



## Clinical trial results:

**Single-Blind, randomized, Phase III B Study in children aged 1-11 years to investigate the immunogenicity, safety and interchangeability of two tick-borne encephalitis (TBE) vaccines administered according to a conventional schedule**

### Summary

EudraCT number	2008-002691-10
Trial protocol	AT CZ
Global end of trial date	20 May 2010

### Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	30 July 2015

### Trial information

#### Trial identification

Sponsor protocol code	700801
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00840801
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B9371022

Notes:

### Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.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?	Yes

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 October 2010
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	20 May 2010
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The objective of this study is to assess the immunogenicity, safety and interchangeability of two different TBE vaccines in children aged 1-11 years, the first and second vaccination with either FSME-IMMUN 0.25 milliliter (mL) Junior or Encepur 0.25 mL children and the third vaccination with FSME-IMMUN 0.25 mL Junior only, administered according the conventional schedule (0, 28 and 360 days).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 February 2009
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	Austria: 140
Country: Number of subjects enrolled	Czech Republic: 162
Worldwide total number of subjects	302
EEA total number of subjects	302

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)	100
Children (2-11 years)	202
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0
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## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

The study was conducted from 06 February 2009 to 20 May 2010 in Austria and Czech Republic

### Period 1

Period 1 title	Part A: Screening-Day 28 postdose 2
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

### Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	Part A: FSME-IMMUN
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Arm description:

Subjects received FSME-IMMUN Junior (FSME-IMMUN) at Day 0 and 28 as first and second vaccination according to the conventional immunization schedule and received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination.

Arm type	Experimental
Investigational medicinal product name	FSME-IMMUN
Investigational medicinal product code	
Other name	FSME-IMMUN 0.25 mL Junior
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received single dose of 0.25 mL FSME-IMMUN Junior (FSME-IMMUN) suspension at Day 0 and 28 as first and second vaccination according to the conventional immunization schedule.

<b>Arm title</b>	Part A: Encepur
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Arm description:

Subjects received Encepur Children (Encepur) at Day 0 and 28 as first and second vaccination according to the conventional immunization schedule and received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination.

Arm type	Active comparator
Investigational medicinal product name	Encepur
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received single dose of 0.25 mL Encepur Children (Encepur) suspension at Day 0 and 28 as first and second vaccination according to the conventional immunization schedule.

Number of subjects in period 1	Part A: FSME- IMMUN	Part A: Encepur
Started	150	152
Completed	149	152
Not completed	1	0
Screen failure	1	-

## Period 2

Period 2 title	Part B:Day 28 postdose2-Day 28 postdose3
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

## Arms

Arm title	Part B: FSME-IMMUN
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Arm description:

Subjects received FSME-IMMUN or Encepur during the first and second vaccination, received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination.

Arm type	Experimental
Investigational medicinal product name	FSME-IMMUN
Investigational medicinal product code	
Other name	FSME-IMMUN 0.25 mL Junior
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received single dose of 0.25 milliliter FSME-IMMUN Junior (FSME-IMMUN) suspension at Day 360 as the third vaccination.

Number of subjects in period 2	Part B: FSME- IMMUN
Started	301
Completed	297
Not completed	4
Unspecified	1
Refused blood draw	2
Lost to follow-up	1

## Baseline characteristics

### Reporting groups

Reporting group title	Part A: FSME-IMMUN
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Reporting group description:

Subjects received FSME-IMMUN Junior (FSME-IMMUN) at Day 0 and 28 as first and second vaccination according to the conventional immunization schedule and received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination.

Reporting group title	Part A: Encepur
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Reporting group description:

Subjects received Encepur Children (Encepur) at Day 0 and 28 as first and second vaccination according to the conventional immunization schedule and received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination.

Reporting group values	Part A: FSME-IMMUN	Part A: Encepur	Total
Number of subjects	150	152	302
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn - gestational age < 37 wk	0	0	0
Newborns (0--27 days)	0	0	0
Infants and toddlers (28 days--23 months)	50	50	100
Children (2--11 years)	100	102	202
Adolescents (12--17 years)	0	0	0
Adults (18--64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	77	74	151
Male	73	78	151

## End points

### End points reporting groups

Reporting group title	Part A: FSME-IMMUN
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Reporting group description:

Subjects received FSME-IMMUN Junior (FSME-IMMUN) at Day 0 and 28 as first and second vaccination according to the conventional immunization schedule and received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination.

Reporting group title	Part A: Encepur
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Reporting group description:

Subjects received Encepur Children (Encepur) at Day 0 and 28 as first and second vaccination according to the conventional immunization schedule and received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination.

Reporting group title	Part B: FSME-IMMUN
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Reporting group description:

Subjects received FSME-IMMUN or Encepur during the first and second vaccination, received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination.

Subject analysis set title	FSME-IMMUN-Third Vaccination
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Subject analysis set type	Safety analysis
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Subject analysis set description:

Safety analysis set included subjects who received FSME-IMMUN or Encepur during the first and second vaccination, received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination

Subject analysis set title	FSME-IMMUN
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Subject analysis set type	Full analysis
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Subject analysis set description:

It Included subjects who received FSME-IMMUN during the first and second vaccination.

Subject analysis set title	Encepur
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Subject analysis set type	Full analysis
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Subject analysis set description:

It Included subjects who received Encepur during the first and second vaccination.

### Primary: Seropositivity Rate as Determined by Neutralization Test (NT) 28 Days After the Second Vaccination

End point title	Seropositivity Rate as Determined by Neutralization Test (NT) 28 Days After the Second Vaccination
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End point description:

Percentage of subjects achieving NT titer greater than or equal to ( $\geq$ ) 10. Per-protocol population included eligible subjects who received first and second vaccination, had negative baseline values in NT, had immunogenicity measurements available at baseline and 28 days after the second vaccination, and no major protocol violations. Here, "Number of subjects analyzed (N)"= total subjects who were evaluable for this end point.

End point type	Primary
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End point timeframe:

28 days after the second vaccination

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	127	134		
Units: Percentage of subjects				
number (confidence interval 95%)	100 (97.1 to 100)	97.8 (93.6 to 99.5)		

## Statistical analyses

Statistical analysis title	Non-inferiority Test on Seropositive Response Rate
Comparison groups	FSME-IMMUN v Encepur
Number of subjects included in analysis	261
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[1]</sup>
P-value	< 0.001
Method	Stratified score test

Notes:

[1] - A stratified score test was used to test the non-inferiority with a margin of -10% at 2.5% type I error (one-sided).

## Secondary: Seropositivity Rate Determined by NT 180 Days After the First Vaccination and 28 Days After the Third Vaccination

End point title	Seropositivity Rate Determined by NT 180 Days After the First Vaccination and 28 Days After the Third Vaccination
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End point description:

Percentage of subjects with NT titer  $\geq 10$ . Modified intent-to-treat (mITT) population included eligible subjects who fulfilled all inclusion and exclusion criteria, received first and second vaccination, did not have positive baseline values in ELISA (IMMUNOZYME FSME ELISA and Enzygnost TBE ELISA) and NT, had immunogenicity measurements available at baseline and 28 days after the second vaccination. "Number of subjects analysed" = total number of subjects included in the mITT population. Here, N = number of subjects who were evaluable at specified timeframe.

