

Case Series Drug Analysis Print

Name: Remeron

Report Run Date: 13-Jun-2023

Data Lock Date: 12-Jun-2023 18:30:04

Earliest Reaction Date: 03-Jul-2006

MedDRA Version: MedDRA 26.0

Remeron: FOI 23/398 - All UK spontaneous suspected Adverse Drug Reaction (ADR) reports for Remeron up to and including 12/06/2023

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Reaction Name	Total	Fatal
Blood disorders		
<i>Neutropenias</i>		
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Thrombotic thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	1	0
Cardiac disorders SOC TOTAL	1	0

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

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

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Reaction Name	Total	Fatal
Eye disorders		
<i>Cataract conditions</i>		
Cataract	1	0
<i>Lacrimation disorders</i>		
Dry eye	1	0
Eye disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	3	0
Flatulence	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Oesophageal achalasia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Dysphagia	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
Gastrointestinal disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	1	0
<i>Febrile disorders</i>		
Pyrexia	1	0
<i>Feelings and sensations NEC</i>		
Feeling cold	1	0
Feeling drunk	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
Gait inability	1	0
<i>Interactions</i>		
Drug interaction	1	0
<i>Oedema NEC</i>		
Localised oedema	1	0
Oedema peripheral	4	0
<i>Therapeutic and nontherapeutic responses</i>		
Drug tolerance	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
General disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Infections		
<i>Lower respiratory tract and lung infections</i>		
Pneumonia	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
Infections SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Injuries		
<i>Non-site specific injuries NEC</i>		
Electric shock	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Product administration error	1	0
Injuries SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Investigations		
<i>Hepatobiliary function diagnostic procedures</i>		
Alanine aminotransferase increased	1	0
Liver function test abnormal	1	0
<i>Protein analyses NEC</i>		
Protein total increased	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	2	0
<i>White blood cell analyses</i>		
White blood cell count decreased	1	0
Investigations SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	1	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	3	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
Muscle & tissue disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
<i>Cortical dysfunction NEC</i>		
Dyspraxia	1	0
<i>Disturbances in consciousness NEC</i>		
Somnolence	1	0
<i>Disturbances in sleep phase rhythm</i>		
Circadian rhythm sleep disorder	1	0
Delayed sleep phase	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Hypokinesia	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	2	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	1
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	1	0
Myoclonus	1	0
<i>Paraesthesias and dysaesthesias</i>		
Paraesthesia	1	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	1	0
<i>Sensory abnormalities NEC</i>		
Restless legs syndrome	1	0
Sensory disturbance	1	0
Nervous system disorders SOC TOTAL	20	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
Pregnancy conditions SOC TOTAL	1	0

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Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product quality issue	1	0
null SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Behaviour and socialisation disturbances</i>		
Paranoia	1	0
<i>Bipolar disorders</i>		
Bipolar disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Irritability	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	1	0
<i>Parasomnias</i>		
Nightmare	1	0
<i>Personality disorders with eccentric behaviour (Cluster A)</i>		
Schizotypal personality disorder	1	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	1	0
<i>Substance related and addictive disorders</i>		
Drug abuse	1	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	1	1
Suicidal ideation	2	0
Psychiatric disorders SOC TOTAL	16	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal failure and impairment</i>		
Renal failure	2	0
Renal impairment	1	0
Renal & urinary disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
Reproductive & breast disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	1	0
Nocturnal dyspnoea	1	0
<i>Parenchymal lung disorders NEC</i>		
Idiopathic pulmonary fibrosis	1	0
<i>Pulmonary oedemas</i>		
Pulmonary oedema	1	0
Respiratory disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Criminal activity</i>		
Homicide	1	0
Social circumstances SOC TOTAL	1	0

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Vascular disorders		
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
Vascular disorders SOC TOTAL	2	0
TOTAL REACTIONS FOR DRUG	104	2
TOTAL REPORTS	41	
TOTAL FATAL OUTCOME REPORTS		2