 / 67 (4.48%)	1 / 68 (1.47%)
occurrences (all)	9	15	3
Fatigue			
subjects affected / exposed	5 / 68 (7.35%)	4 / 67 (5.97%)	7 / 68 (10.29%)
occurrences (all)	8	4	13
Feeling abnormal			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	2 / 68 (2.94%)	9 / 67 (13.43%)	9 / 68 (13.24%)
occurrences (all)	13	62	54
Influenza like illness			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	2	0	1
Injection site anaesthesia			
subjects affected / exposed	1 / 68 (1.47%)	3 / 67 (4.48%)	2 / 68 (2.94%)
occurrences (all)	2	8	4
Injection site bruising			
subjects affected / exposed	7 / 68 (10.29%)	11 / 67 (16.42%)	7 / 68 (10.29%)
occurrences (all)	36	17	23
Injection site discolouration			
subjects affected / exposed	8 / 68 (11.76%)	9 / 67 (13.43%)	14 / 68 (20.59%)
occurrences (all)	22	65	92
Hyperthermia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	0 / 68 (0.00%)	2 / 67 (2.99%)	0 / 68 (0.00%)
occurrences (all)	0	2	0
Injection site hypoaesthesia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Injection site induration			
subjects affected / exposed	3 / 68 (4.41%)	3 / 67 (4.48%)	4 / 68 (5.88%)
occurrences (all)	14	6	13
Injection site nodule			

subjects affected / exposed	1 / 68 (1.47%)	2 / 67 (2.99%)	1 / 68 (1.47%)
occurrences (all)	3	2	1
Injection site pain			
subjects affected / exposed	11 / 68 (16.18%)	15 / 67 (22.39%)	21 / 68 (30.88%)
occurrences (all)	45	59	118
Injection site pruritus			
subjects affected / exposed	14 / 68 (20.59%)	17 / 67 (25.37%)	15 / 68 (22.06%)
occurrences (all)	88	78	100
Injection site swelling			
subjects affected / exposed	4 / 68 (5.88%)	4 / 67 (5.97%)	13 / 68 (19.12%)
occurrences (all)	45	12	70
Injection site warmth			
subjects affected / exposed	1 / 68 (1.47%)	5 / 67 (7.46%)	2 / 68 (2.94%)
occurrences (all)	2	13	2
Malaise			
subjects affected / exposed	1 / 68 (1.47%)	1 / 67 (1.49%)	1 / 68 (1.47%)
occurrences (all)	1	1	1
Nodule			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	1 / 68 (1.47%)
occurrences (all)	0	1	2
Oedema peripheral			
subjects affected / exposed	1 / 68 (1.47%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	1	1	0
Pain			
subjects affected / exposed	1 / 68 (1.47%)	3 / 67 (4.48%)	2 / 68 (2.94%)
occurrences (all)	1	4	2
Peripheral swelling			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	10 / 68 (14.71%)	6 / 67 (8.96%)	10 / 68 (14.71%)
occurrences (all)	14	8	19
Scar inflammation			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Sensation of foreign body			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Immunodeficiency			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Type III immune complex mediated reaction			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Seasonal allergy			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Cervix haemorrhage uterine			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Cervical polyp			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Menstrual disorder			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Genital haemorrhage			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Erectile dysfunction			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	0	0	2
Dysmenorrhoea			
subjects affected / exposed	1 / 68 (1.47%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	1	1	0
Adenomyosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Breast pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Vaginal discharge			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Vulvovaginal swelling			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Hyperventilation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Nasal dryness			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	0 / 68 (0.00%)	3 / 67 (4.48%)	2 / 68 (2.94%)
occurrences (all)	0	3	2
Catarrh			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Dry throat			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	2 / 68 (2.94%)	3 / 67 (4.48%)	2 / 68 (2.94%)
occurrences (all)	2	4	3
Oropharyngeal discomfort			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Nasal pruritus			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Nasal polyps			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Reflux laryngitis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 68 (0.00%)	2 / 67 (2.99%)	1 / 68 (1.47%)
occurrences (all)	0	3	1
Rhinitis allergic			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Stress			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	1 / 68 (1.47%)
occurrences (all)	0	1	1
Insomnia			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	1 / 68 (1.47%)
occurrences (all)	0	2	2
Depression			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Depressed mood			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0

Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 68 (4.41%)	1 / 67 (1.49%)	3 / 68 (4.41%)
occurrences (all)	3	1	3
Antinuclear antibody positive			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	2 / 68 (2.94%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Autoantibody positive			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	7 / 68 (10.29%)	8 / 67 (11.94%)	4 / 68 (5.88%)
occurrences (all)	13	10	6
Albumin urine present			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Antineutrophil cytoplasmic antibody positive			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Complement factor abnormal			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Complement factor C4 decreased			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Complement factor C3 decreased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	2 / 68 (2.94%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	2	0	1
Complement factor increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	1	0	1
Blood creatine increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	7
Glomerular filtration rate decreased			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	1	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0