End point type	Secondary
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End point timeframe:

180 days after the first vaccination, 28 days after the third vaccination

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	149	152		
Units: Percentage of subjects				
number (confidence interval 95%)				
180 Days after Vaccination 1 (N=129, 133)	95.3 (90.2 to 98.3)	91 (84.8 to 95.3)		
28 Days after Vaccination 3 (N=128, 132)	100 (97.2 to 100)	100 (97.2 to 100)		

## Statistical analyses



### Secondary: Seropositivity Rate Determined by ELISA 28 Days After the Second Vaccination, 180 Days After the First Vaccination and 28 Days After the Third Vaccination

End point title	Seropositivity Rate Determined by ELISA 28 Days After the Second Vaccination, 180 Days After the First Vaccination and 28 Days After the Third Vaccination
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#### End point description:

Proportion of subjects with IMMUNOZYM ELISA >126 Vienna Units per milliliter (VIEU/mL) or Enzygnost ELISA >10.32 U/mL. Modified intent-to-treat (mITT) population included eligible subjects who fulfilled all inclusion and exclusion criteria, received first and second vaccination, did not have positive baseline values in ELISA (IMMUNOZYM FSME ELISA and Enzygnost TBE ELISA) and NT, had immunogenicity measurements available at baseline and 28 days after the second vaccination. "Number of subjects analysed" = total number of subjects included in the mITT population. Here, N= number of subjects who were evaluable at specified timeframe.

End point type	Secondary
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#### End point timeframe:

28 days after the second vaccination, 180 days after the first vaccination, 28 days after the third vaccination

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	149	152		
Units: Percentage of subjects				
number (confidence interval 95%)				
180 Days after Vaccination 1 (N=142, 146)	95.1 (90.1 to 98)	81.5 (74.2 to 87.4)		
28 Days after Vaccination 2 (N=143, 148)	100 (97.5 to 100)	97.3 (93.2 to 99.3)		
28 Days after Vaccination 3 (N=141, 145)	100 (97.4 to 100)	100 (97.5 to 100)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody Response Measured by NT 28 Days After the Second Vaccination, 180 Days After the First Vaccination and 28 Days After the Third Vaccination

End point title	Antibody Response Measured by NT 28 Days After the Second Vaccination, 180 Days After the First Vaccination and 28 Days After the Third Vaccination
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#### End point description:

Geometric mean of antibody response measured by NT. Modified intent-to-treat (mITT) population included eligible subjects who fulfilled all inclusion and exclusion criteria, received first and second vaccination, did not have positive baseline values in ELISA (IMMUNOZYM FSME ELISA and Enzygnost TBE ELISA) and NT, had immunogenicity measurements available at baseline and 28 days after the second vaccination. "Number of subjects analysed" = total number of subjects included in the mITT population. Here, N= number of subjects who were evaluable at specified timeframe.

End point type	Secondary
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End point timeframe:

28 days after the second vaccination, 180 days after the first vaccination, 28 days after the third vaccination

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	149	152		
Units: titer				
geometric mean (confidence interval 95%)				
180 Days after Vaccination 1 (N=129, 133)	39.7 (34.4 to 45.8)	25 (21.3 to 29.4)		
28 Days after Vaccination 2 (N=129, 135)	236.8 (199.6 to 281)	118.8 (97.5 to 144.9)		
28 Days after Vaccination 3 (N=128, 132)	538.2 (499.2 to 580.2)	521.3 (476.6 to 570.2)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody Response Measured by ELISA 28 days After the Second Vaccination, 180 Days After the First Vaccination and 28 Days After the Third Vaccination

End point title	Antibody Response Measured by ELISA 28 days After the Second Vaccination, 180 Days After the First Vaccination and 28 Days After the Third Vaccination
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End point description:

Geometric mean of antibody response measured by IMMUNOZYM ELISA (VIEU/mL) and Enzygnost ELISA (U/mL). Modified intent-to-treat (mITT) population included eligible subjects who fulfilled all inclusion and exclusion criteria, received first and second vaccination, did not have positive baseline values in ELISA (IMMUNOZYM FSME ELISA and Enzygnost TBE ELISA) and NT, had immunogenicity measurements available at baseline and 28 days after the second vaccination. "Number of subjects analysed"= total number of subjects included in the mITT population. Here, N= number of subjects who were evaluable at specified timeframe for the specified ELISA assay.

End point type	Secondary
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End point timeframe:

28 days after the second vaccination, 180 days after the first vaccination, 28 days after the third vaccination

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	149	152		
Units: titer				
geometric mean (confidence interval 95%)				
IMMUNOZYM: 180 Days after Vaccination 1(N=142,147)	493.7 (436.5 to 558.5)	161.2 (140.5 to 184.9)		

IMMUNOZYM: 28 Days after Vaccination 2(N=143,149)	3026.3 (2652.2 to 3453.2)	678 (561.2 to 819.2)		
IMMUNOZYM: 28 Days after Vaccination 3(N=141,146)	11292.9 (9693.5 to 13156.3)	10508.6 (8208.4 to 13453.3)		
Enzygnost: 180 Days after Vaccination 1(N=148,149)	47.9 (41.4 to 55.4)	26.7 (22.5 to 31.6)		
Enzygnost: 28 Days after Vaccination 2(N=149,151)	163.3 (152.8 to 174.5)	93.7 (81.6 to 107.5)		
Enzygnost: 28 Days after Vaccination 3(N=147,148)	682.2 (579.6 to 802.9)	673.2 (533.4 to 849.7)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Fold Increase of Antibody Response Measured by NT 28 Days After the Second Vaccination, 180 Days After the First Vaccination and 28 Days After the Third Vaccination as Compared to Baseline

End point title	Fold Increase of Antibody Response Measured by NT 28 Days After the Second Vaccination, 180 Days After the First Vaccination and 28 Days After the Third Vaccination as Compared to Baseline
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End point description:

Geometric mean of fold increase of antibody response measured by NT from day 0 to specified timeframe. Modified intent-to-treat (mITT) population included eligible subjects who fulfilled all inclusion and exclusion criteria, received first and second vaccination, did not have positive baseline values in ELISA (IMMUNOZYM FSME ELISA and Enzygnost TBE ELISA) and NT, had immunogenicity measurements available at baseline and 28 days after the second vaccination. "Number of subjects analysed"= total number of subjects included in the mITT population. Here, N= number of subjects who were evaluable at specified timeframe.

End point type	Secondary
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End point timeframe:

28 days after the second vaccination, 180 days after the first vaccination, 28 days after the third vaccination

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	149	152		
Units: fold rise				
geometric mean (confidence interval 95%)				
180 Days after Vaccination 1 (N=129, 133)	7.9 (6.8 to 9.1)	5 (4.2 to 5.8)		
28 Days after Vaccination 2 (N=129, 135)	46.9 (39.5 to 55.8)	23.6 (19.4 to 28.8)		
28 Days after Vaccination 3 (N=128, 132)	106.7 (98.5 to 115.5)	103.5 (94.6 to 113.2)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Fold Increase of Antibody Response Measured by ELISA 28 Days After the Second Vaccination, 180 Days After the First Vaccination and 28 Days After the Third Vaccination as Compared to Baseline

End point title	Fold Increase of Antibody Response Measured by ELISA 28 Days After the Second Vaccination, 180 Days After the First Vaccination and 28 Days After the Third Vaccination as Compared to Baseline
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#### End point description:

Geometric mean of fold increase of antibody response measured by IMMUNOZYM ELISA (VIEU/ml) and Enzygnost ELISA (U/ml) from day 0 to specified timeframe. Modified intent-to-treat (mITT) population included eligible subjects who fulfilled all inclusion and exclusion criteria, received first and second vaccination, did not have positive baseline values in ELISA (IMMUNOZYM FSME ELISA and Enzygnost TBE ELISA) and NT, had immunogenicity measurements available at baseline and 28 days after the second vaccination. "Number of subjects analysed"= total number of subjects included in the mITT population. Here, N= number of subjects who were evaluable at specified timeframe for the specified ELISA assay.

