

Alzagon

(Memantine HCl)

الزagoon
(ميمانثاين هايڊروكلورايد)

COMPOSITION

Alzagon 5mg Tablet:

Each film coated tablet contains:
Memantine HCl (U.S.P.)5 mg
Product Complies U.S.P. Specs.

Alzagon 10mg Tablet:

Each film coated tablet contains:
Memantine HCl (U.S.P.) 10 mg
Product Complies U.S.P. Specs.

CLINICAL PHARMACOLOGY

Mechanism of Action

Persistent activation of central nervous system N-methyl-D-aspartate (NMDA) receptors 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 uncompetitive (open-channel) NMDA receptor antagonist which binds preferentially to the NMDA receptor-operated cation channels. There is no evidence that memantine prevents or slows neurodegeneration in patients with Alzheimer's disease.

Pharmacodynamics

Memantine showed low to negligible affinity for GABA, benzodiazepine, dopamine, adrenergic, histamine and glycine receptors and for voltage-dependent Ca^{2+} , Na^{+} or K^{+} channels. Memantine also showed antagonistic effects at the $5HT_3$ receptor with a potency similar to that for the NMDA receptor and blocked nicotinic acetylcholine receptors with one-sixth to one-tenth the potency.

In vitro studies have shown that memantine does not affect the reversible inhibition of acetylcholinesterase by donepezil, galantamine, or tacrine.

Pharmacokinetics

Absorption

Memantine is highly absorbed with peak concentrations reached in about 3-7 hours. Memantine has linear pharmacokinetics over the therapeutic dose range. Food has no effect on the absorption of memantine.

Distribution

The mean volume of distribution of memantine is 9-11 L/kg and the plasma protein binding is low (45%).

Metabolism

Memantine undergoes partial hepatic metabolism. The hepatic microsomal CYP₄₅₀ enzyme system does not play a significant role in the metabolism of memantine.

Elimination

Memantine is excreted predominantly (about 48%) unchanged in urine and has a terminal elimination half-life of about 60-80 hours.

INDICATIONS

Alzagon tablet (Memantine hydrochloride) is indicated for the treatment of moderate to severe Alzheimer's disease.

DOSAGE AND ADMINISTRATION

The recommended starting dose of Alzagon tablet is 5 mg once daily. The dose should be increased in 5 mg increments to 10 mg/day (5 mg twice daily). The recommended target dose is 20 mg/day (10 mg twice daily).

The minimum recommended interval between dose increases is one week.

Alzagon tablet can be taken with or without food.

CONTRAINDICATIONS

Alzagon tablet (Memantine hydrochloride) is contraindicated in patients with known hypersensitivity to memantine hydrochloride or to any excipients used in the formulation.

ADVERSE REACTIONS

Common adverse reactions ($\geq 5\%$ and greater than placebo) are dizziness, headache, confusion and constipation.

DRUG INTERACTIONS

Use with Other N-methyl-D-aspartate (NMDA) Antagonists.

The combined use of memantine with other NMDA antagonists (amantadine, ketamine, and dextromethorphan) has not been systematically evaluated and such use should be approached with caution.

USE IN SPECIFIC POPULATIONS

Pregnancy

Memantine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

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

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Renal Insufficiency

No dosage adjustment is needed in patients with mild or moderate renal impairment. A dosage reduction is recommended in patients with severe renal impairment.

Hepatic Impairment

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

WARNINGS AND PRECAUTIONS

Conditions that raise urine pH may decrease the urinary elimination of memantine resulting in increased plasma levels of memantine.

OVERDOSAGE

Signs and symptoms most often accompanying memantine overdose in clinical trials and from worldwide marketing experience, alone or in combination with other drugs and/or alcohol, include agitation, asthenia, bradycardia, confusion, coma, dizziness, ECG changes, increased blood pressure, lethargy, loss of consciousness, psychosis, restlessness, slowed movement, somnolence, stupor, unsteady gait, visual hallucinations, vertigo, vomiting, and weakness. The largest known ingestion of memantine worldwide was 2.0 grams in a patient who took memantine in conjunction with unspecified antidiabetic medications. The patient experienced coma, diplopia, and agitation, but subsequently recovered.

Fatal outcome has been very rarely reported with memantine, and the relationship to memantine was unclear. Because strategies for the management of overdose are continually evolving, it is advisable to contact a poison control center to determine the latest recommendations for the management of an overdose of any drug. As in any cases of overdose, general supportive measures should be utilized, and treatment should be symptomatic. Elimination of memantine can be enhanced by acidification of urine.

PRESENTATION

Alzagon tablets 5 mg are supplied in Alu Alu Blister pack (1x10's).
Alzagon tablets 10 mg are supplied in Alu Alu Blister pack (1x10's).

STORAGE

Store below 30°C in a dry place, protect from light.
To be dispensed on the prescription of a registered medical practitioner only.
Keep out of the reach of children.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
دوا کو 30 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر خشک جگہ پر رکھیں،
روشنی سے بچائیں۔ صرف ریسیپٹ ڈاکٹر کے نسخے پر فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:

Platinum
Pharmaceuticals (Pvt) Ltd.
A-20, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

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