Eosinophil count increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Creatinine urine increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance decreased			
subjects affected / exposed	2 / 68 (2.94%)	6 / 67 (8.96%)	1 / 68 (1.47%)
occurrences (all)	4	21	2
Hepatic enzyme increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Immature granulocyte count increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Hepatitis B DNA assay positive			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Mean cell volume decreased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Urine analysis abnormal			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	3
Urine albumin/creatinine ratio			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Urinary sediment present			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Total complement activity decreased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Red blood cells urine positive			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	4 / 68 (5.88%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	6	0	2
White blood cell count decreased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Urine leukocyte esterase positive			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Animal bite			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	1 / 68 (1.47%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	1	1	0
Back injury			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Epicondylitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Eye injury			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Foot fracture			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Hand fracture			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Injury			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Nail injury			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Post vaccination syndrome			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Procedural pain			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Skin injury			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Tooth avulsion			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Tooth dislocation			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Tooth fracture			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Tooth injury			

subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Vaccination complication			
subjects affected / exposed	2 / 68 (2.94%)	2 / 67 (2.99%)	2 / 68 (2.94%)
occurrences (all)	2	3	2
Congenital, familial and genetic disorders			
Dyschromatosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Atrial fibrillation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 68 (0.00%)	2 / 67 (2.99%)	3 / 68 (4.41%)
occurrences (all)	0	2	4
Somnolence			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	2	0
Sciatica			

subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	1	0	1
Lethargy			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	2 / 68 (2.94%)	2 / 67 (2.99%)	0 / 68 (0.00%)
occurrences (all)	2	6	0
Headache			
subjects affected / exposed	5 / 68 (7.35%)	6 / 67 (8.96%)	8 / 68 (11.76%)
occurrences (all)	10	8	15
Dysgeusia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Coagulopathy			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 68 (0.00%)	3 / 67 (4.48%)	1 / 68 (1.47%)
occurrences (all)	0	4	1
Abnormal clotting factor			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0

Leukocytosis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 68 (1.47%)	2 / 67 (2.99%)	0 / 68 (0.00%)
occurrences (all)	1	3	0
Lymphopenia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Monocytosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 68 (0.00%)	2 / 67 (2.99%)	0 / 68 (0.00%)
occurrences (all)	0	2	0
Polycythaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0

Thrombocytopenia			
subjects affected / exposed	4 / 68 (5.88%)	2 / 67 (2.99%)	1 / 68 (1.47%)
occurrences (all)	6	2	3
Thrombocytosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Deafness			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Ear pain			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Meniere's disease			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Vertigo positional			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Keratitis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	1	0	1
Asthenopia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	0	0	2
Dry eye			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	0	0	2
Eye pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Noninfective conjunctivitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Periorbital swelling			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 68 (1.47%)	2 / 67 (2.99%)	1 / 68 (1.47%)
occurrences (all)	1	2	1
Abdominal distension			
subjects affected / exposed	2 / 68 (2.94%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	3	0	2
Change of bowel habit			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Abdominal pain lower			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	1	0	2
Abdominal pain upper			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	2 / 68 (2.94%)
occurrences (all)	0	1	4
Abdominal tenderness			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Angular cheilitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1

Aphthous ulcer			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	1	0	2
Constipation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	4 / 68 (5.88%)
occurrences (all)	0	0	4
Dental caries			
subjects affected / exposed	2 / 68 (2.94%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	2	0	1
Diarrhoea			
subjects affected / exposed	6 / 68 (8.82%)	2 / 67 (2.99%)	0 / 68 (0.00%)
occurrences (all)	6	2	0
Diverticulum intestinal			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Faecaloma			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Food poisoning			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0

Dyspepsia			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal sounds abnormal			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Gingival bleeding			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Gingival ulceration			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Irritable bowel syndrome			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Large intestine polyp			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	1	0	3
Oesophageal spasm			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	1 / 68 (1.47%)
occurrences (all)	0	2	1
Tooth disorder			
subjects affected / exposed	1 / 68 (1.47%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	1	1	0
Toothache			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	0	0	2
Vomiting			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	1	0	1
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Gallbladder polyp			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Hepatitis acute			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			

subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	2 / 68 (2.94%)
occurrences (all)	0	1	2
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Acne			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Angioedema			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Asteatosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	1 / 68 (1.47%)	1 / 67 (1.49%)	2 / 68 (2.94%)
occurrences (all)	1	1	3
Eczema			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	1	0	3
Ecchymosis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	1 / 68 (1.47%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	1	2	0
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Dermatitis allergic			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	1 / 68 (1.47%)
occurrences (all)	0	1	1
Dermal cyst			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Blood blister			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Papule			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	3 / 68 (4.41%)	2 / 67 (2.99%)	1 / 68 (1.47%)
occurrences (all)	6	2	2
Purpura			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	4 / 68 (5.88%)	1 / 67 (1.49%)	1 / 68 (1.47%)
occurrences (all)	8	7	1
Rash erythematous			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Nail bed bleeding			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	1	0	1
Hand dermatitis			

subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Haemorrhage subcutaneous			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Night sweats			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	0	0	2
Urticarial vasculitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	1	0	3
Skin hyperpigmentation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Skin hypertrophy			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Skin plaque			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Umbilical erythema			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Cylindruria			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Albuminuria			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Glycosuria			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	2 / 68 (2.94%)
occurrences (all)	0	1	2
Ketonuria			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Nephrocalcinosis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Nephrolithiasis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Nephropathy toxic			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	1 / 68 (1.47%)	2 / 67 (2.99%)	2 / 68 (2.94%)
occurrences (all)	3	3	2