End point type	Secondary
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#### End point timeframe:

28 days after the second vaccination, 180 days after the first vaccination, 28 days after the third vaccination

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	149	152		
Units: fold rise				
geometric mean (confidence interval 95%)				
IMMUNOZYM: 180 Days after Vaccination 1(N=142,147)	31.6 (26.8 to 37.2)	9.5 (8.1 to 11)		
IMMUNOZYM: 28 Days after Vaccination 2(N=143,149)	193.7 (163 to 230.1)	39.9 (32.5 to 49)		
IMMUNOZYM: 28 Days after Vaccination 3(N=141,146)	719.9 (591.5 to 876.3)	620.9 (479.7 to 803.6)		
Enzygnost: 180 Days after Vaccination 1(N=148,149)	9.5 (8.2 to 11)	5.3 (4.5 to 6.3)		
Enzygnost: 28 Days after Vaccination 2(N=149,151)	32.5 (30.4 to 34.8)	18.7 (16.3 to 21.5)		
Enzygnost: 28 Days after Vaccination 3(N=147,148)	135.8 (115.3 to 160)	134.6 (106.7 to 169.9)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Frequency and Severity of Systemic Reactions Occuring After First Vaccination

End point title	Frequency and Severity of Systemic Reactions Occuring After First Vaccination
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End point description:

Systemic symptoms included headache, nausea, vomiting, muscle pain, joint pain, swelling of the lymph nodes, loss of appetite and changes in sleeping behavior in all age strata; restlessness in children 1 - 2 years of age; malaise and fatigue in subjects 3 - 11 years of age (Stratum B) as collected in subject diary. The safety analysis set contains all subjects who received the third vaccination of FSME-IMMUN, after first 2 doses of FSME-IMMUN or Encepur.

End point type	Secondary
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End point timeframe:

Within 28 days after the first vaccination

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	150	152		
Units: subjects				
Systemic reactions: None	136	134		
Systemic reactions: Mild	13	15		
Systemic reactions: Moderate	1	3		
Systemic reactions: Severe	0	0		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Frequency and Severity of Systemic Reactions Occuring After Second Vaccination

End point title	Frequency and Severity of Systemic Reactions Occuring After Second Vaccination
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End point description:

Systemic symptoms included headache, nausea, vomiting, muscle pain, joint pain, swelling of the lymph nodes, loss of appetite and changes in sleeping behavior in all age strata; restlessness in children 1 - 2 years of age; malaise and fatigue in subjects 3 - 11 years of age (Stratum B) as collected in subject diary. The safety analysis set contains all subjects who received the third vaccination of FSME-IMMUN, after first 2 doses of FSME-IMMUN or Encepur.

End point type	Secondary
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End point timeframe:

Within 28 days after the second vaccination

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	150	152		
Units: subjects				
Systemic reactions: None	143	144		
Systemic reactions: Mild	7	8		
Systemic reactions: Moderate	0	0		
Systemic reactions: Severe	0	0		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Frequency and Severity of Systemic Reactions Occuring After Third Vaccination

End point title	Frequency and Severity of Systemic Reactions Occuring After Third Vaccination
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End point description:

Systemic symptoms included headache, nausea, vomiting, muscle pain, joint pain, swelling of the lymph nodes, loss of appetite and changes in sleeping behavior in all age strata; restlessness in children 1 - 2 years of age; malaise and fatigue in subjects 3 - 11 years of age (Stratum B) as collected in subject diary. The safety analysis set contains all subjects who received the third vaccination of FSME-IMMUN, after first 2 doses of FSME-IMMUN or Encepur.

End point type	Secondary
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End point timeframe:

Within 28 days after the third vaccination

End point values	FSME-IMMUN- Third Vaccination			
Subject group type	Subject analysis set			
Number of subjects analysed	298			
Units: subjects				
Systemic reactions: None	282			
Systemic reactions: Mild	15			
Systemic reactions: Moderate	1			
Systemic reactions: Severe	0			

## Statistical analyses

No statistical analyses for this end point

## Secondary: Frequency and Severity of Injection Site Reactions Occuring After the First Vaccination

End point title	Frequency and Severity of Injection Site Reactions Occuring After the First Vaccination
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End point description:

Injection site reactions included swelling, induration, redness, injection site pain and tenderness, ecchymosis and hematoma as collected in subject diary. The safety analysis set contains all subjects who received the third vaccination of FSME-IMMUN, after first 2 doses of FSME-IMMUN or Encepur.

End point type	Secondary
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End point timeframe:

Within 6 days of first vaccination (Day 0 to Day 6)

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	150	152		
Units: subjects				
None	131	108		
Unknown	1	0		
Mild	18	41		
Moderate	0	3		
Severe	0	0		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Frequency and Severity of Injection Site Reactions Occuring After the Second Vaccination

End point title	Frequency and Severity of Injection Site Reactions Occuring After the Second Vaccination
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End point description:

Injection site reactions included swelling, induration, redness, injection site pain and tenderness, ecchymosis and hematoma as collected in subject diary. The safety analysis set contains all subjects who received the third vaccination of FSME-IMMUN, after first 2 doses of FSME-IMMUN or Encepur.

End point type	Secondary
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End point timeframe:

Within 6 days of second vaccination (Day 0 to Day 6)

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	150	152		
Units: subjects				
None	137	118		
Mild	12	27		
Moderate	1	7		
Severe	0	0		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Frequency and Severity of Injection Site Reactions Occuring After the Third Vaccination

End point title	Frequency and Severity of Injection Site Reactions Occuring After the Third Vaccination
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End point description:

Injection site reactions included swelling, induration, redness, injection site pain and tenderness, ecchymosis and hematoma as collected in subject diary. The safety analysis set contains all subjects who received the third vaccination of FSME-IMMUN, after first 2 doses of FSME-IMMUN or Encepur.

End point type	Secondary
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End point timeframe:

Within 6 days of third vaccination (Day 0 to Day 6)

<b>End point values</b>	FSME-IMMUN- Third Vaccination			
Subject group type	Subject analysis set			
Number of subjects analysed	298			
Units: subjects				
None	249			
Mild	43			
Moderate	4			
Severe	2			

## Statistical analyses

No statistical analyses for this end point

### Secondary: Frequency and Severity of Adverse Events (AE) Observed Before the Third Vaccination

End point title	Frequency and Severity of Adverse Events (AE) Observed Before the Third Vaccination
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End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. An SAE (serious AE) was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life--threatening experience (immediate risk of dying); persistent or significant disability / incapacity; congenital anomaly. Treatment--emergent are events between first dose of study drug and up to one month after last dose that were absent before treatment or that worsened relative to pre-treatment state. The safety analysis set contains all subjects who received the third vaccination of FSME-IMMUN, after first 2 doses of FSME-IMMUN or Encepur.



End point type	Secondary
End point timeframe:	
Within 28 days after first and second vaccination, after Part A to before the third vaccination	

End point values	FSME-IMMUN	Encepur		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	150	152		
Units: subjects				
Non-Serious AE: within 28 days after Vaccination 1	57	80		
Serious AE: within 28 days after Vaccination 1	1	0		
Non-Serious AE: within 28 days after Vaccination 2	42	66		
Serious AE: within 28 days after Vaccination 2	0	0		
Non-Serious AE: after Part A to before Vaccination 3	97	102		
Serious AE: after Part A to before Vaccination 3	6	10		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Frequency and Severity of Adverse Events (AE) Observed After the Third Vaccination

End point title	Frequency and Severity of Adverse Events (AE) Observed After the Third Vaccination
End point description:	
An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. An SAE (serious AE) was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability / incapacity; congenital anomaly. Treatment-emergent are events between first dose of study drug and up to one month after last dose that were absent before treatment or that worsened relative to pre-treatment state. The safety analysis set contains all subjects who received the third vaccination of FSME-IMMUN, after first 2 doses of FSME-IMMUN or Encepur.	
End point type	Secondary
End point timeframe:	
Within 28 days after third vaccination	

<b>End point values</b>	FSME-IMMUN- Third Vaccination			
Subject group type	Subject analysis set			
Number of subjects analysed	298			
Units: subjects				
Non-Serious AE: within 28 days after Vaccination 3	102			
Serious AE: within 28 days after Vaccination 3	0			

### Statistical analyses

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Within 28 days after first and second vaccination, after Part A to before the third vaccination, within 28 days after third vaccination

Adverse event reporting additional description:

SAEs and AEs were grouped by system organ class and summarized. AEs included AEs collected in subject diary (local and systemic reactions for FSME-IMMUN) and AEs were documented in subject diary (non-systematic assessment).

