PATRIOT
Pharmaceuticals Corp.

Memantine hydrochloride

Zimerz®
10 mg Film-Coated Tablet
Anti-Parkinsonism

FORMULATION :
Each film coated tablet contains:
Memantine hydrochloride.....10mg

INDICATIONS :
For the treatment of Alzheimer's disease (moderate to severe, with or without dementia) and Parkinson's disease with dementia.

PHARMACODYNAMICS :
Memantine is a voltage-dependent, moderate-affinity uncompetitive NMDA-receptor antagonist. It modulates the effects of pathologically elevated tonic levels of glutamate that may lead to neuronal dysfunction.

PHARMACOKINETICS :
Memantine is well absorbed after oral doses. Peak plasma concentrations are achieved in about 3 to 8 hours. Plasma protein binding is about 45%. Memantine undergoes partial hepatic 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 the alkaline conditions the rate of elimination is reduced.

CONTRAINDICATIONS :
Memantine is contraindicated in patients with known hypersensitivity to memantine hydrochloride.

PREGNANCY :
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.

NURSING MOTHERS :
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.

PERDIATRIC USE :
There are no adequate and well-controlled trials documenting the safety and efficacy of memantine in any illness occurring in children.

ADVERSE EFFECTS AND PRECAUTIONS :
Common adverse effects with memantine include constipation, dizziness, headache and somnolence. Less common reactions such as anxiety, hallucinations, confusion, abnormal gait, hypertonia, vomiting, cystitis and increase libido have also occurred.

Dosage adjustment may be required in renal impairment but recommendations vary.

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ADVERSE EFFECTS AND PRECAUTIONS(cont.) :
Only limited clinical data are also 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. Seizures have occurred rarely and caution is recommended in patients at risk of convulsions. Conditions that increase urinary pH, such as drastic changes in diet, renal tubular acidosis, or severe infections of the urinary tract, may decrease elimination of memantine resulting in increased plasma levels; patient monitoring is recommended in such cases.

INTERACTIONS :
Use of the other N-methyl-D-aspartate antagonists such as amantadine, ketamine or dextromethorphan with memantine may increase both the ncidence 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 antispasmodics baclofen and dantrolene. The clearance of memantine is reduced under alkaline urine conditions and drugs such as carbonic anhydrase inhibitors and sodium bicarbonate should be used with caution.

TREATMENT FOR OVERDOSAGE :
In the event of overdose, treatment should be symptomatic. No specific antidote for intoxication or overdose is available. Standard clinical procedures to remove active substance material, e.g. gastric lavage, carbo medicinalis (interruption of potential entero-hepatic recirculation), acidification of urine, forced diuresis should be used as appropriate.

In case of signs and symptoms of general central nervous system (CNS) overstimulation, careful symptomatic clinical treatment should be considered.

DOSAGE AND ADMINISTRATION :
Memantine is a derivative of amantadine and is likewise antagonist of N-methyl-D-aspartate receptors. It is given by mouth as the hydrochloride. It can be taken with or without food.

The initial dose of memantine hydrochloride is 5mg daily in the morning for the first week; this should be increased in weekly increments of 5mg to a maximum dose of 20mg daily. Dose of 10mg daily and over should be taken in 2 divided doses. Reduced doses are recommended in patients with renal impairment. Clinical benefit should be reassessed on a regular basis.

Administration in renal impairment: In UK no dose adjustment is needed when memantine hydrochloride is given to patients with mild renal impairment. However, in those with moderate impairment (creatinine clearance 40 to 60mL/minute per 1.73 m2) the maximum dose should be reduced to 10mg daily, no data are available for patients with severe impairment.

While in US, no dose reduction is required in those with mild to moderate impairment; a target dose of 10mg is recommended in patients with severe impairment (creatinine clearance 5 to 29mL/minute).

CAUTION :
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

AVAILABILITY : Blister Pack x 10's (Box of 100's)

REGISTRATION NUMBER : DR-XY35289

DATE OF FIRST AUTHORIZATION : 10 Jan 2007

REVISION DATE : August 2019

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

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설명서	지머츠 (필리핀) 100정 **_허가 갱신용**	
학술담당	디자인담당	품질담당
심유정 대리	김희라	윤미숙 차장
	변경 전	**현재**
화판번호	(PP)5030436-1150827	(PP)5030436-1190916
사이즈(mm)	105 x 245 mm	변동 없음
지질/평량	모조지	변동 없음
코팅	변동 없음	변동 없음
변경 내역	화판번호, 문안 수정, 로고 변경	
비고	허가 갱신용 디자인	
인쇄소		

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