Renal cyst			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Urine abnormality			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	3 / 68 (4.41%)	3 / 67 (4.48%)	6 / 68 (8.82%)
occurrences (all)	5	4	8
Arthritis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	4 / 68 (5.88%)	5 / 67 (7.46%)	6 / 68 (8.82%)
occurrences (all)	5	5	8
Bone swelling			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Costochondritis			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 68 (1.47%)	2 / 67 (2.99%)	2 / 68 (2.94%)
occurrences (all)	1	2	4
Osteoporosis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	5 / 68 (7.35%)	2 / 67 (2.99%)	4 / 68 (5.88%)
occurrences (all)	5	6	4
Rheumatoid arthritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Muscle twitching			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal stiffness			

subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Sjogren's syndrome			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	2 / 68 (2.94%)	8 / 67 (11.94%)	5 / 68 (7.35%)
occurrences (all)	2	8	5
Cellulitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0

Chronic hepatitis B			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	1 / 68 (1.47%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	1	2	0
Cystitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Epididymitis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Genital herpes			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Gingivitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0

Helicobacter gastritis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Hepatitis B			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	2 / 68 (2.94%)
occurrences (all)	1	0	3
Herpes dermatitis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Otitis externa			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	1 / 68 (1.47%)
occurrences (all)	0	1	1
Otitis media			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Otitis media acute			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0

Periodontitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Oral infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Injection site abscess			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Injection site cellulitis			
subjects affected / exposed	0 / 68 (0.00%)	2 / 67 (2.99%)	0 / 68 (0.00%)
occurrences (all)	0	3	0
Nasopharyngitis			
subjects affected / exposed	1 / 68 (1.47%)	1 / 67 (1.49%)	5 / 68 (7.35%)
occurrences (all)	1	1	5
Oral herpes			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Pustule			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	2	0
Sinusitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0

Tooth infection			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Subcutaneous abscess			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Suspected COVID-19			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Urethritis			
subjects affected / exposed	0 / 68 (0.00%)	1 / 67 (1.49%)	0 / 68 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Vaginal infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Vaginitis gardnerella			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0

Vulvovaginal candidiasis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	1 / 68 (1.47%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Cell death			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Diabetes mellitus			
subjects affected / exposed	1 / 68 (1.47%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	1	0	0
Polydipsia			

subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Vitamin B complex deficiency			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 68 (0.00%)	0 / 67 (0.00%)	0 / 68 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo+GSK3228836 for 12WK each (not on NA)	GSK3228836 for 24Wk (not on NA)	GSK3228836 for 12WK (not on NA)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 24 (79.17%)	65 / 70 (92.86%)	60 / 67 (89.55%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Neoplasm skin			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Leiomyoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Haemangioma of liver			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Cervix carcinoma			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Uterine leiomyoma			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hot flush			

subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	1 / 67 (1.49%)
occurrences (all)	0	2	1
Vasculitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Varicose vein			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Vascular pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Energy increased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	0 / 24 (0.00%)	3 / 70 (4.29%)	1 / 67 (1.49%)
occurrences (all)	0	3	2
Chest discomfort			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 24 (0.00%)	5 / 70 (7.14%)	2 / 67 (2.99%)
occurrences (all)	0	5	2
Injection site erosion			

subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	10 / 24 (41.67%)	34 / 70 (48.57%)	30 / 67 (44.78%)
occurrences (all)	23	264	150
Injection site haematoma			
subjects affected / exposed	1 / 24 (4.17%)	8 / 70 (11.43%)	4 / 67 (5.97%)
occurrences (all)	1	17	12
Fatigue			
subjects affected / exposed	0 / 24 (0.00%)	13 / 70 (18.57%)	7 / 67 (10.45%)
occurrences (all)	0	19	15
Feeling abnormal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Injection site discomfort			
subjects affected / exposed	2 / 24 (8.33%)	4 / 70 (5.71%)	6 / 67 (8.96%)
occurrences (all)	2	13	25
Influenza like illness			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	2 / 67 (2.99%)
occurrences (all)	0	2	3
Injection site anaesthesia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	2	2
Injection site bruising			
subjects affected / exposed	4 / 24 (16.67%)	13 / 70 (18.57%)	10 / 67 (14.93%)
occurrences (all)	10	42	29
Injection site discolouration			
subjects affected / exposed	2 / 24 (8.33%)	13 / 70 (18.57%)	11 / 67 (16.42%)
occurrences (all)	4	39	46
Hyperthermia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Injection site haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Injection site hypoaesthesia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	1 / 24 (4.17%)	6 / 70 (8.57%)	7 / 67 (10.45%)
occurrences (all)	1	20	16
Injection site nodule			
subjects affected / exposed	1 / 24 (4.17%)	0 / 70 (0.00%)	2 / 67 (2.99%)
occurrences (all)	4	0	3
Injection site pain			
subjects affected / exposed	6 / 24 (25.00%)	20 / 70 (28.57%)	13 / 67 (19.40%)
occurrences (all)	41	198	61
Injection site pruritus			
subjects affected / exposed	2 / 24 (8.33%)	23 / 70 (32.86%)	16 / 67 (23.88%)
occurrences (all)	4	198	85
Injection site swelling			
subjects affected / exposed	0 / 24 (0.00%)	10 / 70 (14.29%)	7 / 67 (10.45%)
occurrences (all)	0	69	44
Injection site warmth			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	1 / 67 (1.49%)
occurrences (all)	0	39	34
Malaise			
subjects affected / exposed	1 / 24 (4.17%)	3 / 70 (4.29%)	3 / 67 (4.48%)
occurrences (all)	1	3	4
Nodule			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	2 / 67 (2.99%)
occurrences (all)	0	1	2
Oedema peripheral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	2 / 67 (2.99%)
occurrences (all)	0	1	2
Peripheral swelling			