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	13.0
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### Reporting groups

Reporting group title	Part A (1-2 years of age) FSME-IMMUN: After Vaccination 1
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Reporting group description:

Subjects aged 1 - 2 years who received single dose of 0.25 mL FSME-IMMUN Junior (FSME-IMMUN) suspension at Day 0, assessed after first vaccination.

Reporting group title	Part A (1-2 years of age) FSME-IMMUN: After Vaccination 2
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Reporting group description:

Subjects aged 1 - 2 years who received single dose of 0.25 mL FSME-IMMUN Junior (FSME-IMMUN) suspension at Day 28, assessed after second vaccination.

Reporting group title	Part B (1-2 years of age) FSME-IMMUN: Before Vaccination 3
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Reporting group description:

Subjects aged 1 - 2 years who received single dose of 0.25 mL FSME-IMMUN Junior (FSME-IMMUN) suspension at Day 0 and 28, assessed 28 Days after the second vaccination to prior to third vaccination.

Reporting group title	Part A (3-6 years of age) FSME-IMMUN: After Vaccination 1
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Reporting group description:

Subjects aged 3 - 6 years who received single dose of 0.25 mL FSME-IMMUN Junior (FSME-IMMUN) suspension at Day 0, assessed after first vaccination.

Reporting group title	Part A (3-6 years of age) FSME-IMMUN: After Vaccination 2
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Reporting group description:

Subjects aged 3 - 6 years who received single dose of 0.25 mL FSME-IMMUN Junior (FSME-IMMUN) suspension at Day 28, assessed after second vaccination.

Reporting group title	Part B (3-6 years of age) FSME-IMMUN: Before Vaccination 3
-----------------------	--

Reporting group description:

Subjects aged 3 - 6 years who received single dose of 0.25 mL FSME-IMMUN Junior (FSME-IMMUN) suspension at Day 0 and 28, assessed 28 Days after the second vaccination to prior to third vaccination.

Reporting group title	Part A (7-11 years of age) FSME-IMMUN: After Vaccination 1
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Reporting group description:

Subjects aged 7 - 11 years who received single dose of 0.25 mL FSME-IMMUN Junior (FSME-IMMUN) suspension at Day 0, assessed after first vaccination.

Reporting group title	Part A (7-11 years of age) FSME-IMMUN: After Vaccination 2
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Reporting group description:

Subjects aged 7 - 11 years who received single dose of 0.25 mL FSME-IMMUN Junior (FSME-IMMUN) suspension at Day 28, assessed after second vaccination.

Reporting group title	Part B (7-11 years of age) FSME-IMMUN: Before Vaccination 3
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Reporting group description:

Subjects aged 7 - 11 years who received single dose of 0.25 mL FSME-IMMUN Junior (FSME-IMMUN) suspension at Day 0 and 28, assessed 28 Days after the second vaccination to prior to third vaccination.

Reporting group title	Part A (1-2 years of age) Encepur: After Vaccination 1
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Reporting group description:

Subjects aged 1 - 2 years who received single dose of Encepur Children (Encepur) suspension at Day 0,

assessed after first vaccination.

Reporting group title	Part A (1-2 years of age) Encepur: After Vaccination 2
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Reporting group description:

Subjects aged 1 - 2 years who received single dose of Encepur Children (Encepur) suspension at Day 28, assessed after second vaccination.

Reporting group title	Part B (1-2 years of age) Encepur: Before Vaccination 3
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Reporting group description:

Subjects aged 1 - 2 years who received single dose of Encepur Children (Encepur) suspension at Day 0 and 28, assessed 28 Days after the second vaccination to prior to third vaccination.

Reporting group title	Part A (3-6 years of age) Encepur: After Vaccination 1
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Reporting group description:

Subjects aged 3 - 6 years who received single dose of Encepur Children (Encepur) suspension at Day 0, assessed after first vaccination.

Reporting group title	Part A (3-6 years of age) Encepur: After Vaccination 2
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Reporting group description:

Subjects aged 3 - 6 years who received single dose of Encepur Children (Encepur) suspension at Day 28, assessed after second vaccination.

Reporting group title	Part B (3-6 years of age) Encepur: Before Vaccination 3
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Reporting group description:

Subjects aged 3 - 6 years who received single dose of Encepur Children (Encepur) suspension at Day 0 and 28, assessed 28 Days after the second vaccination to prior to third vaccination.

Reporting group title	Part A (7-11 years of age) Encepur: After Vaccination 1
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Reporting group description:

Subjects aged 7 - 11 years who received single dose of Encepur Children (Encepur) suspension at Day 0, assessed after first vaccination.

Reporting group title	Part A (7-11 years of age) Encepur: After Vaccination 2
-----------------------	---

Reporting group description:

Subjects aged 7 - 11 years who received single dose of Encepur Children (Encepur) suspension at Day 28, assessed after second vaccination.

Reporting group title	Part B (7-11 years of age) Encepur: Before Vaccination 3
-----------------------	--

Reporting group description:

Subjects aged 7 - 11 years who received single dose of Encepur Children (Encepur) suspension at Day 0 and 28, assessed 28 Days after the second vaccination to prior to third vaccination.

Reporting group title	Part B (1-2 years of age) FSME-IMMUN: After Vaccination 3
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Reporting group description:

Subjects aged 1 - 2 years who received either FSME-IMMUN or Encepur during the first and second vaccination, received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination. Assessment of AEs was done after the third vaccination.

Reporting group title	Part B (3-6 years of age) FSME-IMMUN: After Vaccination 3
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Reporting group description:

Subjects aged 3 - 6 years who received either FSME-IMMUN or Encepur during the first and second vaccination, received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination. Assessment of AEs was done after the third vaccination.

Reporting group title	Part B (7-11 years of age) FSME-IMMUN: After Vaccination 3
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Reporting group description:

Subjects aged 7 - 11 years who received either FSME-IMMUN or Encepur during the first and second vaccination, received FSME-IMMUN Junior (FSME-IMMUN) at Day 360 as third vaccination. Assessment of AEs was done after the third vaccination.

