

## Case Series Drug Analysis Print

**Name: FOI 2024/00161 luforbec**

Report Run Date: 18-Jun-2024

Data Lock Date: 24-May-2024 18:30:03

Earliest Reaction Date: 12-Jan-2014

MedDRA Version: MedDRA 27.0

FOI 2024/00161 All UK Spontaneous ADR Reports for Luforbec  
luforbec: 01.01.21 to 24.05.24

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	6	0
<i>Rate and rhythm disorders NEC</i>		
Extrasystoles	2	0
Tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear inflammation	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	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>Cataract conditions</i>		
Cataract	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye swelling	1	0
<i>Visual disorders NEC</i>		
Vision blurred	4	0
<b>Eye disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
Abdominal pain upper	1	0
Oesophageal pain	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
Breath odour	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Noninfective gingivitis	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	9	0
Retching	4	0
Vomiting	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral discomfort	4	0
Oral mucosal exfoliation	1	0
Oral pain	7	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
Mouth swelling	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	3	0
Stomatitis	3	0
<i>Tongue signs and symptoms</i>		
Glossodynia	4	0
Tongue dry	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>48</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	2	0
Fatigue	2	0
Malaise	2	0
<i><b>Febrile disorders</b></i>		
Pyrexia	1	0
<i><b>Feelings and sensations NEC</b></i>		
Feeling abnormal	5	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	1	0
Illness	2	0
Influenza like illness	1	0
Peripheral swelling	1	0
Swelling	1	0
<i><b>Pain and discomfort NEC</b></i>		
Chest discomfort	11	0
Chest pain	7	0
Pain	2	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Drug ineffective	14	0
Drug intolerance	2	0
Therapeutic product ineffective	1	0
Therapeutic response decreased	1	0
Therapy non-responder	1	0
Treatment noncompliance	2	0
<b>General disorders SOC TOTAL</b>	<b>59</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	1	0
Drug hypersensitivity	1	0
Reaction to excipient	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Candida infections</i>		
Candida infection	1	0
Oral candidiasis	6	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	1	0
Gingivitis	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
Vulvovaginal mycotic infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Pneumonia	1	0
<b>Infections SOC TOTAL</b>	<b>12</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Anaesthetic and allied procedural complications</b></i>		
Airway complication of anaesthesia	2	0
<i><b>Chest and respiratory tract injuries NEC</b></i>		
Foreign body in throat	1	0
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Maternal exposure during breast feeding	2	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Device difficult to use	1	0
Medication error	4	0
Wrong technique in device usage process	1	0
Wrong technique in product usage process	3	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Muscle strain	1	0
<i><b>Product administration errors and issues</b></i>		
Product dose omission issue	1	0
<i><b>Product dispensing errors and issues</b></i>		
Product dispensing issue	2	0
<i><b>Product prescribing errors and issues</b></i>		
Product prescribing error	1	0
<b>Injuries SOC TOTAL</b>	<b>19</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Investigations</b>		
<i>Heart rate and pulse investigations</i>		
Heart rate increased	1	0
Heart rate irregular	1	0
<i>Physical examination procedures and organ system status</i>		
Product residue present	3	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Fractional exhaled nitric oxide abnormal	1	0
Fractional exhaled nitric oxide increased	1	0
Peak expiratory flow rate decreased	5	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	1	0
<b>Investigations SOC TOTAL</b>	<b>13</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	1	0
<i>Muscle pains</i>		
Myalgia	2	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	3	0
Muscle tightness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Pain in extremity	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Disturbances in consciousness NEC</i>		
Loss of consciousness	1	0
Syncope	1	0
<i>Headaches NEC</i>		
Headache	12	0
Tension headache	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	1	0
<i>Neurological signs and symptoms NEC</i>		
Brain fog	1	0
Dizziness	9	0
Dizziness postural	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	1	0
<i>Tremor (excl congenital)</i>		
Tremor	6	0
<b>Nervous system disorders SOC TOTAL</b>	<b>36</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b><i>Device information output issues</i></b>		
Device information output issue	2	0
<b><i>Device issues NEC</i></b>		
Device delivery system issue	6	0
<b><i>Device physical property and chemical issues</i></b>		
Device deposit issue	1	0
<b><i>Product physical issues</i></b>		
Product after taste	1	0
Product odour abnormal	1	0
Product physical issue	7	0
Product taste abnormal	5	0
<b><i>Product quality issues NEC</i></b>		
Drug delivery system issue	1	0
Product substitution issue	77	0
<b>null SOC TOTAL</b>	<b>101</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	1	0
Stress	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	3	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	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>Breathing abnormalities</i>		
Dyspnoea	58	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchial wall thickening	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	44	0
Bronchospasm	2	0
Wheezing	29	0
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	180	0
Haemoptysis	1	0
Productive cough	5	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
Nasal inflammation	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	2	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pneumothorax	1	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	1	0
Respiratory tract irritation	3	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking	7	0
Choking sensation	2	0
Dry throat	6	0
Dysphonia	6	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	18	0
Rhinalgia	1	0
Throat irritation	17	0
Throat tightness	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>393</b>	<b>0</b>

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<b>Skin disorders</b>		
<i><b>Bullous conditions</b></i>		
Dermatitis bullous	1	0
<i><b>Dermatitis and eczema</b></i>		
Skin irritation	1	0
<i><b>Erythemas</b></i>		
Erythema	1	0
<i><b>Pruritus NEC</b></i>		
Pruritus	2	0
<i><b>Rashes, eruptions and exantheams NEC</b></i>		
Rash	3	0
Rash macular	1	0
Rash pruritic	1	0
<b>Skin disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>736</b>	<b>0</b>
<b>TOTAL REPORTS</b>	<b>311</b>	