subjects affected / exposed	1 / 24 (4.17%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	1	1	0
Pyrexia			
subjects affected / exposed	4 / 24 (16.67%)	15 / 70 (21.43%)	17 / 67 (25.37%)
occurrences (all)	5	23	38
Scar inflammation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Vaccination site pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Sensation of foreign body			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	1	1
Immunodeficiency			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Type III immune complex mediated reaction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	2 / 24 (8.33%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	2	1	1
Reproductive system and breast disorders			
Cervix haemorrhage uterine			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Cervical polyp			

subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Menstruation irregular			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Menstrual disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Genital haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Adenomyosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Amenorrhoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Vaginal discharge			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			

subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Hyperventilation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	2 / 67 (2.99%)
occurrences (all)	0	1	2
Catarrh			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Dry throat			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 24 (4.17%)	3 / 70 (4.29%)	3 / 67 (4.48%)
occurrences (all)	1	3	3
Oropharyngeal discomfort			

subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Nasal pruritus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Nasal polyps			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Reflux laryngitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Stress			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	2 / 67 (2.99%)
occurrences (all)	0	1	2
Depression			
subjects affected / exposed	1 / 24 (4.17%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Depressed mood			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0

Anxiety			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 24 (8.33%)	8 / 70 (11.43%)	9 / 67 (13.43%)
occurrences (all)	4	11	12
Antinuclear antibody positive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	1	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	1 / 67 (1.49%)
occurrences (all)	0	3	1
Bilirubin conjugated increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Autoantibody positive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Alanine aminotransferase increased			
subjects affected / exposed	4 / 24 (16.67%)	17 / 70 (24.29%)	15 / 67 (22.39%)
occurrences (all)	9	25	18
Albumin urine present			

subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Antineutrophil cytoplasmic antibody positive			
subjects affected / exposed	2 / 24 (8.33%)	1 / 70 (1.43%)	3 / 67 (4.48%)
occurrences (all)	2	1	3
Complement factor abnormal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Complement factor C4 decreased			
subjects affected / exposed	3 / 24 (12.50%)	5 / 70 (7.14%)	4 / 67 (5.97%)
occurrences (all)	3	5	5
Complement factor C3 decreased			
subjects affected / exposed	4 / 24 (16.67%)	7 / 70 (10.00%)	4 / 67 (5.97%)
occurrences (all)	4	8	5
C-reactive protein increased			
subjects affected / exposed	0 / 24 (0.00%)	3 / 70 (4.29%)	2 / 67 (2.99%)
occurrences (all)	0	3	2
Complement factor increased			
subjects affected / exposed	0 / 24 (0.00%)	6 / 70 (8.57%)	1 / 67 (1.49%)
occurrences (all)	0	6	1
Blood pressure increased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Blood potassium increased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Blood creatine increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	1 / 24 (4.17%)	2 / 70 (2.86%)	0 / 67 (0.00%)
occurrences (all)	1	2	0

Glomerular filtration rate decreased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Eosinophil count increased			
subjects affected / exposed	1 / 24 (4.17%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Crystal urine present			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Creatinine urine increased			
subjects affected / exposed	1 / 24 (4.17%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	1	1	0
Creatinine renal clearance decreased			
subjects affected / exposed	2 / 24 (8.33%)	1 / 70 (1.43%)	2 / 67 (2.99%)
occurrences (all)	3	1	10
Hepatic enzyme increased			
subjects affected / exposed	1 / 24 (4.17%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	2	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Immature granulocyte count increased			
subjects affected / exposed	1 / 24 (4.17%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Hepatitis B DNA assay positive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Mean cell volume decreased			

subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Urine analysis abnormal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Urinary sediment present			
subjects affected / exposed	1 / 24 (4.17%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Transaminases increased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Total complement activity decreased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Red blood cells urine positive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	1	1
Platelet count decreased			
subjects affected / exposed	0 / 24 (0.00%)	8 / 70 (11.43%)	3 / 67 (4.48%)
occurrences (all)	0	11	6

White blood cell count decreased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Urine leukocyte esterase positive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Back injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 24 (4.17%)	2 / 70 (2.86%)	1 / 67 (1.49%)
occurrences (all)	1	4	1
Epicondylitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Eye injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Muscle strain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Hand fracture			

subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Nail injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Post vaccination syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	2
Skin injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Sunburn			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Tooth avulsion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Tooth dislocation			

subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Tooth injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Vaccination complication			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
Dyschromatosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Supraventricular extrasystoles			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	5	1
Palpitations			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	1 / 24 (4.17%)	3 / 70 (4.29%)	4 / 67 (5.97%)
occurrences (all)	1	3	6
Somnolence			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	1	2
Headache			
subjects affected / exposed	4 / 24 (16.67%)	14 / 70 (20.00%)	14 / 67 (20.90%)
occurrences (all)	4	25	50
Dysgeusia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Coagulopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1

