

## Case Series Drug Analysis Print

**Name: All UK spontaneous Vixelis reports received up to and including 12/02/2023**

Report Run Date: 13-Feb-2024

Data Lock Date: 12-Feb-2024 18:30:04

Earliest Reaction Date: 21-Mar-2022

MedDRA Version: MedDRA 26.1

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Nausea and vomiting symptoms</i>		
Nausea	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral pain	1	0
<i>Stomatitis and ulceration</i>		
Stomatitis	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Febrile disorders</i>		
Pyrexia	1	0
<i>General signs and symptoms NEC</i>		
High-pitched crying	1	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	1	0
<b>General disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Medication errors, product use errors and issues NEC</i>		
Product use in unapproved indication	1	0
<i>Product administration errors and issues</i>		
Incorrect route of product administration	1	0
<b>Injuries SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Urticaria	1	0
<b>Skin disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Site specific vascular disorders NEC</i>		
Pallor	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>13</b>	<b>0</b>
<b>TOTAL REPORTS</b>	<b>6</b>	