

Medicine summary -duloxetine (to date)

			Case Group	Death Outcomes	Sole
Case Count			366	8	317
Reaction Count	Blood and lymphatic system disorders	Anaemia	1	0	1
		Pancytopenia	1	0	1
		Thrombocytopenia	1	0	1
		Leukopenia	2	0	0
		Febrile neutropenia	1	0	1
		Neutropenia	3	0	0
		Blood and lymphatic system disorders	9	0	4
	Cardiac disorders	Arrhythmia	1	0	1
		Bradycardia	1	0	0
		Extrasystoles	1	0	1
		Tachycardia	4	0	3
		Atrial fibrillation	4	0	4
		Ventricular extrasystoles	1	0	1
		Palpitations	13	0	13
		Acute myocardial infarction	2	0	1
		Myocardial ischaemia	1	0	0
		Cardiomyopathy	1	0	1
		Myocarditis	2	0	0
		Cardiac disorders	31	0	25
		Ear and labyrinth disorders	Hyperacusis	1	0
	Tinnitus		1	0	1
	Vertigo		6	0	6
	Ear and labyrinth disorders		8	0	7
	Eye disorders	Eye disorder	1	0	1
		Glaucoma	1	0	1
		Eye movement disorder	1	0	1
		Mydriasis	3	0	3
		Photophobia	1	0	1
		Diplopia	2	0	2
		Photopsia	1	0	1
		Vision blurred	9	0	9
		Visual impairment	1	0	1
		Eye disorders	20	0	20
	Gastrointestinal disorders	Gastrointestinal haemorrhage	1	0	1
		Haematemesis	1	0	1
		Colitis	1	0	1
		Colitis ischaemic	1	0	1
		Reflux oesophagitis	2	0	2
		Diarrhoea	17	0	16
		Diarrhoea haemorrhagic	1	0	1
		Constipation	4	0	3

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Reaction Count	Gastrointestinal disorders	Dyspepsia	2	0	2	
		Eructation	1	0	1	
		Faeces discoloured	1	0	1	
		Flatulence	2	0	2	
		Abdominal pain	4	0	4	
		Abdominal pain upper	8	0	8	
		Gastrointestinal pain	1	0	0	
		Abdominal discomfort	3	0	2	
		Dysphagia	3	0	3	
		Nausea	44	1	40	
		Retching	2	0	2	
		Vomiting	26	0	24	
		Lip swelling	2	0	2	
		Oral pain	1	0	1	
		Paraesthesia oral	1	0	1	
		Mouth ulceration	3	0	3	
		Dry mouth	4	0	3	
		Swollen tongue	6	0	5	
			Gastrointestinal disorders	142	1	130
		General disorders and administration site conditions	Pyrexia	2	0	1
			Death	4	4	4
			Asthenia	5	0	4
			Fatigue	3	0	3
			Malaise	8	0	8
			Abasia	1	0	1
			Gait disturbance	3	0	2
			Condition aggravated	6	1	6
			Influenza like illness	3	0	2
			Irritability	1	0	1
	Oedema		1	0	1	
	Oedema peripheral		2	0	1	
	Chest pain		4	0	4	
	Pain		3	0	2	
	Chest discomfort		4	0	4	
	Chills		2	0	1	
	Feeling abnormal		5	0	5	
	Feeling cold	1	0	0		
	Feeling hot	1	0	1		
	Feeling jittery	1	0	1		
	Feeling of body temperature change	1	0	1		
	Hangover	1	0	1		
	Thirst	3	0	3		

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Reaction Count	General disorders and administration site conditions	Alcohol interaction	1	0	0
		Drug interaction	4	0	0
		Drug effect increased	1	0	1
		Drug ineffective	9	1	8
		Therapeutic product ineffective for unapproved indication	1	0	1
		Drug withdrawal syndrome	3	0	3
		General disorders and administration site conditions	84	6	70
	Hepatobiliary disorders	Bile duct obstruction	1	0	1
		Jaundice	1	0	0
		Liver disorder	3	0	3
		Liver injury	4	0	4
		Hepatic function abnormal	4	0	4
		Hepatic failure	1	0	1
		Hepatomegaly	2	0	2
		Liver tenderness	1	0	1
		Hepatic steatosis	1	0	1
		Hepatitis	5	0	5
		Hepatocellular injury	1	0	0
		Hepatotoxicity	1	0	1
		Hepatobiliary disorders	25	0	23
	Immune system disorders	Hypersensitivity	3	0	3
		Anaphylactic reaction	2	0	2
		Immune system disorders	5	0	5
	Infections and infestations	Diverticulitis	1	0	1
		Gastrointestinal infection	1	0	1
		Labyrinthitis	1	0	1
		Pneumonia	1	0	0
		Nasopharyngitis	2	0	2
		Influenza	1	0	1
		Infections and infestations	7	0	6
	Injury, poisoning and procedural complications	Spinal fracture	1	0	0
		Drug exposure during pregnancy	5	0	3
		Subdural haematoma	1	0	1
Fall		8	1	6	
Head injury		1	1	1	
Drug prescribing error		1	0	1	
Medication error		1	0	0	
Intentional overdose		2	0	2	
Overdose		3	0	3	
Injury, poisoning and procedural complications		23	2	17	