Anaemia			
subjects affected / exposed	1 / 24 (4.17%)	2 / 70 (2.86%)	0 / 67 (0.00%)
occurrences (all)	1	2	0
Abnormal clotting factor			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 24 (0.00%)	3 / 70 (4.29%)	0 / 67 (0.00%)
occurrences (all)	0	3	0
Lymph node pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Monocytosis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	2 / 67 (2.99%)
occurrences (all)	0	2	2
Increased tendency to bruise			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Eosinophilia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	0 / 24 (0.00%)	4 / 70 (5.71%)	2 / 67 (2.99%)
occurrences (all)	0	5	2

Polycythaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Splenomegaly			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	0 / 24 (0.00%)	5 / 70 (7.14%)	2 / 67 (2.99%)
occurrences (all)	0	9	2
Thrombocytosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	1 / 67 (1.49%)
occurrences (all)	0	3	1
Meniere's disease			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Vertigo positional			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Asthenopia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Noninfective conjunctivitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 24 (4.17%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	1	2	1
Abdominal distension			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	2 / 67 (2.99%)
occurrences (all)	0	1	3
Change of bowel habit			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	1 / 67 (1.49%)
occurrences (all)	0	2	1
Abdominal pain upper			
subjects affected / exposed	0 / 24 (0.00%)	3 / 70 (4.29%)	3 / 67 (4.48%)
occurrences (all)	0	4	3

Abdominal tenderness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 24 (0.00%)	4 / 70 (5.71%)	2 / 67 (2.99%)
occurrences (all)	0	5	5
Constipation			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	1 / 67 (1.49%)
occurrences (all)	0	2	1
Dental caries			
subjects affected / exposed	1 / 24 (4.17%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	2	0	0
Diarrhoea			
subjects affected / exposed	0 / 24 (0.00%)	3 / 70 (4.29%)	3 / 67 (4.48%)
occurrences (all)	0	3	3
Diverticulum intestinal			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Faecaloma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0

Flatulence			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal sounds abnormal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	1	1
Gingival bleeding			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Gingival ulceration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0

Large intestine polyp			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Haematochezia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 24 (0.00%)	7 / 70 (10.00%)	4 / 67 (5.97%)
occurrences (all)	0	9	5
Oesophageal spasm			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 24 (0.00%)	3 / 70 (4.29%)	0 / 67 (0.00%)
occurrences (all)	0	3	0
Vomiting			
subjects affected / exposed	1 / 24 (4.17%)	3 / 70 (4.29%)	0 / 67 (0.00%)
occurrences (all)	1	3	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	1	3
Gallbladder polyp			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Hepatic cytolysis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			

subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hepatitis acute			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Hypertransaminasaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Acne			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Angioedema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Asteatosis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	2 / 67 (2.99%)
occurrences (all)	0	2	2
Eczema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Drug reaction with eosinophilia and systemic symptoms			

subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	2
Dermatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Dermal cyst			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Blood blister			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	1 / 24 (4.17%)	5 / 70 (7.14%)	4 / 67 (5.97%)
occurrences (all)	1	5	12
Purpura			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 24 (4.17%)	1 / 70 (1.43%)	7 / 67 (10.45%)
occurrences (all)	2	1	11
Rash erythematous			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Nail bed bleeding			

subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	3
Hyperhidrosis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hand dermatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	3 / 67 (4.48%)
occurrences (all)	0	2	4
Urticarial vasculitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	1	3
Rash pruritic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Skin discolouration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Skin hypertrophy			

subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Skin plaque			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Umbilical erythema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Cylindruria			
subjects affected / exposed	1 / 24 (4.17%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Albuminuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	1	1
Glycosuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 24 (4.17%)	3 / 70 (4.29%)	3 / 67 (4.48%)
occurrences (all)	2	3	3
Ketonuria			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Leukocyturia			
subjects affected / exposed	1 / 24 (4.17%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	2	1	0
Nephrocalcinosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1

Nephropathy toxic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 24 (4.17%)	2 / 70 (2.86%)	0 / 67 (0.00%)
occurrences (all)	1	4	0
Renal cyst			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Urine abnormality			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Arthralgia			
subjects affected / exposed	1 / 24 (4.17%)	1 / 70 (1.43%)	3 / 67 (4.48%)
occurrences (all)	1	1	6
Arthritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	2 / 24 (8.33%)	4 / 70 (5.71%)	4 / 67 (5.97%)
occurrences (all)	2	6	4
Bone swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	2 / 67 (2.99%)
occurrences (all)	0	0	3
Pain in extremity			
subjects affected / exposed	1 / 24 (4.17%)	4 / 70 (5.71%)	3 / 67 (4.48%)
occurrences (all)	1	4	6
Osteoporosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	3 / 24 (12.50%)	10 / 70 (14.29%)	7 / 67 (10.45%)
occurrences (all)	3	12	10
Rheumatoid arthritis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	1	1
Muscular weakness			
subjects affected / exposed	1 / 24 (4.17%)	0 / 70 (0.00%)	2 / 67 (2.99%)
occurrences (all)	1	0	3
Muscle twitching			

subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Musculoskeletal stiffness			
subjects affected / exposed	1 / 24 (4.17%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	1	1	1
Tendonitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Sjogren's syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Bacteriuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0

COVID-19			
subjects affected / exposed	1 / 24 (4.17%)	3 / 70 (4.29%)	6 / 67 (8.96%)
occurrences (all)	1	3	6
Cellulitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Chronic hepatitis B			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Furuncle			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Epididymitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Fungal skin infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0

