

**Case Series Drug Analysis Print**  
**Name: FOI 22/1193 - Supemtek DAP**

Report Run Date: 10-Jan-2023  
Data Lock Date: 13-Dec-2022 18:30:05  
Earliest Reaction Date: 19-Nov-2021  
MedDRA Version: MedDRA 25.1

FOI 22/1193 - FOI 22/1193 All spontaneous suspected UK Adverse  
Supemtek DAP: Drug Reaction (ADR) reports associated with the  
Supemtek vaccine received up to and including  
13/12/2022

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Ocular hyperaemia	1	0
<b>Eye disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain upper	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Gastric dilatation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
<i>Nausea and vomiting symptoms</i>		
Retching	1	0
Vomiting	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Fatigue	1	0
Malaise	3	0
<i><b>Febrile disorders</b></i>		
Pyrexia	1	0
<i><b>Feelings and sensations NEC</b></i>		
Feeling hot	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	1	0
<i><b>Pain and discomfort NEC</b></i>		
Pain	1	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site erythema	1	0
Vaccination site pain	3	0
Vaccination site pruritus	1	0
Vaccination site swelling	1	0
<b>General disorders SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Bacterial infections NEC</i>		
Bacterial infection	1	0
<b>Infections SOC TOTAL</b>	<b>1</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle tone abnormalities</i>		
Muscle rigidity	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Musculoskeletal chest pain	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Disturbances in consciousness NEC</i>		
Somnolence	1	0
<i>Headaches NEC</i>		
Headache	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>



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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Respiratory disorders</b>		
<i>Bronchospasm and obstruction</i>		
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Rhinorrhoea	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Skin disorders</b>		
<i>Pruritus NEC</i>		
Pruritus	2	0
<i>Rashes, eruptions and exantheams NEC</i>		
Rash	2	0
Rash pruritic	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<b>Skin disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>

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<b>Vascular disorders</b>		
<i>Circulatory collapse and shock</i>		
Shock	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>40</b>	<b>0</b>
<b>TOTAL REPORTS</b>	<b>8</b>	