

## Case Series Drug Analysis Print

**Name: FSME-IMMUN 0.5ML BAXTER (TicoVac) FOI 21/1063**

Report Run Date: 07-Oct-2021  
Data Lock Date: 30-Sep-2021 18:30:04  
Earliest Reaction Date: 06-Nov-2014  
MedDRA Version: MedDRA 24.0

FSME-IMMUN 0.5ML BAXTER (TicoVac) FOI 21/1063: All UK spontaneous reports received up until 30-Sep-2021 for the FSME-IMMUN 0.5ML BAXTER (TicoVac) Vaccine analysis print. A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Inner ear signs and symptoms</i>		
Vertigo	1	0
<b>Ear disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<b>Eye disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Nausea and vomiting symptoms</i>		
Nausea	3	0
Vomiting	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	1	0
Fatigue	1	0
Malaise	3	0
<i><b>Febrile disorders</b></i>		
Pyrexia	1	0
<i><b>General signs and symptoms NEC</b></i>		
Influenza like illness	1	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site pain	1	0
Vaccination site reaction	1	0
<b>General disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	1	0
<b>Injuries SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle pains</i>		
Myalgia	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Pain in extremity	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Coordination and balance disturbances</b></i>		
Balance disorder	1	0
<i><b>Demyelinating disorders NEC</b></i>		
Demyelination	1	0
<i><b>Disturbances in consciousness NEC</b></i>		
Depressed level of consciousness	1	0
Somnolence	1	0
Syncope	1	0
<i><b>Headaches NEC</b></i>		
Cold-stimulus headache	1	0
Headache	2	0
<i><b>Neurological signs and symptoms NEC</b></i>		
Dizziness	1	0
<i><b>Seizures and seizure disorders NEC</b></i>		
Seizure	1	0
<i><b>Sensory abnormalities NEC</b></i>		
Taste disorder	3	0
<b>Nervous system disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Pruritus NEC</i>		
Pruritus	1	0
<i>Rashes, eruptions and exantheams NEC</i>		
Rash	1	0
Rash macular	1	0
<i>Urticarias</i>		
Urticaria	1	0
<b>Skin disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>43</b>	<b>0</b>
<b>TOTAL REPORTS</b>	<b>13</b>	