MEMANTO™

Memantine Hydrochloride USP Film Coated Tablet

DESCRIPTION

Memanto™ is a preparation of Memantine Hydrochloride. Memantine Hydrochloride is an orally active N-methyl-D-aspartate (NMDA) receptor antagonist. 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. 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.

INDICATIONS

For the treatment of moderate to severe dementia of the Alzheimer's type.

DOSAGE AND ADMINISTRATION

The dosage of Memantine Hydrochloride shown to be effective in controlled clinical trials is 20 mg/day. The recommended starting dose is 5 mg once daily.

The recommended target dose is 20 mg/day. The dose should be increased in 5 mg increments to 10 mg/day (5 mg twice a day), 15 mg/day (5 mg and 10 mg as separate doses), and 20 mg/day (10 mg twice a day). The minimum recommended interval between dose increases is one week.

Memantine Hydrochloride can be taken with or without food.

CONTRAINDICATIONS

Contraindicated in patients with known hypersensitivity to Memantine Hydrochloride.

SIDE EFFECTS

- Fatigue
- Pain
- Hypertension
- Dizziness and Headache
- Constipation
- Confusion

PRECAUTION AND WARNING

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). Seizures: Memantine has not been systematically evaluated in patients with a seizure disorder. In clinical trials of Memantine, seizures occurred in 0.2% of patients treated with Memantine and 0.5% of patients treated with placebo. Conditions that raise urine pH may decrease the urinary elimination of Memantine resulting in increased plasma levels of Memantine.

USE IN PREGNANCY AND LACTATION

Pregnancy Category B. 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.

PHARMACEUTICAL PRECAUTION

Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Memanto™ **5 Tablet:** Box containing 3 strips of 10 tablets each. Each film coated tablet contains Memantine Hydrochloride USP 5 mg.

Memanto™ **10 Tablet:** Box containing 2 strips of 10 tablets each. Each film coated tablet contains Memantine Hydrochloride USP 10 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

™ TRADEMARK

PM06305 V01