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			Case Group	Death Outcomes	Sole	
Reaction Count	Investigations	Ejection fraction decreased	1	0	1	
		Heart rate abnormal	1	0	1	
		Heart rate increased	3	0	2	
		Heart rate irregular	2	0	1	
		Blood pressure increased	7	0	7	
		Blood testosterone increased	1	0	1	
		Blood creatine phosphokinase increased	2	0	1	
		Troponin increased	2	0	0	
		Blood alkaline phosphatase increased	1	0	1	
		International normalised ratio increased	1	0	1	
		White blood cell count decreased	1	0	0	
		Alanine aminotransferase increased	2	0	2	
		Aspartate aminotransferase increased	1	0	1	
		Gamma-glutamyltransferase increased	2	0	2	
		Liver function test	1	0	1	
		Liver function test abnormal	6	0	4	
		Transaminases increased	1	0	1	
		Urine bilirubin increased	1	0	1	
		Urobilinogen urine	1	0	1	
		Lipids increased	1	0	1	
		Blood glucose increased	1	0	1	
		Electroencephalogram abnormal	1	0	0	
		Intraocular pressure increased	1	0	1	
		Apgar score low	1	0	1	
		Weight decreased	1	0	1	
		Weight increased	4	0	4	
		Creatinine renal clearance decreased	1	0	0	
		Urine output decreased	1	0	1	
		Drug level increased	2	0	0	
		Blood sodium decreased	1	0	1	
			Investigations	52	0	40
		Metabolism and nutrition disorders	Lactic acidosis	1	1	1
			Decreased appetite	2	0	2
			Hypophagia	1	0	1
Increased appetite	1		0	1		
Hypokalaemia	2		0	2		
Hyponatraemia	14		0	9		
Dehydration	2		0	2		
Diabetes mellitus	1		0	1		
Hypoglycaemia	1		0	1		
	Metabolism and nutrition disorders		25	1	20	

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			Case Group	Death Outcomes	Sole	
Reaction Count	Musculoskeletal and connective tissue disorders	Arthralgia	2	0	1	
		Joint stiffness	1	0	1	
		Myalgia	5	0	4	
		Muscle spasms	4	0	3	
		Muscle tightness	2	0	1	
		Muscle twitching	3	0	2	
		Trismus	3	0	2	
		Muscular weakness	6	0	5	
		Musculoskeletal stiffness	1	0	1	
		Neck pain	1	0	1	
		Pain in extremity	2	0	2	
		Musculoskeletal and connective tissue disorders	30	0	23	
		Nervous system disorders	Cerebrovascular accident	1	0	1
			Cerebral amyloid angiopathy	1	0	1
	Transient ischaemic attack		1	0	1	
	Headache		23	0	21	
	Migraine		5	0	4	
	Dementia		1	0	1	
	Transient global amnesia		1	0	1	
	Disturbance in attention		3	0	2	
	Akathisia		1	0	0	
	Dyskinesia		2	0	2	
	Hypokinesia		1	0	1	
	Movement disorder		1	0	1	
	Psychomotor hyperactivity		1	0	1	
	Tardive dyskinesia		1	0	1	
	Dystonia		2	0	2	
	Hemiparesis		1	0	1	
	Tremor		27	0	23	
	Perineurial cyst		1	0	1	
	Hyperreflexia		1	0	1	
	Hyporeflexia		1	0	1	
	Reflexes abnormal		1	0	1	
Balance disorder	2		0	1		
Coordination abnormal	1		0	1		
Nystagmus	2		0	2		
Aphasia	2		0	2		
Lethargy	4		0	3		
Loss of consciousness	2	0	1			
Somnolence	4	0	2			
Syncope	10	0	9			

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			Case Group	Death Outcomes	Sole	
Reaction Count	Nervous system disorders	Dizziness	31	0	28	
		Myoclonus	5	0	4	
		Presyncope	1	0	1	
		Crying	2	0	2	
		Burning sensation	1	0	1	
		Paraesthesia	15	0	14	
		Hypoaesthesia	2	0	2	
		Restless legs syndrome	1	0	1	
		Sensory loss	1	0	1	
		Dysarthria	1	0	1	
		Incoherent	1	0	1	
		Drop attacks	1	0	0	
		Neuroleptic malignant syndrome	2	0	0	
		Serotonin syndrome	24	0	19	
		Neuropathy peripheral	1	0	1	
		Convulsion	7	0	4	
		Epilepsy	1	0	1	
		Spinal cord compression	1	0	0	
			Nervous system disorders	202	0	170
		Pregnancy, puerperium and perinatal conditions		Abortion spontaneous	3	0
Pre-eclampsia	1			0	1	
Ectopic pregnancy	1			0	1	
Premature baby	1			0	1	
Small for dates baby	1			0	1	
Delivery	1			0	1	
Pregnancy, puerperium and perinatal conditions	8			0	6	
Psychiatric disorders		Agitation	16	1	14	
		Anxiety	9	0	9	
		Nervousness	1	0	1	
		Agoraphobia	1	0	1	
		Fear of death	1	0	1	
		Panic attack	4	0	4	
		Panic reaction	1	0	1	
		Restlessness	1	0	1	
		Bruxism	4	0	3	
		Confusional state	3	0	3	
		Disorientation	1	0	1	
		Delirium	4	0	2	
		Depression	8	1	7	
		Depressed mood	1	0	1	
		Depersonalisation	1	0	1	

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			Case Group	Death Outcomes	Sole		
Reaction Count	Psychiatric disorders	Dissociation	1	0	1		
		Delusion	1	0	1		
		Hallucination	5	0	4		
		Thinking abnormal	1	0	1		
		Hypomania	2	0	2		
		Mania	6	0	4		
		Anger	4	0	4		
		Emotional disorder	1	0	1		
		Emotional distress	1	0	0		
		Apathy	1	0	1		
		Aggression	4	0	4		
		Homicidal ideation	1	0	1		
		Violence-related symptom	2	0	2		
		Abnormal behaviour	1	0	1		
		Alcoholism	1	0	1		
		Intentional drug misuse	1	0	1		
		Withdrawal syndrome	14	0	14		
		Psychotic disorder	1	0	1		
		Anorgasmia	1	0	1		
		Loss of libido	2	0	2		
		Insomnia	19	0	16		
		Abnormal dreams	4	0	4		
		Nightmare	4	0	4		
		Sleep disorder	3	0	3		
		Completed suicide	4	4	4		
		Intentional self-injury	2	0	2		
		Suicidal behaviour	4	0	4		
		Suicidal ideation	22	0	20		
		Suicide attempt	3	0	3		
			Psychiatric disorders		172	6	157
		Renal and urinary disorders	Renal and urinary disorders	Renal failure chronic	1	0	1
				Renal impairment	1	0	1
				Dysuria	4	0	3
				Micturition disorder	1	0	1
Pollakiuria	3			0	3		
Urinary hesitation	3			0	3		
Urinary incontinence	2			0	2		
Urinary retention	9			0	8		
Urine flow decreased	2			0	1		
Chromaturia	2			0	2		
Nocturia	3			0	2		
	Renal and urinary disorders				31	0	27

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Reaction Count			Case Group	Death Outcomes	Sole
	Reproductive system and breast disorders	Prostatitis	2	0	2
		Benign prostatic hyperplasia	1	0	1
		Ejaculation delayed	2	0	2
		Ejaculation disorder	1	0	1
		Testicular atrophy	1	0	1
		Reproductive system and breast disorders	7	0	7
	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	1	0	1
		Pulmonary embolism	1	1	1
		Dyspnoea	6	0	6
		Hyperventilation	1	0	1
		Respiratory distress	1	0	1
		Cough	2	0	0
		Choking sensation	2	0	2
		Dysphonia	1	0	1
		Oropharyngeal pain	2	0	2
		Throat irritation	1	0	1
		Throat tightness	1	0	1
		Epistaxis	1	0	1
		Respiratory, thoracic and mediastinal disorders	20	1	18
		Skin and subcutaneous tissue disorders	Angioedema	1	0
	Urticaria		4	0	4
	Blister		1	0	1
	Dry skin		2	0	2
	Hypoaesthesia facial		1	0	1
	Swelling face		1	0	1
	Skin irritation		1	0	1
	Erythema		1	0	1
	Rash erythematous		1	0	1
	Skin exfoliation		1	0	1
	Lichen planus		1	0	1
	Pityriasis rosea		1	0	1
	Rash papular		1	0	1
	Pruritus		7	0	7
	Pruritus generalised		1	0	1
Rash pruritic	3		0	3	
Psoriasis	1		0	1	
Rash	8		0	8	
Rash macular	1		0	1	
Alopecia	1		0	1	
Madarosis	1	0	1		
Cold sweat	5	0	5		

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Reaction Count	Skin and subcutaneous tissue disorders	Hyperhidrosis	15	0	11	
		Night sweats	1	0	1	
		Onychoclasia	1	0	1	
		Hair disorder	1	0	1	
		Rosacea	1	0	1	
		Skin and subcutaneous tissue disorders	64	0	60	
	Social circumstances	Sexual abuse	1	0	1	
		Alcohol use	1	0	1	
		Impaired driving ability	1	0	1	
		Impaired work ability	1	0	1	
		Walking aid user	1	0	0	
		Social circumstances	5	0	4	
	Surgical and medical procedures	Cholecystectomy	1	0	1	
		Off label use	4	0	4	
		Therapy regimen changed	2	0	2	
		Surgical and medical procedures	7	0	7	
	Vascular disorders	Vascular occlusion	1	0	1	
		Vasoconstriction	1	0	1	
		Hypotension	7	0	3	
		Orthostatic hypotension	4	0	4	
		Flushing	4	0	4	
		Hot flush	7	0	7	
		Pallor	1	0	1	
		Hypertension	14	0	11	
		Vasculitis	1	0	1	
		Vascular disorders	40	0	33	
	Reaction			1017	17	879