

Fultium D3 Product Analysis Print

All UK spontaneous suspected ADR reports received up to and including 21/04/2025

Run date: 23/04/2025

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
Cardiac disorders	Cardiac arrhythmias	Supraventricular arrhythmias	Atrial tachycardia	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	2	0
Ear and labyrinth disorders	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Tinnitus	2	0
Endocrine disorders	Parathyroid gland disorders	Hyperparathyroid disorders	Hyperparathyroidism	2	0
Eye disorders	Eye disorders NEC	Lacrimation disorders	Dry eye	1	0
			Tear discolouration	1	0
	Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Eyelid oedema	1	0
			Swelling of eyelid	1	0
		Ocular infections, inflammations and associated manifestations	Eye inflammation	1	0
			Eye pruritus	1	0
	Vision disorders	Visual disorders NEC	Diplopia	1	0
		Visual impairment and blindness (excl colour blindness)	Visual impairment	1	0
Gastrointestinal disorders	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	5	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	2	0
		Gastrointestinal spastic and hypermotility disorders	Irritable bowel syndrome	1	0
	Gastrointestinal signs and symptoms	Dyspeptic signs and symptoms	Dyspepsia	3	0
			Eructation	1	0
		Flatulence, bloating and distension	Abdominal distension	1	0
			Flatulence	2	0
		Gastrointestinal and abdominal pains (excl oral and	Abdominal pain	2	0
			Abdominal pain upper	8	0

		throat)	Abdominal tenderness	1	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	1	0
		Nausea and vomiting	Nausea	15	0
			Vomiting	2	0
	Oral soft tissue conditions	Oral soft tissue signs and	Oral pain	1	0
			Paraesthesia oral	2	0
		Oral soft tissue swelling and oedema	Lip swelling	3	0
	Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	2	0
	Tongue conditions	Tongue signs and symptoms	Swollen tongue	1	0
General disorders and administration site conditions	General system disorders NEC	Asthenic conditions	Fatigue	5	0
			Malaise	5	0
		Feelings and sensations NEC	Feeling cold	1	0
		General signs and symptoms NEC	Condition aggravated	1	0
			Illness	1	0
			Secretion discharge	1	0
			Swelling	1	0
			Swelling face	2	0
		Pain and discomfort NEC	Chest pain	1	0
			Discomfort	1	0
			Pain	2	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Adverse drug reaction	1	0
	Tissue disorders NEC	Trophic disorders	Calcinosis	1	0
Immune system disorders	Allergic conditions	Allergies to foods, food additives, drugs and other chemicals	Allergic reaction to excipient	2	0
			Reaction to colouring	1	0
			Reaction to excipient	2	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	1	0
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Bacterial vaginosis	1	0
	Infections - pathogen unspecified	Lower respiratory tract and lung infections	Lower respiratory tract infection	2	0
	Viral infectious disorders	Viral infections NEC	Sweating fever	1	0
Injury, poisoning and procedural	Bone and joint injuries	Limb fractures and dislocations	Hip fracture	1	0

complications	Exposures, chemical injuries and poisoning	Poisoning and toxicity	Toxicity to various agents	1	0
	Injuries NEC	Non-site specific injuries NEC	Soft tissue injury	1	0
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Medication error	2	0
			Extra dose administered	1	0
			Wrong patient received product	1	0
			Wrong product administered	1	0
		Product dispensing errors and issues	Drug dispensed to wrong patient	1	0
			Product dispensing error	1	0
Investigations	Endocrine investigations (incl sex hormones)	Parathyroid analyses	Blood parathyroid hormone increased	2	0
	Haematology investigations (incl blood groups)	Coagulation and bleeding analyses	Bleeding time prolonged	1	0
	Metabolic, nutritional and blood gas investigations	Carbohydrate tolerance analyses (incl diabetes)	Blood glucose increased	2	0
			Glycosylated haemoglobin increased	1	0
	Physical examination and organ system	Physical examination procedures and	Lymph node palpable	1	0
			Weight decreased	1	0
Metabolism and nutrition disorders	Acid-base disorders	Metabolic alkaloses	Metabolic alkalosis	1	0
			Milk-alkali syndrome	4	0
	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	1	0
			Increased appetite	1	0
	Bone, calcium, magnesium and phosphorus metabolism disorders	General nutritional disorders NEC	Abnormal loss of weight	1	0
			Hypercalcaemia	3	0
			Hypocalcaemia	3	0
	Electrolyte and fluid balance conditions	Total fluid volume decreased	Dehydration	1	0
	Glucose metabolism disorders (incl diabetes mellitus)	Diabetes mellitus (incl subtypes)	Diabetes mellitus inadequate control	1	0

Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms	Bone pain	2	0
	Joint disorders	Joint related disorders NEC	Greater trochanteric pain syndrome	1	0
		Joint related signs and symptoms	Arthralgia	4	0
			Joint swelling	1	0
	Muscle disorders	Muscle pains	Myalgia	2	0
		Muscle related signs and symptoms NEC	Muscle spasms	1	0
		Muscle weakness conditions	Muscular weakness	3	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue pain and discomfort	Neck pain	1	0
		Soft tissue disorders NEC	Groin pain	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin neoplasms malignant and unspecified	Skin neoplasms malignant and unspecified (excl melanoma)	Basal cell carcinoma	1	0
Nervous system disorders	Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Facial paresis	1	0
	Headaches	Headaches NEC	Headache	8	0
		Migraine headaches	Migraine	1	0
	Mental impairment disorders	Mental impairment (excl dementia and memory loss)	Disturbance in attention	1	0
	Movement disorders (incl parkinsonism)	Tremor (excl congenital)	Tremor	1	0
	Neurological disorders NEC	Cortical dysfunction NEC	Aphasia	1	0
		Disturbances in consciousness NEC	Lethargy	1	0
			Loss of consciousness	2	0
			Somnolence	3	0
			Syncope	1	0
		Neurological signs and symptoms NEC	Brain fog	1	0
			Dizziness	6	0
		Paraesthesias and dysaesthesias	Hypoaesthesia	1	0
			Paraesthesia	2	0
	Seizures (incl subtypes)	Seizures and seizure disorders NEC	Epilepsy	1	0
Product issues	Product quality, supply, distribution, manufacturing	Product physical issues	Product colour issue	1	0
		Product quality issues NEC	Product substitution issue	1	0

Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Anxiety	1	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	2	0
		Deliria	Delirium	1	0
	Depressed mood disorders and disturbances	Depressive disorders	Depression	1	0
	Mood disorders and disturbances NEC	Emotional and mood disturbances NEC	Euphoric mood	1	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	4	0
		Parasomnias	Abnormal dreams	1	0
Renal and urinary disorders	Renal disorders (excl	Renal failure and impairment	Acute kidney injury	2	0
			Renal failure	1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Dysuria	1	0
			Pollakiuria	2	0
		Urinary abnormalities	Chromaturia	1	0
		Urinary tract signs and symptoms NEC	Polyuria	1	0
			Renal colic	1	0
	Urolithiasis	Renal lithiasis	Nephrolithiasis	2	0
Reproductive system and breast disorders	Breast disorders	Breast signs and symptoms	Nipple pain	1	0
	Vulvovaginal disorders (excl infections and inflammations)	Vulvovaginal disorders NEC	Vaginal haemorrhage	1	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Asthma	1	0
			Wheezing	2	0
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	4	0
		Coughing and associated symptoms	Cough	3	0
	Upper respiratory tract disorders (excl infections)	Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal swelling	1	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	1	0
		Urticarias	Urticaria	13	0
	Epidermal and dermal conditions	Bullous conditions	Blister	1	0
		Dermal and epidermal conditions NEC	Dry skin	1	0
			Skin disorder	1	0
			Skin lesion	1	0
			Skin texture abnormal	1	0

		Dermatitis and eczema	Eczema	2	0
			Skin irritation	4	0
		Erythemas	Erythema	4	0
		Exfoliative conditions	Skin exfoliation	2	0
		Pruritus NEC	Pruritus	16	0
		Rashes, eruptions and exanthems NEC	Rash	12	0
			Rash erythematous	1	0
			Rash macular	3	0
			Rash maculo-papular	1	0
			Rash pruritic	1	0
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Skin mass	1	0
	Skin appendage conditions	Apocrine and eccrine gland disorders	Sweat discolouration	1	0
Surgical and medical procedures	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Self-medication	1	0
Vascular disorders	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	1	0
			Hot flush	1	0
Total reactions for drug				291	
Total reports for drug				115	
Total fatal outcome reports for drug				0	