Serious adverse events	Part A (1-2 years of age) FSME-IMMUN: After Vaccination 1	Part A (1-2 years of age) FSME-IMMUN: After Vaccination 2	Part B (1-2 years of age) FSME-IMMUN: Before Vaccination 3
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)

number of deaths (all causes) number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Foreign body			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hypospadias			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Orchidopexy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Eustachian tube disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
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			
Acquired phimosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
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			
Adenoidal disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
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			
Laryngitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (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
Bronchitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			

subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute tonsillitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Part A (3-6 years of age) FSME-IMMUN: After Vaccination 1	Part A (3-6 years of age) FSME-IMMUN: After Vaccination 2	Part B (3-6 years of age) FSME-IMMUN: Before Vaccination 3
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	3 / 51 (5.88%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Foreign body			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hypospadias			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Orchidopexy			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Eustachian tube disorder			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Acquired phimosis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Adenoidal disorder			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			



subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Laryngitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute tonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Part A (7-11 years of age) FSME-IMMUN: After Vaccination 1	Part A (7-11 years of age) FSME-IMMUN: After Vaccination 2	Part B (7-11 years of age) FSME-IMMUN: Before Vaccination 3
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	2 / 48 (4.17%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Foreign body			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hypospadias			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Orchidopexy			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Eustachian tube disorder			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
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			

Acquired phimosis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adenoidal disorder			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
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			
Laryngitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Otitis media chronic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute tonsillitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Part A (1-2 years of age) Encepur: After Vaccination 1	Part A (1-2 years of age) Encepur: After Vaccination 2	Part B (1-2 years of age) Encepur: Before Vaccination 3
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	4 / 50 (8.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Foreign body			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hypospadias			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			

subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Orchidopexy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Eustachian tube disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
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			
Adenoidal disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			

subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Infections and infestations</b>			
Laryngitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute tonsillitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Part A (3-6 years of age) Encepur: After Vaccination 1	Part A (3-6 years of age) Encepur: After Vaccination 2	Part B (3-6 years of age) Encepur: Before Vaccination 3
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	3 / 51 (5.88%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Foreign body			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hypospadias			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Orchidopexy			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Eustachian tube disorder			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Acquired phimosis			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Adenoidal disorder			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
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			
Laryngitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0



Otitis media chronic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute tonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Part A (7-11 years of age) Encepur: After Vaccination 1	Part A (7-11 years of age) Encepur: After Vaccination 2	Part B (7-11 years of age) Encepur: Before Vaccination 3
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	3 / 51 (5.88%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Foreign body			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hypospadias			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Orchidopexy			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Eustachian tube disorder			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Acquired phimosis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Adenoidal disorder			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Infections and infestations</b>			
Laryngitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute tonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Part B (1-2 years of age) FSME-IMMUN: After Vaccination 3	Part B (3-6 years of age) FSME-IMMUN: After Vaccination 3	Part B (7-11 years of age) FSME-IMMUN: After Vaccination 3
<b>Total subjects affected by serious adverse events</b>			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
<b>Injury, poisoning and procedural complications</b>			
Foreign body			

subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hypospadias			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Orchidopexy			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Eustachian tube disorder			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
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			
Acquired phimosis			

subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
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			
Adenoidal disorder			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
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			
Laryngitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Otitis media chronic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute tonsillitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

<b>Non-serious adverse events</b>	Part A (1-2 years of age) FSME-IMMUN: After Vaccination 1	Part A (1-2 years of age) FSME-IMMUN: After Vaccination 2	Part B (1-2 years of age) FSME-IMMUN: Before Vaccination 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 50 (34.00%)	13 / 50 (26.00%)	37 / 50 (74.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			

subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Injection site pain			
subjects affected / exposed	1 / 50 (2.00%)	2 / 50 (4.00%)	0 / 50 (0.00%)
occurrences (all)	1	2	0
Injection site swelling			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Injection site haemorrhage			
subjects affected / exposed	2 / 50 (4.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Influenza like illness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Allergic oedema			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Multiple allergies			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Reproductive system and breast disorders			
Balanitis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Acquired phimosis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Tonsillar hypertrophy subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Adenoidal hypertrophy subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Adenoidal disorder subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Asthma subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Tracheal pain subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Psychiatric disorders			



Restlessness subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 2	2 / 50 (4.00%) 2	0 / 50 (0.00%) 0
Sleep disorder subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 2	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Attention deficit/hyperactivity disorder subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Tic subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Investigations Blood thyroid stimulating hormone increased subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Body temperature increased subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Heart rate increased subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Joint sprain subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Head injury subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Arthropod bite subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1

Limb injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Mouth injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Clavicle fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Forearm fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Heat stroke			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0

Open wound subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Wrist fracture subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Traumatic liver injury subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Congenital, familial and genetic disorders Cryptorchism subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Lymphadenitis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Middle ear inflammation subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Eye disorders			

Conjunctivitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	4 / 50 (8.00%)
occurrences (all)	0	0	4
Nausea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	3 / 50 (6.00%)
occurrences (all)	0	0	3
Dyspepsia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Enterocolitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Aphthous stomatitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Anal fissure			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Eczema			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Micturition disorder subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Endocrine disorders Thyroiditis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Musculoskeletal and connective tissue disorders Pain in extremity subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Arthralgia subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Arthritis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Foot deformity subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Infections and infestations Acute tonsillitis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	5 / 50 (10.00%) 5
Bronchitis subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 50 (0.00%) 0	4 / 50 (8.00%) 7
Erythema infectiosum subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	2 / 50 (4.00%) 2	0 / 50 (0.00%) 0

Impetigo			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	3 / 50 (6.00%)
occurrences (all)	0	1	4
Otitis media			
subjects affected / exposed	1 / 50 (2.00%)	3 / 50 (6.00%)	8 / 50 (16.00%)
occurrences (all)	1	3	11
Pharyngitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 50 (0.00%)	2 / 50 (4.00%)	10 / 50 (20.00%)
occurrences (all)	0	3	12
Tracheitis			
subjects affected / exposed	1 / 50 (2.00%)	2 / 50 (4.00%)	17 / 50 (34.00%)
occurrences (all)	1	2	24
Viral infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	4 / 50 (8.00%)
occurrences (all)	0	0	4
Cellulitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	3 / 50 (6.00%)
occurrences (all)	1	0	3
Varicella			
subjects affected / exposed	2 / 50 (4.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	2	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Bacterial infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1

Cystitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Genital candidiasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0



Conjunctivitis infective			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Enterobiasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Exanthema subitum			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Herpangina			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Pseudocroup			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Respiratory tract infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Bronchopneumonia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0

Scarlet fever			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Viral tonsillitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Bronchitis bacterial			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Underweight			

subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Part A (3-6 years of age) FSME-IMMUN: After Vaccination 1	Part A (3-6 years of age) FSME-IMMUN: After Vaccination 2	Part B (3-6 years of age) FSME-IMMUN: Before Vaccination 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 51 (29.41%)	11 / 51 (21.57%)	30 / 51 (58.82%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	4 / 51 (7.84%)	3 / 51 (5.88%)	3 / 51 (5.88%)
occurrences (all)	6	3	3
Fatigue			
subjects affected / exposed	2 / 51 (3.92%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	2	0	0
Malaise			
subjects affected / exposed	1 / 51 (1.96%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Injection site erythema			
subjects affected / exposed	1 / 51 (1.96%)	2 / 51 (3.92%)	0 / 51 (0.00%)
occurrences (all)	1	2	0
Injection site induration			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Injection site pain			

subjects affected / exposed	3 / 51 (5.88%)	3 / 51 (5.88%)	0 / 51 (0.00%)
occurrences (all)	3	4	0
Injection site swelling			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Injection site haematoma			
subjects affected / exposed	1 / 51 (1.96%)	2 / 51 (3.92%)	0 / 51 (0.00%)
occurrences (all)	1	2	0
Injection site haemorrhage			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 51 (0.00%)	2 / 51 (3.92%)	0 / 51 (0.00%)
occurrences (all)	0	3	0
Allergic oedema			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Multiple allergies			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Balanitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Acquired phimosis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
Epistaxis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Adenoidal disorder			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Asthma			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Tracheal pain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Restlessness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			

subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Tic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Joint sprain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	3 / 51 (5.88%)
occurrences (all)	0	0	3
Limb injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Burns second degree			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Forearm fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Muscle strain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Ankle fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Heat stroke			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Open wound			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			

subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Traumatic liver injury subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Congenital, familial and genetic disorders Cryptorchism subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Lymphadenitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Middle ear inflammation subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Conjunctivitis allergic			



subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	1 / 51 (1.96%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 51 (1.96%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Toothache			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Enterocolitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Anal fissure subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Hepatobiliary disorders Hepatic steatosis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Skin and subcutaneous tissue disorders Dermatitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Dermatitis diaper subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1	1 / 51 (1.96%) 1
Urticaria subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Dermatitis atopic subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Dermatitis allergic subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Renal and urinary disorders Micturition disorder subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Endocrine disorders			