Genital herpes			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Helicobacter gastritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Hepatitis B			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	2 / 67 (2.99%)
occurrences (all)	0	5	2
Herpes virus infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Hordeolum			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Herpes dermatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0

Otitis media acute			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Parotitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Periodontitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Injection site abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Injection site cellulitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 24 (4.17%)	4 / 70 (5.71%)	2 / 67 (2.99%)
occurrences (all)	1	6	2
Oral herpes			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	2 / 67 (2.99%)
occurrences (all)	0	4	2
Pharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	2 / 67 (2.99%)
occurrences (all)	0	2	2
Pustule			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0

Respiratory tract infection viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	1 / 24 (4.17%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 24 (4.17%)	3 / 70 (4.29%)	3 / 67 (4.48%)
occurrences (all)	1	4	4
Urethritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 24 (4.17%)	3 / 70 (4.29%)	0 / 67 (0.00%)
occurrences (all)	1	4	0
Vaginal infection			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	1 / 67 (1.49%)
occurrences (all)	0	1	2

Vaginitis gardnerella			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 24 (0.00%)	2 / 70 (2.86%)	0 / 67 (0.00%)
occurrences (all)	0	2	0
Viral infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 70 (1.43%)	0 / 67 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	2 / 67 (2.99%)
occurrences (all)	0	0	15
Cell death			

subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	1 / 67 (1.49%)
occurrences (all)	0	0	1
Vitamin B complex deficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 70 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	GSK3228836+Placebo for 12WK (not on NA)	Placebo+GSK322883 6 300mg for 12WK each (on NA)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	61 / 68 (89.71%)	16 / 23 (69.57%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Neoplasm skin			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Leiomyoma			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Haemangioma of liver			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Cervix carcinoma			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Uterine leiomyoma			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Hypertension			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Vasculitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Varicose vein			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Vascular pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Energy increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Asthenia			
subjects affected / exposed	7 / 68 (10.29%)	0 / 23 (0.00%)	
occurrences (all)	11	0	
Chest discomfort			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Chest pain			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	3 / 68 (4.41%)	1 / 23 (4.35%)	
occurrences (all)	4	1	
Injection site erosion			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Injection site erythema			
subjects affected / exposed	37 / 68 (54.41%)	5 / 23 (21.74%)	
occurrences (all)	179	22	
Injection site haematoma			
subjects affected / exposed	2 / 68 (2.94%)	1 / 23 (4.35%)	
occurrences (all)	3	2	
Fatigue			
subjects affected / exposed	8 / 68 (11.76%)	1 / 23 (4.35%)	
occurrences (all)	11	1	
Feeling abnormal			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Injection site discomfort			
subjects affected / exposed	4 / 68 (5.88%)	1 / 23 (4.35%)	
occurrences (all)	25	2	
Influenza like illness			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Injection site anaesthesia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Injection site bruising			
subjects affected / exposed	14 / 68 (20.59%)	4 / 23 (17.39%)	
occurrences (all)	33	13	
Injection site discolouration			
subjects affected / exposed	6 / 68 (8.82%)	2 / 23 (8.70%)	
occurrences (all)	37	3	
Hyperthermia			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Injection site haemorrhage			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Injection site hypoaesthesia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Injection site induration			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	5	0	
Injection site nodule			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Injection site pain			
subjects affected / exposed	14 / 68 (20.59%)	6 / 23 (26.09%)	
occurrences (all)	66	16	
Injection site pruritus			
subjects affected / exposed	19 / 68 (27.94%)	2 / 23 (8.70%)	
occurrences (all)	98	3	
Injection site swelling			
subjects affected / exposed	5 / 68 (7.35%)	1 / 23 (4.35%)	
occurrences (all)	13	2	
Injection site warmth			
subjects affected / exposed	4 / 68 (5.88%)	0 / 23 (0.00%)	
occurrences (all)	19	0	
Malaise			
subjects affected / exposed	0 / 68 (0.00%)	2 / 23 (8.70%)	
occurrences (all)	0	3	
Nodule			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			

subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Peripheral swelling			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	17 / 68 (25.00%)	6 / 23 (26.09%)	
occurrences (all)	23	7	
Scar inflammation			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Swelling			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Vaccination site pain			
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Sensation of foreign body			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Immunodeficiency			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Type III immune complex mediated reaction			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Seasonal allergy			

subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Reproductive system and breast disorders			
Cervix haemorrhage uterine			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Cervical polyp			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Pelvic pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Menstruation irregular			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Menstrual disorder			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Genital haemorrhage			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Erectile dysfunction			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Dysmenorrhoea			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Adenomyosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Amenorrhoea			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Breast pain			

subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Vaginal discharge			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal swelling			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Vulvovaginal inflammation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hyperventilation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Nasal dryness			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Catarrh			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Dry throat			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal discomfort			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Nasal pruritus			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Nasal polyps			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Reflux laryngitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Rhinitis allergic			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Stress			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Sleep disorder			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	

