



Presentation

Remtin[®] 5: Each film coated tablet contains Memantine Hydrochloride USP 5 mg.

Description

Memantine Hydrochloride is a low affinity, voltage dependent, uncompetitive NMDA (N-methyl-D-aspartate) receptor antagonist. Persistant activation of NMDA receptors in central nervous system by the excitatory amino acid glutamate contributes to the symptomatology of Alzheimer's disease. Memantine exert its therapeutic effect through its action as a low to moderate affinity uncompetitive NMDA receptor antagonist and binds preferentially to the NMDA receptor-operated cation channels.

Indications

Memantine Hydrochloride is indicated for the treatment of moderate to severe dementia of the Alzheimer's type.

Dosage and administration

The recommended starting dose of Memantine Hydrochloride is 5 mg once daily and the maintanence dose is 20 mg/day. In order to reduce the risk of side effects this dose is achieved gradually by the following treatment scheme:

No. of weeks (daily dose)	Morning dose	Night dose
Week 1	1 tablet	None
Week 2	1 tablet	1 tablet
Week 3	2 tablets	1 tablet
Week 4 and beyond	2 tablets	2 tablets

Memantine Hydrochloride can be taken with or without food.

In case of renal impairment: A target dose of 5 mg BID is recommended in patients with severe renal impairment (creatinine clearance: 5-29 ml/min).

In case of hepatic impairment. No dosage adjustment is needed in patients with mild or moderate hepatic impairment. Memantine Hydrochloride should be administered with caution to patients with severe hepatic impairment.

Side-effects

The most common side effects (frequency 2% and less) are hallucinations, confusion, dizziness, headache and tiredness. Uncommon side effects are anxiety, hypertonia (increased muscle tone), vomiting, bladder infections and increased sexual drive.In case of epileptic seizure patients, Remtin may increase the chances of at least one occurring.

Contraindications

Memantine Hydrochloride is contraindicated in patients with known hypersensitivity to Memantine Hydrochloride or to any excipients used in the formulation.

Precaution

Memantine Hydrochloride has not been systematically evaluated in patients with seizure disorder. Conditions that raise urine pH may decrese the urinary elimination of Memantine resulting in increased plasma levels of Memantine. There is no evidence of carcinogenesis, mutagenesis and impairment of fertility.

Use in pregnancy and lactation

Pregnancy: Pregnancy Category B.

Nursing mothers: It is not known whether Memantine is excreted in human milk and therefore caution should be exercised when Memantine is administered to a nursing mother.

Drug interaction

Use with other NMDA antagonists e.g. amantadine, ketamine & dextromethorphan has not been systematically evaluated. Drugs that are eliminated via renal mechanisms e.g. hydrochlorothiazide, triametrene, metformin, cimetidine, ranitidine, quinidine & nicotine are contraindicated. Drugs that make urine alkaline e.g. carbonic anhydrase inhibitors, sodium bicarbonate etc. are also contraindicated when given with Memantine.

Overdose

Signs and symptoms associated with Memantine overdosage in clinical trials include agitation, confusion, ECG changes, loss of consciousness, psychosis, restlessness, slowed movement, somnolence, stupor, unsteady gait, visual hallucinations, vertigo, vomiting and weakness.

Storage

Do not store above 30 $^{\circ}\text{C}.$ Keep away from light and out of the reach of children.

Commercial Pack

Remtin 5: Each box contains 3 blister strips of 10 tablets.

