xxxxxxxx-5343

MEMANTINE HYDROCHLORIDE

AMINT-10

10 mg Film-Coated Tablet
Anti-Dementia

FORMULATION:
Each film-coated tablet contains:
Memantine Hydrochloride ..... 10 mg

PRODUCT DESCRIPTION
Memantine Hydrochloride (Amint-10) 10 mg Film-Coated Tablet is a white to off white colored, oblong shaped biconvex, film coated tablet debossed '10' on one side and breakline on other side.

MECHANISM OF ACTION:
Memantine belongs to a class of drugs called NMDA receptor antagonists, which help reduce abnormal activity in the brain by binding to NMDA receptors on brain cells and blocking the activity of the neurotransmitter glutamate. At normal levels, glutamate aids in memory and learning, but if levels are too high, glutamate appears to overstimulate nerve cells, killing off key brain cells.

PHARMACOKINETICS:
Memantine is well absorbed after oral administration. Plasma protein binding is about 45%. Memantine undergoes only limited metabolism; the main metabolites are N-3,5-dimethyl-gludantan and 1-nitroso-3,5-dimethyl-adamantane. The majority of a dose is excreted unchanged via the kidney; some active renal tubular secretion and reabsorption occurs. The terminal half-life ranges from 60 to 100 hours although under alkaline conditions the rate of elimination is reduced.

INDICATION:
Memantine is indicated for the treatment of moderately severe to severe Alzheimer's disease.

CONTRAINDICATIONS:
Memantine is contraindicated to patients with known hypersensitivity to the active ingredient or any of its components.

WARNINGS & PRECAUTIONS:
Treatment with Memantine is not recommended in patients with severe renal impairment, as no data are available for such patients. A reduced dose is required in those with moderate renal impairment.
Only limited clinical data are available for patients with recent myocardial infarction, uncompensated congestive heart failure, and uncontrolled hypertension and use of Memantine in these patients should be closely monitored. Caution is also recommended in patients with epilepsy.

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 for 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.

Effects on ability to drive and use machines:
Moderate to severe Alzheimer's disease usually causes impairment of driving performance and compromises the ability to use machinery. Furthermore, Memantine has minor or moderate influence on the ability to drive and use machines, such that outpatients should take special care.

DOSAGE AND ADMINISTRATION:
Alzheimer's disease: The initial dose of Memantine Hydrochloride is 5mg daily in the morning for the first week; this should be increased in weekly increments of 5 mg to a maximum dose of 20 mg daily. Doses of 10 mg and over should be taken in 2 divided doses.
Renal impairment: No dose adjustment is needed when Memantine hydrochloride is given for Alzheimer's disease in patients with mild renal impairment; however, in those with moderate impairment (creatinine clearance 40 to 60 mL/minute per 1.73m^2) the maximum dose should be reduced to 10 mg daily. No data is available for patients with severe impairment.

DRUG INTERACTIONS:
Use of other N-methyl-D-aspartate antagonists such as amantadine, ketamine, or dextromethorphan with Memantine may increase both the incidence and severity of adverse effects and should be avoided. The effects of dopaminergics and antimuscarinics may also be enhanced whereas Memantine may reduce the actions of barbiturates and antipsychotics.
Memantine may alter the effects of the antispasmodics baclofen and dantrolene.

ADVERSE EFFECTS:
Common adverse effects with Memantine include hallucination, confusion, dizziness, headache, and tiredness. Less common reactions such as anxiety, hypertonia, vomiting, cystitis, and increased libido have also occurred.

"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph or to TORRENT: www.torrentpharma.com".
Patient to seek medical attention immediately at the first sign of any adverse drug reaction shall appear.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE AND CONDITION:
Store at temperatures not exceeding 30^{o}C.

AVAILABILITY
Memantine Hydrochloride (Amint-10) 10 mg Film-Coated Tablet - Alu-Alu Blister pack of 10's (Box of 30's)– DRP-6443

DATE OF FIRST AUTHORIZATION
October 08, 2012

DATE OF REVISION
May 2016

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.

Imported and Distributed by :
TORRENT PHARMA PHILIPPINES INC.
Units 3 & 4, 34th Floor, Zuellig Building
Makati Avenue Corner Paseo de Roxas
Makati City, PHILIPPINES

PRODUCT NAME :	Amint	**COUNTRY :** Philippines	**LOCATION :** Chhatral		**REMARK :**		
ITEM / PACK :	Insert	**NO. OF COLORS:** 1	**SUBSTRATE :**				
DESIGN STYLE :	Front-Back	**PANTONE SHADE NOS.:**					
CODE :	xxxxxxxxx-5343	Black	**Activities**	**Department**	**Name**	**Signature**	**Date**
DIMENSIONS (MM) :	150 x 220		Prepared By	**Pkg.Dev**			
ART WORK SIZE :	S/S		Reviewed By	**Pkg.Dev**			
DATE :	22-06-2016		Approved By	**Quality**			