Insomnia			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	3	0	
Depression			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Depressed mood			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Anxiety			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Irritability			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	7 / 68 (10.29%)	3 / 23 (13.04%)	
occurrences (all)	9	3	
Antinuclear antibody positive			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Blood calcium decreased			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Blood bilirubin increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	3	0	
Bilirubin conjugated increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Autoantibody positive			

subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Alanine aminotransferase increased			
subjects affected / exposed	12 / 68 (17.65%)	5 / 23 (21.74%)	
occurrences (all)	21	5	
Albumin urine present			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Antineutrophil cytoplasmic antibody positive			
subjects affected / exposed	1 / 68 (1.47%)	1 / 23 (4.35%)	
occurrences (all)	1	1	
Complement factor abnormal			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Complement factor C4 decreased			
subjects affected / exposed	4 / 68 (5.88%)	1 / 23 (4.35%)	
occurrences (all)	4	1	
Complement factor C3 decreased			
subjects affected / exposed	6 / 68 (8.82%)	1 / 23 (4.35%)	
occurrences (all)	6	1	
C-reactive protein increased			
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Complement factor increased			
subjects affected / exposed	4 / 68 (5.88%)	1 / 23 (4.35%)	
occurrences (all)	4	1	
Blood pressure increased			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Blood potassium increased			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Blood creatine increased			
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Body temperature increased			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Glomerular filtration rate decreased			
subjects affected / exposed	1 / 68 (1.47%)	1 / 23 (4.35%)	
occurrences (all)	1	1	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Eosinophil count increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Crystal urine present			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Creatinine urine increased			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Creatinine renal clearance decreased			
subjects affected / exposed	1 / 68 (1.47%)	1 / 23 (4.35%)	
occurrences (all)	3	1	
Hepatic enzyme increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Liver function test abnormal			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	

International normalised ratio increased			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Immature granulocyte count increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hepatitis B DNA assay positive			
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Mean cell volume decreased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Neutrophil count decreased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Urine analysis abnormal			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Urine albumin/creatinine ratio			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Urinary sediment present			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Transaminases increased			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Total complement activity decreased			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Red blood cells urine positive			

subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Prothrombin time prolonged			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Protein urine present			
subjects affected / exposed	3 / 68 (4.41%)	0 / 23 (0.00%)	
occurrences (all)	3	0	
Platelet count decreased			
subjects affected / exposed	3 / 68 (4.41%)	1 / 23 (4.35%)	
occurrences (all)	3	1	
White blood cell count decreased			
subjects affected / exposed	1 / 68 (1.47%)	1 / 23 (4.35%)	
occurrences (all)	1	1	
Urine leukocyte esterase positive			
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Animal bite			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Arthropod bite			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Back injury			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Contusion			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Epicondylitis			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Eye injury			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Muscle strain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Foot fracture			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hand fracture			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Injury			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Ligament sprain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Nail injury			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Post vaccination syndrome			
subjects affected / exposed	1 / 68 (1.47%)	1 / 23 (4.35%)	
occurrences (all)	1	1	
Procedural pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Skin abrasion			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Skin injury			

subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Skin laceration			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Sunburn			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Tooth avulsion			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Tooth dislocation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Tooth fracture			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Tooth injury			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Vaccination complication			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Congenital, familial and genetic disorders			
Dyschromatosis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Atrial fibrillation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Supraventricular extrasystoles			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Nervous system disorders			
Ageusia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Dizziness			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Somnolence			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Sciatica			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Migraine			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Lethargy			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Hypoaesthesia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	

Headache			
subjects affected / exposed	14 / 68 (20.59%)	3 / 23 (13.04%)	
occurrences (all)	26	3	
Dysgeusia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Coagulopathy			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Anaemia			
subjects affected / exposed	1 / 68 (1.47%)	1 / 23 (4.35%)	
occurrences (all)	1	1	
Abnormal clotting factor			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Leukocytosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Lymph node pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Lymphadenopathy			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Lymphopenia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Monocytosis			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Increased tendency to bruise			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Eosinophilia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Neutropenia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Polycythaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Splenomegaly			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	3 / 68 (4.41%)	0 / 23 (0.00%)	
occurrences (all)	5	0	
Thrombocytosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Deafness			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Ear pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	

Meniere's disease			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Vertigo positional			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Asthenopia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Blepharitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Dry eye			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Eye pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Noninfective conjunctivitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Ocular hyperaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Periorbital swelling			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Abdominal distension			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Change of bowel habit			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Abdominal pain lower			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Abdominal pain upper			
subjects affected / exposed	3 / 68 (4.41%)	0 / 23 (0.00%)	
occurrences (all)	4	0	
Abdominal tenderness			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Angular cheilitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Aphthous ulcer			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	1 / 68 (1.47%)	1 / 23 (4.35%)	
occurrences (all)	1	1	
Constipation			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Dental caries			
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	2 / 68 (2.94%)	1 / 23 (4.35%)	
occurrences (all)	2	1	

Diverticulum intestinal			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Dry mouth			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Gastritis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Faecaloma			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Faeces discoloured			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Food poisoning			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Dyspepsia			
subjects affected / exposed	3 / 68 (4.41%)	0 / 23 (0.00%)	
occurrences (all)	3	0	
Gastrointestinal sounds abnormal			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Gingival bleeding			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Gingival pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	

Gingival ulceration				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Mouth ulceration				
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)		
occurrences (all)	1	0		
Haemorrhoidal haemorrhage				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Haemorrhoids				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Irritable bowel syndrome				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Large intestine polyp				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Haematochezia				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Nausea				
subjects affected / exposed	2 / 68 (2.94%)	1 / 23 (4.35%)		
occurrences (all)	2	1		
Oesophageal spasm				
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)		
occurrences (all)	1	0		
Stomatitis				
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)		
occurrences (all)	2	0		
Tooth disorder				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Toothache				
subjects affected / exposed	2 / 68 (2.94%)	1 / 23 (4.35%)		
occurrences (all)	3	1		

