

## Case Series Drug Analysis Print

**Name: FOI 22/847 E-cigarettes**

Report Run Date: 02-Aug-2022

Data Lock Date: 01-Aug-2022 18:30:03

Earliest Reaction Date: 01-Jan-2010

MedDRA Version: MedDRA 25.0

FOI 22/847 E-cigarettes: All UK Spontaneous Adverse Reaction reports associated with E-cigarettes.

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Haematological disorders</i>		
Methaemoglobinaemia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
<i>Cardiac disorders NEC</i>		
Cardiovascular disorder	2	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	7	0
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	2	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Tachycardia	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	2	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	1
Ventricular extrasystoles	2	0
Ventricular fibrillation	1	0
Ventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>25</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Vertigo	3	0
<b>Ear disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Eye disorders</b>		
<i>Lacrimation disorders</i>		
Lacrimation increased	2	0
<i>Ocular disorders NEC</i>		
Eye pain	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	1	0
Eye pruritus	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<b>Eye disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	5	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Gastrooesophageal reflux disease	3	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	3	0
Breath odour	1	0
Dysphagia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival discomfort	1	0
Gingival erythema	1	0
Gingival pain	1	0
Gingival recession	1	0
Gingival swelling	2	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	3	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	21	0
Post-tussive vomiting	1	0
Vomiting	5	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	1	0
Oral disorder	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	1	0
<i>Oral soft tissue signs and symptoms</i>		
Coating in mouth	1	0
Hypoaesthesia oral	1	0
Oral discomfort	4	0
Oral mucosal blistering	2	0
Oral mucosal erythema	1	0
Oral pain	1	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
Mouth swelling	3	0
<i>Stomatitis and ulceration</i>		

