

**Medicine summary -reboxetine (to date)**

			Case Group	Death Outcomes	Sole		
Case Count			242	0	196		
Reaction Count	Blood and lymphatic system disorders	Haemolytic anaemia	1	0	1		
		Lymphadenopathy	2	0	1		
<b>Blood and lymphatic system disorders</b>		<b>3</b>	<b>0</b>	<b>2</b>			
Cardiac disorders		Arrhythmia	1	0	1		
		Bradycardia	1	0	1		
		Tachycardia	8	0	5		
		Atrial fibrillation	1	0	1		
		Atrial flutter	1	0	0		
		Supraventricular tachycardia	2	0	2		
		Ventricular extrasystoles	1	0	1		
		Palpitations	8	0	8		
		Myocardial infarction	1	0	1		
		Cardiac failure congestive	1	0	1		
		Congestive cardiomyopathy	1	0	1		
		Cardiomegaly	1	0	1		
		<b>Cardiac disorders</b>	<b>27</b>	<b>0</b>	<b>23</b>		
		Ear and labyrinth disorders		Tinnitus	1	0	1
				<b>Ear and labyrinth disorders</b>	<b>1</b>	<b>0</b>	<b>1</b>
Endocrine disorders		Inappropriate antidiuretic hormone secretion	2	0	2		
		<b>Endocrine disorders</b>	<b>2</b>	<b>0</b>	<b>2</b>		
Eye disorders		Dry eye	2	0	2		
		Mydriasis	1	0	0		
		Vision blurred	1	0	1		
		Visual impairment	1	0	0		
		<b>Eye disorders</b>	<b>5</b>	<b>0</b>	<b>3</b>		
Gastrointestinal disorders		Rectal haemorrhage	1	0	1		
		Haematemesis	1	0	1		
		Reflux oesophagitis	1	0	1		
		Constipation	23	0	21		
		Gastrooesophageal reflux disease	1	0	1		
		Dyspepsia	2	0	2		
		Epigastric discomfort	1	0	1		
		Abdominal distension	2	0	1		
		Abdominal pain	6	0	4		
		Abdominal pain lower	2	0	2		
		Abdominal pain upper	1	0	1		
		Abdominal discomfort	1	0	1		
		Nausea	22	0	17		
		Vomiting	10	0	8		
		Lip swelling	1	0	0		
		Dry mouth	11	0	10		

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Reaction Count	Gastrointestinal disorders	Glossitis	1	0	1
		Tongue ulceration	1	0	1
		Swollen tongue	2	0	1
		<b>Gastrointestinal disorders</b>	<b>90</b>	<b>0</b>	<b>75</b>
	General disorders and administration site conditions	Pyrexia	2	0	1
		Asthenia	3	0	3
		Fatigue	5	0	4
		Malaise	3	0	3
		Irritability	4	0	4
		Local swelling	1	0	1
		Oedema	1	0	0
		Oedema peripheral	1	0	1
		Chest pain	5	0	5
		Pain	2	0	2
		Chills	6	0	3
		Feeling abnormal	3	0	2
		Feeling cold	2	0	2
		Feeling jittery	1	0	1
		Drug interaction	1	0	0
		Drug ineffective	7	0	6
		Drug withdrawal syndrome	1	0	1
		<b>General disorders and administration site conditions</b>	<b>48</b>	<b>0</b>	<b>39</b>
	Hepatobiliary disorders	Hepatic function abnormal	1	0	0
		Hepatomegaly	1	0	1
		Liver tenderness	1	0	1
		Hepatitis	1	0	0
		<b>Hepatobiliary disorders</b>	<b>4</b>	<b>0</b>	<b>2</b>
	Immune system disorders	Anaphylactic reaction	1	0	1
		Anaphylactic shock	1	0	1
		<b>Immune system disorders</b>	<b>2</b>	<b>0</b>	<b>2</b>
	Infections and infestations	Orchitis	1	0	1
		Rhinitis	1	0	1
		Urinary tract infection	2	0	2
<b>Infections and infestations</b>		<b>4</b>	<b>0</b>	<b>4</b>	
Injury, poisoning and procedural complications	Drug exposure during pregnancy	4	0	3	
	Fall	4	0	3	
	Chillblains	3	0	2	
	Overdose	2	0	0	
	<b>Injury, poisoning and procedural complications</b>	<b>13</b>	<b>0</b>	<b>8</b>	
Investigations	Echocardiogram abnormal	1	0	0	
	Ejection fraction decreased	1	0	0	