Vomiting			
subjects affected / exposed	1 / 68 (1.47%)	1 / 23 (4.35%)	
occurrences (all)	1	2	
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	2 / 68 (2.94%)	1 / 23 (4.35%)	
occurrences (all)	2	1	
Gallbladder polyp			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hepatic cytolysis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Hepatic steatosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hepatitis acute			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Acne			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Angioedema			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Asteatosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Erythema			

subjects affected / exposed	2 / 68 (2.94%)	1 / 23 (4.35%)		
occurrences (all)	6	1		
Eczema				
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)		
occurrences (all)	2	0		
Ecchymosis				
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)		
occurrences (all)	0	1		
Dry skin				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Drug reaction with eosinophilia and systemic symptoms				
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)		
occurrences (all)	1	0		
Dermatitis contact				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Dermatitis allergic				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Dermatitis				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Dermal cyst				
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)		
occurrences (all)	1	0		
Blood blister				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Papule				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		
Petechiae				
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)		
occurrences (all)	0	0		

Pruritus			
subjects affected / exposed	3 / 68 (4.41%)	1 / 23 (4.35%)	
occurrences (all)	7	1	
Purpura			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	5 / 68 (7.35%)	0 / 23 (0.00%)	
occurrences (all)	13	0	
Rash erythematous			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Nail bed bleeding			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hand dermatitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Night sweats			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	2 / 68 (2.94%)	1 / 23 (4.35%)	
occurrences (all)	2	1	
Urticarial vasculitis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Rash macular			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	

Rash maculo-papular			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Rash pruritic			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Skin discolouration			
subjects affected / exposed	3 / 68 (4.41%)	0 / 23 (0.00%)	
occurrences (all)	4	0	
Skin hyperpigmentation			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	3	0	
Skin hypertrophy			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Skin plaque			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Umbilical erythema			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Cylindruria			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Albuminuria			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Glycosuria			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Haematuria			

subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	3	0	
Ketonuria			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Leukocyturia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Nephrocalcinosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Nephrolithiasis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Nephropathy toxic			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Proteinuria			
subjects affected / exposed	3 / 68 (4.41%)	0 / 23 (0.00%)	
occurrences (all)	3	0	
Renal cyst			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Urinary tract obstruction			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Urine abnormality			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hypothyroidism			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	

Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Joint swelling			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Arthralgia			
subjects affected / exposed	4 / 68 (5.88%)	1 / 23 (4.35%)	
occurrences (all)	5	1	
Arthritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	3 / 68 (4.41%)	0 / 23 (0.00%)	
occurrences (all)	5	0	
Bone swelling			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Costochondritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Flank pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Osteoporosis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Osteoarthritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Neck pain			

subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Myalgia			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Rheumatoid arthritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Muscular weakness			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Muscle twitching			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Musculoskeletal stiffness			
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Tendonitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Sjogren's syndrome			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Sacral pain			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Rotator cuff syndrome			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Asymptomatic bacteriuria			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Bacterial infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Bacteriuria			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
COVID-19			
subjects affected / exposed	4 / 68 (5.88%)	1 / 23 (4.35%)	
occurrences (all)	4	1	
Cellulitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Chronic hepatitis B			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Conjunctivitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Cystitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Furuncle			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Epididymitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	

Folliculitis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Fungal infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Fungal skin infection			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Diarrhoea infectious			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Genital herpes			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Gingivitis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Helicobacter gastritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hepatitis B			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Herpes simplex			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Herpes virus infection			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	

Herpes zoster			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Hordeolum			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Herpes dermatitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Otitis externa			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Otitis media			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Otitis media acute			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Parotitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Periodontitis			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	3	0	
Oral infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Injection site abscess			
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Injection site cellulitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	4 / 68 (5.88%)	4 / 23 (17.39%)	
occurrences (all)	6	4	

Oral herpes			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Influenza			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Pustule			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Respiratory tract infection viral			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Sinusitis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Tooth infection			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Subcutaneous abscess			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Suspected COVID-19			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Tonsillitis			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Tooth abscess			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	

Skin infection			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			
subjects affected / exposed	2 / 68 (2.94%)	0 / 23 (0.00%)	
occurrences (all)	2	0	
Urethritis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	4 / 68 (5.88%)	0 / 23 (0.00%)	
occurrences (all)	4	0	
Vaginal infection			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	3	0	
Vaginitis gardnerella			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 68 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Hypocalcaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hypoglycaemia			

subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Iron deficiency			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Decreased appetite			
subjects affected / exposed	1 / 68 (1.47%)	1 / 23 (4.35%)	
occurrences (all)	1	1	
Cell death			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Diabetes mellitus			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Polydipsia			
subjects affected / exposed	0 / 68 (0.00%)	0 / 23 (0.00%)	
occurrences (all)	0	0	
Vitamin B complex deficiency			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Vitamin D deficiency			
subjects affected / exposed	1 / 68 (1.47%)	0 / 23 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 April 2020	Original Protocol
10 May 2021	Amendment 01
23 September 2021	Amendment 02

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported