Memantine Hydrochloride

Xolvmantine

10 mg Film Coated Tablet Anti-dementia

FORMULATION
Each film coated tablet contains:
Memantine Hydrochloride ..... 10 mg
Excipients ……..q.s.
Color: Yellow Oxide of Iron, Indigo Carmine & Titanium Dioxide BP

PRODUCT DESCRIPTION
Olive green colored, round shape biconvex, film coated tablet plain on both sides.

PHARMACOKINETICS
Memantine is well absorbed after oral administration and has linear pharmacokinetics over the therapeutic dose range. It is excreted predominantly in the urine, unchanged, and has a terminal elimination half-life of about 60-80 hours.
(For complete details on its Pharmacology please refer to the product insert.)

INDICATION
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. 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.
Doses in Special Populations: A target dose of 5 mg BID is recommended in patients with severe renal impairment or as prescribed by the physician.

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

WARNINGS AND PRECAUTION
Information for Patients and Care givers: Care givers 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).
(For Special Conditions – Neurological, Genitourinary and Special Populations – Hepatic Impairment & Renal impairment: Pls. refer to the refer to the product insert)

FERTILITY, PREGNANCY AND LACTATION
Use In Pregnancy: The are no or limited amount of data from the use of memantine in pregnant women. Animal studies indicate a potential for reducing intrauterine growth at exposure levels, which are identical or slightly higher than at human exposure. The potential risk for humans is

unknown. Memantine should not be used during pregnancy unless clearly necessary. .
Use in lactation: 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 breastfeed.
Fertility: No adverse reactions of memantine were noted on male and female fertility

ADVERSE DRUG REACTIONS
Fatigue, pain, dizziness, headache, hypertension & joint pain may occur. Serious side effects: mental/mood changes (e.g., depression, agitation, anxiety), swelling of hands or feet, trouble breathing.
(For complete details on Adverse Drug Reactions please refer to the product insert.)

DRUG INTERACTIONS
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.
(For complete details on Drug Interactions please refer to the product insert.)

OVERDOSE ANDTREATMENT
Signs and symptoms associated with memantine overdosage in clinical trials and from worldwide marketing experience include agitation, confusion, ECG changes, 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.
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.

CAUTION
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION
Store at temperature snot exceeding 30'C. Keep all medicines out of reach of children.

AVAILABILITY
Alu/Alu PVC Blister Pack x 10's (Box of 30s)

DRP- 6167- 01
Date of First Authorization: April 29, 2019
Date of Revision of Package Insert: November 08, 2022

(For complete Product Information please refer to the product insert.)