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Reaction Count	Investigations	Electrocardiogram ST segment depression	1	0	1
		Heart rate increased	3	0	3
		Blood pressure decreased	1	0	1
		Blood pressure increased	6	0	5
		Blood creatine phosphokinase increased	1	0	0
		Blood alkaline phosphatase increased	1	0	1
		Platelet adhesiveness decreased	1	0	0
		Hepatic enzyme increased	1	0	1
		Weight decreased	9	0	7
		Weight increased	2	0	0
		Blood creatinine increased	1	0	1
		Semen analysis abnormal	1	0	1
		Spermatozoa abnormal	1	0	1
		Blood osmolarity decreased	1	0	1
			<b>Investigations</b>	<b>32</b>	<b>0</b>
Metabolism and nutrition disorders		Decreased appetite	4	0	4
		Hypophagia	1	0	1
		Increased appetite	2	0	0
		Polydipsia	4	0	1
		Hyponatraemia	10	0	9
		Dehydration	1	0	0
			<b>Metabolism and nutrition disorders</b>	<b>22</b>	<b>0</b>
Musculoskeletal and connective tissue disorders		Myalgia	3	0	1
		Muscular weakness	1	0	1
		Neck pain	1	0	1
		Pain in extremity	1	0	1
			<b>Musculoskeletal and connective tissue disorders</b>	<b>6</b>	<b>0</b>
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Prolactin-producing pituitary tumour	1	0	1
		Neoplasm malignant	1	0	1
			<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>2</b>	<b>0</b>
Nervous system disorders		Haemorrhage intracranial	1	0	1
		Transient ischaemic attack	1	0	1
		Parosmia	1	0	1
		Hypertensive encephalopathy	1	0	1
		Hypoxic-ischaemic encephalopathy	1	0	1
		Headache	11	0	9
		Amnesia	3	0	2
		Disturbance in attention	2	0	2
		Mental impairment	1	0	1
		Akathisia	2	0	1

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Reaction Count	Nervous system disorders	Extrapyramidal disorder	1	0	0	
		Cogwheel rigidity	1	0	0	
		Tremor	4	0	4	
		Balance disorder	1	0	1	
		Coma	1	0	0	
		Depressed level of consciousness	1	0	0	
		Lethargy	4	0	4	
		Loss of consciousness	1	0	1	
		Somnolence	1	0	0	
		Syncope	6	0	4	
		Dizziness	21	0	16	
		Dizziness postural	1	0	1	
		Myoclonus	1	0	1	
		Presyncope	1	0	1	
		Crying	1	0	0	
		Formication	1	0	1	
		Paraesthesia	6	0	5	
		Dysgeusia	1	0	1	
		Hypoaesthesia	2	0	2	
		Adrenergic syndrome	1	0	0	
		Neuroleptic malignant syndrome	1	0	0	
		Serotonin syndrome	2	0	1	
		Neuropathy peripheral	1	0	1	
		Petit mal epilepsy	1	0	0	
		Grand mal convulsion	1	0	1	
		Convulsion	4	0	2	
	Poor quality sleep	1	0	0		
		<b>Nervous system disorders</b>		<b>92</b>	<b>0</b>	<b>67</b>
	Pregnancy, puerperium and perinatal conditions	Foetal growth restriction	Foetal growth restriction	1	0	0
			Foetal malpresentation	1	0	1
			Antepartum haemorrhage	1	0	1
			Umbilical cord prolapse	1	0	1
			<b>Pregnancy, puerperium and perinatal conditions</b>		<b>4</b>	<b>0</b>
	Psychiatric disorders	Agitation	10	0	6	
		Anxiety	6	0	4	
		Nervousness	1	0	0	
Tension		1	0	1		
Restlessness		2	0	2		
Tic		1	0	0		
Confusional state		5	0	4		
Disorientation		1	0	0		