Thyroiditis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Pain in extremity subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Arthralgia subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Arthritis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Foot deformity subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Infections and infestations			
Acute tonsillitis subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0	4 / 51 (7.84%) 4
Bronchitis subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Erythema infectiosum subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Impetigo subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Laryngitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Otitis media			

subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	1	0	2
Tonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	2
Tracheitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	7 / 51 (13.73%)
occurrences (all)	0	0	9
Viral infection			
subjects affected / exposed	2 / 51 (3.92%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	2	0	2
Cellulitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	4 / 51 (7.84%)
occurrences (all)	0	1	4
Varicella			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	3 / 51 (5.88%)
occurrences (all)	0	1	3
Nasopharyngitis			

subjects affected / exposed	2 / 51 (3.92%)	1 / 51 (1.96%)	7 / 51 (13.73%)
occurrences (all)	2	1	8
Genital candidiasis			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	2 / 51 (3.92%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	2	0	2
Oral herpes			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	2
Otitis media acute			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pseudocroup			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Bronchopneumonia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Scarlet fever			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Parotitis			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Viral tonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	3
Bronchitis bacterial			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Underweight			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Part A (7-11 years of age) FSME-IMMUN: After Vaccination 1	Part A (7-11 years of age) FSME-IMMUN: After Vaccination 2	Part B (7-11 years of age) FSME-IMMUN: Before Vaccination 3
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Total subjects affected by non-serious adverse events subjects affected / exposed	14 / 49 (28.57%)	10 / 49 (20.41%)	30 / 48 (62.50%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Melanocytic naevus subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	0 / 49 (0.00%) 0	0 / 48 (0.00%) 0
Surgical and medical procedures Tooth extraction subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	0 / 49 (0.00%) 0	0 / 48 (0.00%) 0
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	4 / 49 (8.16%) 4	1 / 49 (2.04%) 2	5 / 48 (10.42%) 5
Fatigue subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	2 / 49 (4.08%) 2	0 / 48 (0.00%) 0
Malaise subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	0 / 49 (0.00%) 0	0 / 48 (0.00%) 0
Injection site erythema subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	0 / 49 (0.00%) 0	0 / 48 (0.00%) 0
Injection site induration subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 2	1 / 49 (2.04%) 1	0 / 48 (0.00%) 0
Injection site pain subjects affected / exposed occurrences (all)	10 / 49 (20.41%) 15	5 / 49 (10.20%) 7	0 / 48 (0.00%) 0
Injection site swelling subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	0 / 49 (0.00%) 0	0 / 48 (0.00%) 0
Injection site haematoma subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	0 / 49 (0.00%) 0	0 / 48 (0.00%) 0
Injection site haemorrhage			



subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Allergic oedema			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Multiple allergies			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Acquired phimosis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	3 / 48 (6.25%)
occurrences (all)	0	0	4
Epistaxis			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Adenoidal disorder			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	2
Tracheal pain			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Psychiatric disorders			
Restlessness			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Tic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Investigations			

Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Body temperature increased			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Joint sprain			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
Limb injury			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Burns second degree			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Mouth injury			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Forearm fracture			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Heat stroke			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Open wound			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Wrist fracture			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Traumatic liver injury			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Cryptorchism			

subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	0 / 49 (0.00%) 0	0 / 48 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	0 / 49 (0.00%) 0	0 / 48 (0.00%) 0
Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all)  Anaemia subjects affected / exposed occurrences (all)  Lymphadenitis subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0  0 / 49 (0.00%) 0  0 / 49 (0.00%) 0	0 / 49 (0.00%) 0  0 / 49 (0.00%) 0  0 / 49 (0.00%) 0	0 / 48 (0.00%) 0  0 / 48 (0.00%) 0  0 / 48 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)  Middle ear inflammation subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0  0 / 49 (0.00%) 0	1 / 49 (2.04%) 1  1 / 49 (2.04%) 1	0 / 48 (0.00%) 0  0 / 48 (0.00%) 0
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)  Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0  0 / 49 (0.00%) 0	0 / 49 (0.00%) 0  0 / 49 (0.00%) 0	0 / 48 (0.00%) 0  0 / 48 (0.00%) 0
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)  Enteritis subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0  0 / 49 (0.00%) 0	0 / 49 (0.00%) 0  0 / 49 (0.00%) 0	0 / 48 (0.00%) 0  0 / 48 (0.00%) 0

Nausea			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	3 / 49 (6.12%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	3	0	0
Toothache			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Enterocolitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			

subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	0 / 49 (0.00%) 0	0 / 48 (0.00%) 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Dermatitis atopic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Micturition disorder			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Thyroiditis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0

Arthralgia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Foot deformity			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute tonsillitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	3 / 48 (6.25%)
occurrences (all)	0	1	4
Erythema infectiosum			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	3 / 49 (6.12%)	0 / 49 (0.00%)	9 / 48 (18.75%)
occurrences (all)	3	0	9
Tonsillitis			



subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	5 / 48 (10.42%)
occurrences (all)	1	0	6
Tracheitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	2 / 49 (4.08%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	2	0	1
Cellulitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
Nasopharyngitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	6 / 48 (12.50%)
occurrences (all)	0	1	6
Genital candidiasis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 49 (2.04%)	1 / 49 (2.04%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
Oral herpes			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Pneumonia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Pseudocroup			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Scarlet fever			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	2 / 48 (4.17%)
occurrences (all)	0	0	2
Tooth infection			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Viral tonsillitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Otitis externa			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Pharyngotonsillitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Viral rash			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Bronchitis bacterial			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Underweight			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Part A (1-2 years of age) Encepur: After Vaccination 1	Part A (1-2 years of age) Encepur: After Vaccination 2	Part B (1-2 years of age) Encepur: Before Vaccination 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 50 (50.00%)	13 / 50 (26.00%)	39 / 50 (78.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			

Tooth extraction subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
General disorders and administration site conditions			
Pyrexia subjects affected / exposed occurrences (all)	9 / 50 (18.00%) 9	3 / 50 (6.00%) 3	0 / 50 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Malaise subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Injection site erythema subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Injection site induration subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Injection site pain subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 4	1 / 50 (2.00%) 1	0 / 50 (0.00%) 0
Injection site swelling subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Injection site haematoma subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Injection site haemorrhage subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Influenza like illness subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Tenderness			

subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Injection site pruritus subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Immune system disorders			
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Allergic oedema subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Multiple allergies subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Reproductive system and breast disorders			
Balanitis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	2 / 50 (4.00%) 2	2 / 50 (4.00%) 2
Acquired phimosis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Tonsillar hypertrophy subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Adenoidal hypertrophy			

subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Adenoidal disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Tracheal pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Restlessness			
subjects affected / exposed	5 / 50 (10.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	5	1	0
Sleep disorder			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Tic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			

subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	3 / 50 (6.00%)
occurrences (all)	0	0	4
Joint sprain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Limb injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Joint dislocation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Forearm fracture			



subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Heat stroke			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Open wound			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Traumatic liver injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Cryptorchism			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Lymphadenitis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Middle ear inflammation subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Enteritis subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 50 (0.00%) 0	3 / 50 (6.00%) 4
Nausea subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Toothache			

subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Dyspepsia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Enterocolitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Dermatitis diaper			

subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	3 / 50 (6.00%)
occurrences (all)	1	0	4
Eczema			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Dermatitis atopic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Micturition disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Thyroiditis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Arthritis			

subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Foot deformity subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Infections and infestations			
Acute tonsillitis subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 2	1 / 50 (2.00%) 1	5 / 50 (10.00%) 7
Bronchitis subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 2	1 / 50 (2.00%) 1	0 / 50 (0.00%) 0
Erythema infectiosum subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Impetigo subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Laryngitis subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3	1 / 50 (2.00%) 1	2 / 50 (4.00%) 3
Otitis media subjects affected / exposed occurrences (all)	5 / 50 (10.00%) 5	1 / 50 (2.00%) 1	8 / 50 (16.00%) 10
Pharyngitis subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Tonsillitis subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3	0 / 50 (0.00%) 0	12 / 50 (24.00%) 13
Tracheitis subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	3 / 50 (6.00%) 3	12 / 50 (24.00%) 22
Viral infection subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	1 / 50 (2.00%) 1	1 / 50 (2.00%) 1

Cellulitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Varicella			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	2 / 50 (4.00%)
occurrences (all)	0	1	2
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	5 / 50 (10.00%)
occurrences (all)	0	0	7
Genital candidiasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	4 / 50 (8.00%)
occurrences (all)	0	0	4
Rhinitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Otitis media acute			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Conjunctivitis infective			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	3
Ear infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Enterobiasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Exanthema subitum			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Fungal skin infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Herpangina			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1

Pseudocroup			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	3
Respiratory tract infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Respiratory tract infection viral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	3 / 50 (6.00%)
occurrences (all)	0	0	3
Bronchopneumonia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Scarlet fever			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Viral tonsillitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0



Sinusitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Bronchitis bacterial			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 50 (4.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
Underweight			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Obesity			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Part A (3-6 years of age) Encepur: After Vaccination 1	Part A (3-6 years of age) Encepur: After Vaccination 2	Part B (3-6 years of age) Encepur: Before Vaccination 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 51 (64.71%)	19 / 51 (37.25%)	33 / 51 (64.71%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	5 / 51 (9.80%)	3 / 51 (5.88%)	2 / 51 (3.92%)
occurrences (all)	5	4	2
Fatigue			

subjects affected / exposed	3 / 51 (5.88%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	3	1	0
Malaise			
subjects affected / exposed	1 / 51 (1.96%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Injection site erythema			
subjects affected / exposed	3 / 51 (5.88%)	2 / 51 (3.92%)	0 / 51 (0.00%)
occurrences (all)	3	2	0
Injection site induration			
subjects affected / exposed	3 / 51 (5.88%)	3 / 51 (5.88%)	0 / 51 (0.00%)
occurrences (all)	3	3	0
Injection site pain			
subjects affected / exposed	10 / 51 (19.61%)	6 / 51 (11.76%)	0 / 51 (0.00%)
occurrences (all)	13	8	0
Injection site swelling			
subjects affected / exposed	1 / 51 (1.96%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Injection site haematoma			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Injection site haemorrhage			
subjects affected / exposed	2 / 51 (3.92%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	2	0	0
Influenza like illness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Allergic oedema subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Multiple allergies subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Reproductive system and breast disorders Balanitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Acquired phimosis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	2 / 51 (3.92%) 2	3 / 51 (5.88%) 3	1 / 51 (1.96%) 1
Epistaxis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Tonsillar hypertrophy subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Adenoidal hypertrophy subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Adenoidal disorder subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Asthma			

subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Tracheal pain subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Psychiatric disorders			
Restlessness subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Sleep disorder subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Attention deficit/hyperactivity disorder subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Tic subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Investigations			
Blood thyroid stimulating hormone increased subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Body temperature increased subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Heart rate increased subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Joint sprain subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0

Head injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Limb injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Forearm fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Skin laceration subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Heat stroke subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Open wound subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Wrist fracture subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Traumatic liver injury subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Congenital, familial and genetic disorders Cryptorchism subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1	4 / 51 (7.84%) 4	0 / 51 (0.00%) 0
Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Lymphadenitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Ear and labyrinth disorders Ear pain			

subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Middle ear inflammation subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Eye disorders			
Conjunctivitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Enteritis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	2 / 51 (3.92%) 2	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	3 / 51 (5.88%) 3	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Abdominal pain			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Enterocolitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Dermatitis atopic			



subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Dermatitis allergic subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Renal and urinary disorders Micturition disorder subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Haematuria subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Endocrine disorders Thyroiditis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Musculoskeletal and connective tissue disorders Pain in extremity subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Arthralgia subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	2 / 51 (3.92%) 2	0 / 51 (0.00%) 0
Arthritis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Foot deformity subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Infections and infestations Acute tonsillitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	4 / 51 (7.84%) 4

Bronchitis			
subjects affected / exposed	0 / 51 (0.00%)	2 / 51 (3.92%)	4 / 51 (7.84%)
occurrences (all)	0	2	5
Erythema infectiosum			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Impetigo			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	1 / 51 (1.96%)	1 / 51 (1.96%)	2 / 51 (3.92%)
occurrences (all)	1	1	2
Pharyngitis			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	5 / 51 (9.80%)
occurrences (all)	0	1	5
Tonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	3 / 51 (5.88%)
occurrences (all)	0	0	6
Tracheitis			
subjects affected / exposed	0 / 51 (0.00%)	2 / 51 (3.92%)	6 / 51 (11.76%)
occurrences (all)	0	2	10
Viral infection			
subjects affected / exposed	2 / 51 (3.92%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	2	0	1
Cellulitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	0 / 51 (0.00%)	3 / 51 (5.88%)	5 / 51 (9.80%)
occurrences (all)	0	3	5

Viral upper respiratory tract infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	1 / 51 (1.96%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Influenza			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	1 / 51 (1.96%)	1 / 51 (1.96%)	7 / 51 (13.73%)
occurrences (all)	1	1	7
Genital candidiasis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
Rhinitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	0	1	1
Otitis media acute			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1

Paronychia			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Acute sinusitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	2
Exanthema subitum			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	2
Herpes simplex			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Pseudocroup			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Bronchopneumonia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	2
Gastroenteritis viral			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Scarlet fever			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Parotitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Viral tonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Bronchitis bacterial			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	2 / 51 (3.92%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	2	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Underweight			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Part A (7-11 years of age) Encepur: After Vaccination 1	Part A (7-11 years of age) Encepur: After Vaccination 2	Part B (7-11 years of age) Encepur: Before Vaccination 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 51 (58.82%)	26 / 51 (50.98%)	30 / 51 (58.82%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	4 / 51 (7.84%)	2 / 51 (3.92%)	3 / 51 (5.88%)
occurrences (all)	5	2	4
Fatigue			
subjects affected / exposed	2 / 51 (3.92%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	2	0	0
Malaise			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			

subjects affected / exposed occurrences (all)	3 / 51 (5.88%) 3	4 / 51 (7.84%) 4	0 / 51 (0.00%) 0
Injection site induration subjects affected / exposed occurrences (all)	4 / 51 (7.84%) 4	2 / 51 (3.92%) 2	0 / 51 (0.00%) 0
Injection site pain subjects affected / exposed occurrences (all)	24 / 51 (47.06%) 30	24 / 51 (47.06%) 30	0 / 51 (0.00%) 0
Injection site swelling subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	3 / 51 (5.88%) 3	0 / 51 (0.00%) 0
Injection site haematoma subjects affected / exposed occurrences (all)	2 / 51 (3.92%) 2	3 / 51 (5.88%) 3	0 / 51 (0.00%) 0
Injection site haemorrhage subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Influenza like illness subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Tenderness subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Injection site pruritus subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Immune system disorders			
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Allergic oedema subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Multiple allergies subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Reproductive system and breast disorders			
Balanitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Acquired phimosis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	2 / 51 (3.92%) 2
Epistaxis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Tonsillar hypertrophy subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Adenoidal hypertrophy subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Adenoidal disorder subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Asthma subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Tracheal pain subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Psychiatric disorders			



