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Patient Information

Memantine Hydrochloride Tablets, USP (me-MAN-teen HYE-droe-KLOR-ide)

Read this Patient Information that comes with memantine hydrochloride tablets before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What are memantine hydrochloride tablets?

Memantine hydrochloride tablets are a prescription medicine used for the treatment of moderate to severe dementia in people with Alzheimer's disease. Memantine hydrochloride tablets belong to a class of medicines called NMDA (N-methyl-D-aspartate) inhibitors.

It is not known if memantine hydrochloride tablets are safe and effective in children.

Who should not take memantine hydrochloride tablets?

Do not take memantine hydrochloride tablets if you are allergic to memantine or any of the ingredients in memantine hydrochloride tablets. See the end of this leaflet for a complete list of ingredients in memantine hydrochloride tablets.

What should I tell my doctor before taking memantine hydrochloride tablets?

Before you take memantine hydrochloride tablets, tell your doctor if you:

- have or have had seizures
- have or have had problems passing urine
- have or have had bladder or kidney problems
- have liver problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if memantine hydrochloride tablets will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if memantine passes into your breast milk.

Talk to your doctor about the best way to feed your baby if you take memantine hydrochloride tablets.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Taking memantine hydrochloride tablets with certain other medicines may affect each other. Taking memantine hydrochloride tablets with other medicines can cause serious side effects.

Especially tell your doctor if you take:

- other NMDA antagonists such as amantadine, ketamine, and dextromethorphan
- medicines that make your urine alkaline such as carbonic anhydrase inhibitors and sodium bicarbonate

Ask your doctor or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take memantine hydrochloride tablets?

- Your doctor will tell you how many memantine hydrochloride tablets to take and when to take it.
- Your doctor may change your dose if needed.
- Memantine hydrochloride tablets can be taken with food or without food.
- Do not use any tablet of memantine hydrochloride that is damaged or show signs of tampering.
- If you forget to take one dose of memantine hydrochloride tablets, do not double up on the next dose. You should take only the next dose as scheduled.
- If you have forgotten to take memantine hydrochloride tablets for several days, you should not take the next dose until you talk to your doctor.
- If you take too many memantine hydrochloride tablets, call your doctor or poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.

What are the possible side effects of memantine hydrochloride tablets?

Memantine hydrochloride tablets may cause side effects, including:

The most common side effects of memantine hydrochloride tablets include:

- dizziness
- headache
- confusion
- constipation

These are not all the possible side effects of memantine hydrochloride tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store memantine hydrochloride tablets?

- Store memantine hydrochloride tablets at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).

What are the ingredients in memantine hydrochloride tablets?

Memantine hydrochloride tablets:

Active ingredients: memantine hydrochloride

Inactive ingredients: microcrystalline cellulose, anhydrous lactose, colloidal silicon dioxide, talc, and magnesium stearate.

Inactive ingredients of tablet film coating: hypromellose, titanium dioxide, polyethylene glycol, talc, iron oxide red, yellow iron oxide, and FD&C yellow #6 aluminum lake (5 mg tablets), and hypromellose, titanium dioxide, polyethylene glycol, talc and black iron oxide (10 mg tablets).

Keep memantine hydrochloride tablets and all medicines out of the reach of children.

General information about the safe and effective use of memantine hydrochloride tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not take memantine hydrochloride tablets for a condition for which it was not prescribed. Do not give memantine hydrochloride tablets to other people, even if they have the same condition. It may harm them.

This Patient Information leaflet summarizes the most important information about memantine hydrochloride tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about memantine hydrochloride tablets that was written for healthcare professionals.

For more information about memantine hydrochloride tablets, call Sun Pharmaceutical Industries, Inc. at 1-800-818-4555.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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Distributed by:

Sun Pharmaceutical Industries, Inc.

Cranbury, NJ 08512



Manufactured by:

Sun Pharmaceutical Industries Limited

Survey No. 1012, Dadra-396 193,

U.T. of D & NH and Daman & Diu, India.

Revised: 10/2023
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