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Aphthous ulcer	1	0
Mouth ulceration	6	0
Stomatitis	4	0
<b>Tongue disorders</b>		
Glossitis	1	0
<b>Tongue signs and symptoms</b>		
Swollen tongue	3	0
Tongue discomfort	2	0
Tongue eruption	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>101</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	6	0
Malaise	11	0
<i><b>Febrile disorders</b></i>		
Pyrexia	4	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	1	0
Feeling abnormal	3	0
Feeling cold	1	0
Feeling hot	2	0
Feeling of body temperature change	1	0
<i><b>Fibrosis NEC</b></i>		
Fibrosis	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	4	0
Exercise tolerance decreased	1	0
Influenza like illness	1	0
Swelling	2	0
Swelling face	1	0
<i><b>Inflammations</b></i>		
Inflammation	2	0
<i><b>Interactions</b></i>		
Drug interaction	4	0
<i><b>Oedema NEC</b></i>		
Oedema	1	0
<i><b>Pain and discomfort NEC</b></i>		
Chest discomfort	17	0
Chest pain	25	0
Discomfort	1	0
Non-cardiac chest pain	5	0
Pain	1	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Drug tolerance	1	0
<b>General disorders SOC TOTAL</b>	<b>97</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	8	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Reaction to excipient	8	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	1	0
Anaphylactic shock	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>19</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Infections</b>		
<i><b>Coronavirus infections</b></i>		
Severe acute respiratory syndrome	1	0
<i><b>Ear infections</b></i>		
Ear infection	1	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	2	0
Infectious pleural effusion	1	0
Pneumonia	3	0
<i><b>Upper respiratory tract infections</b></i>		
Croup infectious	1	0
Pharyngitis	1	0
Rhinitis	3	0
Sinusitis	4	0
<b>Infections SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Non-occupational environmental exposures</i>		
Environmental exposure	12	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Expired product administered	1	0
Incorrect route of product administration	1	0
<i>Thermal burns</i>		
Airway burns	1	0
Thermal burn	1	0
<b>Injuries SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	1	0
Heart rate increased	1	0
<i>Hepatobiliary function diagnostic procedures</i>		
Gamma-glutamyltransferase increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
Breath sounds abnormal	1	0
Weight decreased	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Total lung capacity decreased	1	0
<i>Therapeutic drug monitoring analyses</i>		
Antipsychotic drug level increased	1	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	1	0
<b>Investigations SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	1	0
<i>Hyperglycaemic conditions NEC</i>		
Glucose tolerance impaired	1	0
Hyperglycaemia	1	0
<i>Mixed acid-base disorders</i>		
Acidosis	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>4</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>		
Arthralgia	3	0
<i>Muscle pains</i>		
Myalgia	2	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	1	0
Muscle tightness	2	0
Muscle twitching	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Musculoskeletal chest pain	2	0
Neck pain	1	0
Pain in extremity	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral infarction	1	0
Subarachnoid haemorrhage	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	3	0
Loss of consciousness	1	0
Somnolence	2	0
Syncope	1	0
<i>Encephalopathies NEC</i>		
Posterior reversible encephalopathy syndrome	1	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	14	0
Medication overuse headache	1	0
Tension headache	1	0
<i>Memory loss (excl dementia)</i>		
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	1	0
<i>Migraine headaches</i>		
Migraine	2	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	17	0
Dizziness postural	1	0
Head discomfort	1	0
Presyncope	2	0
Slow response to stimuli	1	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	3	0
Paraesthesia	2	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	2	0
Seizure	2	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	2	0
<i>Tremor (excl congenital)</i>		
Tremor	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>66</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><i>Product label issues</i></b>		
Product expiration date issue	1	0
Product label on wrong product	1	0
<b><i>Product physical issues</i></b>		
Liquid product physical issue	1	0
Product colour issue	1	0
Product leakage	1	0
Product odour abnormal	4	0
Product physical issue	6	0
Product taste abnormal	14	0
<b><i>Product quality issues NEC</i></b>		
Product substitution issue	1	0
Suspected product quality issue	1	0
<b>null SOC TOTAL</b>	<b>31</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Anxiety disorders NEC</i>		
Anxiety disorder	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	1	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
<i>Depressive disorders</i>		
Depression	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
<i>Mood disorders NEC</i>		
Laziness	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Substance related and addictive disorders</i>		
Dependence	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>11</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	46	0
Dyspnoea at rest	2	0
Dyspnoea exertional	1	0
Respiration abnormal	1	0
Respiratory distress	2	0
Tachypnoea	3	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	9	0
Bronchial hyperreactivity	1	0
Chronic obstructive pulmonary disease	1	0
Wheezing	13	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	1	0
Hypoxia	4	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	97	0
Haemoptysis	6	0
Productive cough	6	0
Sputum increased	1	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Alveolitis	1	0
Diffuse alveolar damage	1	0
Hypersensitivity pneumonitis	3	0
Pneumonia lipoid	3	1
Pneumonitis	2	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	2	0
Lung opacity	3	0
Pleuritic pain	2	0
Pulmonary pain	4	0
Rales	1	0
Rhonchi	1	0
<i><b>Mediastinal disorders</b></i>		
Pneumomediastinum	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	3	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	3	0
Nasal dryness	2	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Cystic lung disease	1	0
Emphysema	1	0
Idiopathic pulmonary fibrosis	1	1
Interstitial lung disease	2	0
Lung consolidation	3	0
Organising pneumonia	2	0
Probable e-cigarette or vaping product use associated lung injury	1	0
Pulmonary air leakage	1	0
Pulmonary alveolar haemorrhage	3	0
Pulmonary fibrosis	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal disorder	1	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Pharyngeal swelling	2	0
<b>Pleural conditions NEC</b>		
Bronchopleural fistula	1	0
Pleural adhesion	1	0
<b>Pneumothorax and pleural effusions NEC</b>		
Pleural effusion	3	0
Pneumothorax	3	0
Pneumothorax spontaneous	1	0
<b>Pulmonary oedemas</b>		
Acute lung injury	7	1
Acute respiratory distress syndrome	3	0
Pulmonary congestion	2	0
Pulmonary oedema	1	0
<b>Pulmonary thrombotic and embolic conditions</b>		
Pulmonary embolism	1	0
<b>Respiratory failures (excl neonatal)</b>		
Respiratory failure	2	0
<b>Respiratory tract disorders NEC</b>		
Allergic respiratory disease	1	0
Lung disorder	2	0
Respiratory disorder	3	0
Respiratory tract irritation	2	0
<b>Upper respiratory tract signs and symptoms</b>		
Aphonia	1	0
Catarrh	1	0
Choking	2	0
Dry throat	3	0
Dysphonia	4	0
Nasal discomfort	1	0
Oropharyngeal pain	44	0
Rhinalgia	2	0
Rhinorrhoea	4	0
Sneezing	3	0
Throat irritation	28	0
<b>Respiratory disorders SOC TOTAL</b>	<b>371</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Angioedemas</i>		
Angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Hyperhidrosis	2	0
<i>Bullous conditions</i>		
Blister	2	0
<i>Dermal and epidermal conditions NEC</i>		
Papule	1	0
Skin discolouration	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	2	0
<i>Erythemas</i>		
Erythema	2	0
<i>Pruritus NEC</i>		
Pruritus	5	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	7	0
Rash papular	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
Subcutaneous emphysema	1	0
<i>Urticarias</i>		
Urticaria	2	0
<b>Skin disorders SOC TOTAL</b>	<b>29</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Vascular disorders</b>		
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Vasospasm	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>829</b>	<b>5</b>
<b>TOTAL REPORTS</b>	<b>295</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>5</b>