

Abixa[®]

Memantine

Description

Abixa[®] is a preparation of memantine which is an antidementia drug with low to moderate affinity to voltage-dependent NMDA (N-methyl-D-aspartate) receptor antagonist. Memantine selectively blocks the excitotoxic effects associated with abnormal transmission of glutamate, while allowing for the physiological transmission associated with normal cell functioning.

Indication and usage

Abixa[®] is indicated for the treatment of moderate to severe dementia in Alzheimer's disease.

Dosage and administration

Initial dose

The recommended initial dose is 5 mg once daily, which is stepwise increased over the first 4 weeks and the recommended maximum daily dose is 20 mg.

Maintenance dose

The recommended maintenance dose is 20 mg daily.

In case renal impairment

In patients with moderate renal impairment (creatinine clearance 30-49 ml/min) daily dose should be 10 mg (1 ml solution, equivalent to two downward strokes). If tolerated well after at least 7 days of treatment, the dose could be increased up to 20 mg/day according to standard titration scheme. In patients with severe renal impairment (creatinine clearance 5-29 ml/min) daily dose should be 10 mg (1 ml solution, equivalent to two downward strokes) per day.

In case of hepatic impairment

In patients with mild or moderate hepatic impaired function, no dosage adjustment is needed. Administration of memantine is not recommended in patients with severe hepatic impairment.

Children under 18 years

Memantine is not recommended for use in children below 18 years due to lack of data on safety and efficacy.

Use in pregnancy and lactation

No clinical data on exposed pregnancies are available. Animal studies indicate a potential for reducing intrauterine growth at exposure levels that are identical or slightly higher than at human exposure. The potential risk of humans is unknown. Memantine should not be used during pregnancy unless clearly necessary.

It is not known whether memantine is excreted in human breast milk but, taking into consideration the lipophilicity of the substance, this probably occurs. Women taking memantine should not breast-feed.

Side effects

The most common side effects are headache, dizziness, drowsiness, constipation, dyspnea, hypertension; Less common side effects are vomiting, confusion, fatigue, hallucination, abnormal gait, thrombosis, heart failure; Very rare side effects are seizures, pancreatitis, psychosis, depression and suicidal ideation.

Precautions

Mamantine should be used with caution in patients with epilepsy, former history of convulsions or patients with predisposing factors for epilepsy. Some factors that may raise urine pH may necessitate careful monitoring of the patient. These factors include drastic changes in diet, e.g. from a carnivore to a vegetarian diet, or a massive ingestion of alkalizing gastric buffets. Urine pH may also be elevated by states of renal tubular acidosis (RTA) or severe infection of the urinary tracts with *Proteus* bacteria.

Contraindications

Memantine is contraindicated in patients with a known hypersensitivity to memantine or any of the excipients.

Drug interactions

Due to the pharmacological effects and mechanism of action of memantine suggests that the effects of L-dopa, dopaminergic agonists, and anticholinergics may be enhanced by concomitant treatment with NMDA-antagonists such as memantine. The effects of barbiturates and neuroleptics may be reduced. Concomitant administration of memantine with the antispasmodic agents, dantrolene or baclofen, can modify their effects and a dosage adjustment may be necessary. Memantine should not be used with amantadine, ketamine, dextromethorphan, phenytoin, cimetidine, ranitidine, procainamide, quinidine, quinidine, quinine & nicotine.

Pharmaceutical precautions

Keep away from the reach of children. Store in a cool and dry place protected from light. To be taken and sold only on the prescription of a registered physician.

Presentation

Abixa® 10 tablet: Each tablet contains memantine 10 mg as Hydrochloride INN.

Packaging

Abixa® 10 tablet: Carton of 20 tablets in blister pack.

® Registered Trade Mark



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