

Dementa

Memantine Hydrochloride USP

Description

Dementa (Memantine HCl) is a voltage dependent, uncompetitive, with moderate affinity, NMDA (N-methyl-D-aspartate) receptor antagonist that binds to the NMDA receptor channel and regulates the Calcium influx into the neurons. The chemical name of Memantine Hydrochloride is 1-amino-3, 5 -dimethyladamantane Hydrochloride.

Composition

Dementa 5 Tablet: Each film coated tablet contains Memantine Hydrochloride USP 5 mg.

Dementa 10 Tablet: Each film coated tablet contains Memantine Hydrochloride USP 10 mg.

Mode of Action

Persistent activation of N-methyl-D-aspartate (NMDA) receptors in Central Nervous System by the excitatory amino acid glutamate has been hypothesized to contribute to the symptomatology of Alzheimer's disease. Memantine is postulated to exert its therapeutic effect through its action as a low to moderate affinity as an uncompetitive (open-channel) NMDA receptor antagonist which binds preferentially to the NMDA receptor-operated cation channels.

Pharmacokinetics

Memantine (**Dementa**) is well absorbed after oral administration and has linear pharmacokinetics over the therapeutic dose range. It is excreted predominantly unchanged in the urine and has a terminal elimination half life of about 60-80 hours.

Following oral administration, Memantine (**Dementa**) is highly absorbed with peak concentrations reached in about 3-7 hours. Food has no effect on the absorption of Memantine. The mean volume of distribution of Memantine is 9-11 L/kg and the plasma protein binding is low (45%).

Memantine (**Dementa**) undergoes partial hepatic metabolism. About 48% of administered drug is excreted unchanged in urine; the remainder is converted primarily to three polar metabolites which possess minimal NMDA receptor antagonistic activity: the N-glucuronide conjugate, 6-hydroxy Memantine and 1-nitroso-deaminated Memantine. A total of 74% of the administered dose is excreted as the sum of the parent drug and the N-glucuronide conjugate. The hepatic microsomal CYP-450 enzyme system does not play a significant role in the metabolism of Memantine.

Indications

Dementa is indicated for the treatment of all forms of dementia of the Alzheimer's type. Memantine may also be indicated in other types of dementia.

Dosage and Administration

The recommended maintenance dose of Dementa for adults and older patients is 20 mg every day. In order to lower the risk of side effects, the dose should be achieved by upward titration with 5 mg per week over 3 weeks, achieving the maintenance dose of 20 mg/day from the start of week 4 according to the following dosage guideline:

	A.M. (Morning)	P.M. (Night)
Week 1 (Everyday)	5 mg	-
Week 2 (Everyday)	5 mg	5 mg
Week 3 (Everyday)	10 mg	5 mg
Week 4 and onwards (Everyday)	10 mg	10 mg

Side Effects

Most frequent side effects (frequency of 2% or less) include hallucination, confusion, dizziness, headache and fatigue. Occasional side effects include anxiety, hypertonus (heightened muscle tension), vomiting, bladder infections and increased sexual drive.

If there is a history of epileptic seizures, there is a slight chance that Dementa may increase the probability of an attack.

Drug Interactions

Amantadine, Anticholinergics, Anticonvulsives, Baclofen, Barbiturates, Cimetidine, Dantrolene, Dextromethorphan, Dopaminergic, Hydrochlorothiazide, Ketamine, Neuroleptics, Nicotine, Procinamide, Quinidine, Quinine, Ranitidine.

Contraindications

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

Precautions

Caregivers should be instructed in the recommended administration (twice per day for doses above 5 mg) and dose escalation (minimum interval of one week between dose increases). If the patients suffer from kidney dysfunction, the kidney function should be monitored at regular basis.

Neurological Conditions

Seizures: Memantine has not been systematically evaluated in patients with a seizure disorder. One clinical trial shows that seizures occurred in 0.2% of patients treated with Memantine and 0.5% of patients treated with placebo.

Carcinogenesis, Mutagenesis and Impairment of Fertility

Study shows that no risk of carcinogenesis, mutagenesis and impairment of fertility are caused after Memantine use.

Pregnancy and Lactation

Pregnancy Category B. Yet there are no adequate and well-controlled studies of Memantine in pregnant women. Memantine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether Memantine is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when Memantine is administered to a nursing mother.

Operating Vehicles or Machinery

Taking Memantine may alter the reaction time significantly; therefore safe driving and safe operation of machinery may no longer be possible.

Missed Dose

If any dose is missed, just wait and take the next dose at the usual time. Do not double the dose to compensate for the missed dose.

Storage Condition

Do not store above 30°C and keep in a dry place. Protect from light. Keep this medication out of the reach of children.

Packaging

Dementa 5 Tablet: Each carton contains 3x10's Tablets in blister pack.

Dementa 10 Tablet: Each carton contains 2x10's Tablets in blister pack.

Manufactured by

ZISKA PHARMA Ziska Pharmaceuticals Ltd.
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