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Reaction Count	Psychiatric disorders	Delirium	3	0	1	
		Depression	4	0	2	
		Depersonalisation	2	0	2	
		Dissociation	1	0	1	
		Hallucination	1	0	1	
		Hallucination, visual	1	0	1	
		Thinking abnormal	4	0	4	
		Hypomania	1	0	1	
		Mania	2	0	1	
		Affect lability	1	0	0	
		Anger	4	0	4	
		Euphoric mood	1	0	1	
		Mood altered	1	0	1	
		Mood swings	1	0	1	
		Apathy	1	0	1	
		Aggression	13	0	11	
		Homicidal ideation	2	0	2	
		Paranoia	1	0	0	
		Violence-related symptom	1	0	1	
		Mental status changes	1	0	1	
		Withdrawal syndrome	2	0	1	
		Psychotic disorder	1	0	0	
		Premature ejaculation	2	0	2	
		Disturbance in sexual arousal	1	0	1	
		Libido decreased	2	0	2	
		Libido increased	3	0	2	
		Insomnia	20	0	15	
		Abnormal dreams	1	0	1	
		Nightmare	2	0	2	
		Sleep disorder	4	0	4	
		Self injurious behaviour	1	0	0	
		Suicidal ideation	12	0	9	
		Suicide attempt	1	0	0	
		<b>Psychiatric disorders</b>	<b>125</b>	<b>0</b>	<b>93</b>	
		Renal and urinary disorders	Anuria	1	0	1
			Renal failure	1	0	1
			Dysuria	10	0	10
			Micturition disorder	4	0	4
			Pollakiuria	4	0	4
			Urinary hesitation	11	0	9
			Urinary incontinence	3	0	2
		Urinary retention	17	0	15	

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Reaction Count	Renal and urinary disorders	Urine flow decreased	3	0	3
		Proteinuria	1	0	1
		Nocturia	1	0	1
		Polyuria	2	0	1
		<b>Renal and urinary disorders</b>	<b>58</b>	<b>0</b>	<b>52</b>
	Reproductive system and breast disorders	Breast discharge	1	0	1
		Breast pain	1	0	1
		Nipple pain	1	0	1
		Menstrual disorder	1	0	1
		Metrorrhagia	1	0	1
		Menorrhagia	1	0	1
		Penile discharge	1	0	1
		Penile pain	1	0	1
		Penile size reduced	1	0	1
		Penis disorder	2	0	2
		Scrotal disorder	1	0	1
		Scrotal swelling	1	0	1
		Ejaculation delayed	2	0	2
		Ejaculation disorder	11	0	11
		Erectile dysfunction	9	0	8
		Retrograde ejaculation	1	0	1
		Female sexual arousal disorder	1	0	1
		Sexual dysfunction	2	0	1
		Spermatorrhoea	1	0	1
		Testicular disorder	1	0	0
		Testicular pain	5	0	5
		Vaginal haemorrhage	1	0	1
		<b>Reproductive system and breast disorders</b>	<b>47</b>	<b>0</b>	<b>44</b>
	Respiratory, thoracic and mediastinal disorders	Neonatal asphyxia	1	0	1
		Neonatal respiratory depression	1	0	1
		Pulmonary hypertension	1	0	0
		Apnoea	1	0	1
		Dyspnoea	4	0	4
		Rhinorrhoea	1	0	1
		Epistaxis	1	0	1
		Sinus congestion	1	0	1
		<b>Respiratory, thoracic and mediastinal disorders</b>	<b>11</b>	<b>0</b>	<b>10</b>
	Skin and subcutaneous tissue disorders	Angioedema	1	0	1
		Urticaria	8	0	7
		Urticaria papular	1	0	1
		Blister	1	0	1
		Erythema multiforme	1	0	1

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			Case Group	Death Outcomes	Sole	
Reaction Count	Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	1	0	1	
		Skin burning sensation	1	0	1	
		Swelling face	2	0	2	
		Erythema	1	0	0	
		Skin exfoliation	1	0	1	
		Photosensitivity reaction	2	0	2	
		Pruritus	5	0	5	
		Rash	5	0	5	
		Rash macular	1	0	0	
		Rash maculo-papular	1	0	0	
		Rash vesicular	1	0	0	
		Acne	2	0	2	
		Hyperhidrosis	19	0	19	
		Night sweats	1	0	0	
		<b>Skin and subcutaneous tissue disorders</b>			<b>55</b>	<b>0</b>
	Surgical and medical procedures	Off label use	1	0	1	
		Therapy regimen changed	1	0	0	
		<b>Surgical and medical procedures</b>			<b>2</b>	<b>0</b>
	Vascular disorders	Raynaud's phenomenon	2	0	2	
		Peripheral coldness	1	0	1	
		Circulatory collapse	1	0	0	
		Hypotension	5	0	3	
		Orthostatic hypotension	1	0	1	
		Deep vein thrombosis	1	0	0	
		Angiopathy	1	0	1	
		Flushing	3	0	2	
		Hot flush	3	0	2	
		Pallor	2	0	2	
		Hypertension	6	0	5	
		Phlebitis	1	0	1	
		<b>Vascular disorders</b>			<b>27</b>	<b>0</b>
	<b>Reaction</b>			<b>682</b>	<b>0</b>	<b>544</b>