Restlessness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Tic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 51 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Heart rate increased			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Joint sprain			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
Head injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1

Limb injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Forearm fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Joint injury			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Skin laceration			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Heat stroke			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Open wound subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Wrist fracture subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Traumatic liver injury subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Congenital, familial and genetic disorders Cryptorchism subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Lymphadenitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Middle ear inflammation subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Eye disorders			

Conjunctivitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Enteritis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	2 / 51 (3.92%) 2	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Enterocolitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Stomatitis			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Dermatitis allergic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	2
Renal and urinary disorders			

Micturition disorder subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Endocrine disorders Thyroiditis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Musculoskeletal and connective tissue disorders Pain in extremity subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Arthralgia subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Arthritis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Foot deformity subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Infections and infestations Acute tonsillitis subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	2 / 51 (3.92%) 2
Bronchitis subjects affected / exposed occurrences (all)	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0	4 / 51 (7.84%) 5
Erythema infectiosum subjects affected / exposed occurrences (all)	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0

Impetigo			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	5 / 51 (9.80%)
occurrences (all)	1	0	5
Tonsillitis			
subjects affected / exposed	1 / 51 (1.96%)	1 / 51 (1.96%)	2 / 51 (3.92%)
occurrences (all)	1	1	2
Tracheitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	3 / 51 (5.88%)
occurrences (all)	1	0	3
Cellulitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Cystitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 51 (5.88%)	1 / 51 (1.96%)	7 / 51 (13.73%)
occurrences (all)	3	1	7
Genital candidiasis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Otitis media acute			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1



Conjunctivitis infective			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	2
Exanthema subitum			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pseudocroup			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1

Scarlet fever			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Viral tonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	2
Bronchitis bacterial			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 51 (1.96%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Underweight			

subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 51 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1

<b>Non-serious adverse events</b>	Part B (1-2 years of age) FSME-IMMUN: After Vaccination 3	Part B (3-6 years of age) FSME-IMMUN: After Vaccination 3	Part B (7-11 years of age) FSME-IMMUN: After Vaccination 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 99 (23.23%)	29 / 100 (29.00%)	30 / 99 (30.30%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	3 / 99 (3.03%)	8 / 100 (8.00%)	0 / 99 (0.00%)
occurrences (all)	3	8	0
Fatigue			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	3 / 99 (3.03%)
occurrences (all)	0	1	3
Malaise			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Injection site erythema			
subjects affected / exposed	1 / 99 (1.01%)	4 / 100 (4.00%)	4 / 99 (4.04%)
occurrences (all)	1	4	4
Injection site induration			
subjects affected / exposed	0 / 99 (0.00%)	3 / 100 (3.00%)	6 / 99 (6.06%)
occurrences (all)	0	3	6
Injection site pain			

subjects affected / exposed	2 / 99 (2.02%)	13 / 100 (13.00%)	27 / 99 (27.27%)
occurrences (all)	2	17	38
Injection site swelling			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	7 / 99 (7.07%)
occurrences (all)	0	1	7
Injection site haematoma			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	3 / 99 (3.03%)
occurrences (all)	0	1	3
Injection site haemorrhage			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Injection site pruritus			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Allergic oedema			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Multiple allergies			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Balanitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Acquired phimosis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	1 / 99 (1.01%)
occurrences (all)	0	1	1
Epistaxis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Adenoidal disorder			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Tracheal pain			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Restlessness			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			

subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Tic			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Joint sprain			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Burns second degree			

subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Forearm fracture			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Heat stroke			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Open wound			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			

subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Traumatic liver injury subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Congenital, familial and genetic disorders Cryptorchism subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	3 / 100 (3.00%) 3	7 / 99 (7.07%) 7
Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 100 (1.00%) 1	0 / 99 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Lymphadenitis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 100 (1.00%) 1	0 / 99 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Middle ear inflammation subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Conjunctivitis allergic			



subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 99 (0.00%)	3 / 100 (3.00%)	1 / 99 (1.01%)
occurrences (all)	0	4	1
Toothache			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Enterocolitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0

Anal fissure subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 100 (1.00%) 1	0 / 99 (0.00%) 0
Hepatobiliary disorders Hepatic steatosis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Skin and subcutaneous tissue disorders Dermatitis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Dermatitis diaper subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Urticaria subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Dermatitis atopic subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Dermatitis allergic subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Renal and urinary disorders Micturition disorder subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Endocrine disorders			

Thyroiditis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Pain in extremity subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 100 (1.00%) 1	0 / 99 (0.00%) 0
Arthralgia subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 100 (1.00%) 1	0 / 99 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	1 / 100 (1.00%) 1	2 / 99 (2.02%) 2
Arthritis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Foot deformity subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Infections and infestations			
Acute tonsillitis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Bronchitis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	2 / 100 (2.00%) 2	0 / 99 (0.00%) 0
Erythema infectiosum subjects affected / exposed occurrences (all)	1 / 99 (1.01%) 1	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Impetigo subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Laryngitis subjects affected / exposed occurrences (all)	0 / 99 (0.00%) 0	0 / 100 (0.00%) 0	0 / 99 (0.00%) 0
Otitis media			

subjects affected / exposed	5 / 99 (5.05%)	2 / 100 (2.00%)	0 / 99 (0.00%)
occurrences (all)	5	2	0
Pharyngitis			
subjects affected / exposed	0 / 99 (0.00%)	6 / 100 (6.00%)	1 / 99 (1.01%)
occurrences (all)	0	7	2
Tonsillitis			
subjects affected / exposed	3 / 99 (3.03%)	2 / 100 (2.00%)	0 / 99 (0.00%)
occurrences (all)	3	2	0
Tracheitis			
subjects affected / exposed	5 / 99 (5.05%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	5	0	0
Viral infection			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	2	0	0
Cellulitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Varicella			
subjects affected / exposed	3 / 99 (3.03%)	1 / 100 (1.00%)	0 / 99 (0.00%)
occurrences (all)	3	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			

subjects affected / exposed	0 / 99 (0.00%)	2 / 100 (2.00%)	3 / 99 (3.03%)
occurrences (all)	0	2	3
Genital candidiasis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 99 (0.00%)	2 / 100 (2.00%)	1 / 99 (1.01%)
occurrences (all)	0	2	1
Oral herpes			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis infective			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			

subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Exanthema subitum			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Herpangina			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Pseudocroup			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Bronchopneumonia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Scarlet fever			
subjects affected / exposed	1 / 99 (1.01%)	1 / 100 (1.00%)	0 / 99 (0.00%)
occurrences (all)	1	1	0
Tooth infection			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Parotitis			

subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Viral tonsillitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	2	0	0
Bronchitis bacterial			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 99 (0.00%)	2 / 100 (2.00%)	0 / 99 (0.00%)
occurrences (all)	0	2	0
Hyperglycaemia			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Underweight			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported