

## Case Series Drug Analysis Print

**Name: Inflexal FOI 21/1063**

Report Run Date: 07-Oct-2021  
Data Lock Date: 30-Sep-2021 18:30:04  
Earliest Reaction Date: 01-Oct-2002  
MedDRA Version: MedDRA 24.0

Inflexal FOI 21/1063: All UK spontaneous reports received up until 30-Sep-2021 for the Inflexal 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>Cardiac disorders</b>		
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	1	0
Tachycardia paroxysmal	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	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>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>1</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	1	0
<i><b>Febrile disorders</b></i>		
Pyrexia	1	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	1	0
<i><b>General signs and symptoms NEC</b></i>		
Swelling	1	0
<i><b>Injection site reactions</b></i>		
Injection site induration	1	0
Injection site pain	1	0
<i><b>Pain and discomfort NEC</b></i>		
Pain	1	0
<b>General disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Coagulation and bleeding analyses</i>		
International normalised ratio increased	1	0
<b>Investigations SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Arthropathies NEC</i>		
Arthropathy	1	0
<i>Muscle pains</i>		
Myalgia	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Pain in extremity	2	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>



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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Nervous system disorders</b>		
<i>Headaches NEC</i>		
Headache	2	0
<i>Paraesthesias and dysaesthesias</i>		
Paraesthesia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
<i>Parasomnias</i>		
Abnormal dreams	1	0
<i>Perception disturbances NEC</i>		
Illusion	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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<b>Skin disorders</b>		
<i>Apocrine and eccrine gland disorders</i>		
Night sweats	1	0
<i>Erythemas</i>		
Erythema	1	0
<i>Pruritus NEC</i>		
Pruritus	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash macular	1	0
<b>Skin disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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<b>Vascular disorders</b>		
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>34</b>	<b>0</b>
<b>TOTAL REPORTS</b>	<b>14</b>	