

## Case Series Drug Analysis Print

**Name: Copy of Grazax: All UK Spontaneous Reports**

Report Run Date: 21-Jun-2023  
Data Lock Date: 06-Jun-2023 18:30:04  
Earliest Reaction Date: 07-Mar-2007  
MedDRA Version: MedDRA 26

All UK spontaneous Grazax reports received up to and including 06/06/2023  
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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pruritus	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
<b>Ear disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Ocular disorders NEC</i>		
Eye pain	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>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
Crohn's disease	1	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	6	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	4	0
Abdominal pain upper	5	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Dysphagia	4	0
Oesophageal food impaction	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	3	0
<i>Nausea and vomiting symptoms</i>		
Nausea	3	0
Vomiting	6	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	1	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	4	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue disorders NEC</i>		
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Oral discomfort	1	0
Oral mucosal blistering	1	0
Oral mucosal exfoliation	1	0
Oral pain	3	0
Oral pruritus	5	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	10	0
Mouth swelling	11	0
<i>Salivary gland disorders NEC</i>		
Salivary gland mass	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	6	0
Stomatitis	1	0
<i>Tongue disorders</i>		
Glossitis	2	0
Tongue disorder	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	2	0
Swollen tongue	7	0
Tongue discomfort	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>105</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	4	0
<i><b>Febrile disorders</b></i>		
Pyrexia	1	0
<i><b>Feelings and sensations NEC</b></i>		
Feeling abnormal	1	0
Feeling hot	2	0
Sensation of foreign body	4	0
<i><b>General signs and symptoms NEC</b></i>		
Swelling	3	0
Swelling face	4	0
<i><b>Mucosal findings abnormal</b></i>		
Mucosal discolouration	1	0
<i><b>Oedema NEC</b></i>		
Face oedema	1	0
<i><b>Pain and discomfort NEC</b></i>		
Chest discomfort	8	0
Chest pain	8	0
Non-cardiac chest pain	1	0
Pain	2	0
<i><b>Ulcers NEC</b></i>		
Ulcer	1	0
<b>General disorders SOC TOTAL</b>	<b>42</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	6	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	5	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>12</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Herpes viral infections</i>		
Oral herpes	1	0
<i>Upper respiratory tract infections</i>		
Tonsillitis	1	0
Upper respiratory tract infection	1	0
<b>Infections SOC TOTAL</b>	<b>3</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Joint related signs and symptoms</i>		
Joint swelling	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Musculoskeletal chest pain	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Disturbances in consciousness NEC</i>		
Syncope	2	0
<i>Headaches NEC</i>		
Headache	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	1	0
Myoclonus	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	2	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	10	0
Respiratory distress	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	1	0
Bronchospasm	1	0
Obstructive airways disorder	1	0
Wheezing	3	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	2	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Laryngeal oedema	1	0
Stridor	1	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Hypersensitivity pneumonitis	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Oropharyngeal spasm	1	0
Pharyngeal oedema	2	0
Pharyngeal swelling	5	0
Tonsillolith	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Allergic respiratory symptom	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Catarrh	1	0
Dry throat	1	0
Dysphonia	2	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	2	0
Rhinorrhoea	3	0
Throat irritation	8	0
Throat tightness	6	0
<b>Respiratory disorders SOC TOTAL</b>	<b>57</b>	<b>0</b>

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<b>Skin disorders</b>		
<i><b>Alopecias</b></i>		
Alopecia	1	0
Diffuse alopecia	1	0
<i><b>Angioedemas</b></i>		
Angioedema	8	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Hyperhidrosis	1	0
<i><b>Bullous conditions</b></i>		
Blister	2	0
<i><b>Dermatitis and eczema</b></i>		
Eczema	1	0
<i><b>Erythemas</b></i>		
Erythema	2	0
<i><b>Exfoliative conditions</b></i>		
Skin exfoliation	1	0
<i><b>Pruritus NEC</b></i>		
Pruritus	6	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	7	0
Rash pruritic	1	0
<i><b>Urticarias</b></i>		
Urticaria	4	0
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<b>Vascular disorders</b>		
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>274</b>	<b>0</b>
<b>TOTAL REPORTS</b>	<b>87</b>	