

PATIENT INFORMATION
Memantine Hydrochloride Extended-release Capsules
[me-MAN-teen HYE-droe-KLOR-ide]

Rx Only

Read this Patient Information that comes with memantine hydrochloride extended-release capsules 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 extended-release capsules?

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

It is not known if memantine hydrochloride extended-release capsule is safe and effective in children.

Who should not take memantine hydrochloride extended-release capsules?

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

What should I tell my doctor before taking memantine hydrochloride extended-release capsules?

Before you take memantine hydrochloride extended-release capsules, 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 extended-release 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 extended-release.

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

Taking memantine hydrochloride extended-release capsules with certain other medicines may affect each other. Taking memantine hydrochloride extended-release capsules 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 extended-release capsules?

- Your doctor will tell you how much memantine hydrochloride extended-release capsules to take and when to take it.
- Your doctor may change your dose if needed.
- Memantine hydrochloride extended-release capsules may be taken with food or without food.
- Memantine hydrochloride extended-release capsules may be opened and sprinkled on applesauce before swallowing, but the contents of the entire capsule should be taken and the dose should not be divided. Except when opened and sprinkled on applesauce, memantine hydrochloride extended-release capsules must be swallowed whole and never crushed, divided or chewed.
- Do not use any capsules of memantine hydrochloride extended-release that are damaged or show signs of tampering.
- If you are currently taking another formulation of memantine, talk to your healthcare professional about how to switch to memantine hydrochloride extended-release capsules.
- If you forget to take one dose of memantine hydrochloride extended-release capsules, 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 extended-release capsules for several days, you should not take the next dose until you talk to your doctor.
- If you take too much memantine hydrochloride extended-release capsules call your doctor or poison control center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What are the possible side effects of memantine hydrochloride extended-release capsules?

Memantine hydrochloride extended-release capsules may cause side effects, including:

The most common side effects of memantine hydrochloride extended-release capsules include:

- headache
- diarrhea
- dizziness

These are not all the possible side effects of memantine hydrochloride extended-release capsules. 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.

You may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or visit our website at www.lupinpharmaceuticals.com.

How should I store memantine hydrochloride extended-release capsules?

Store memantine hydrochloride extended-release capsules at room temperature between 68 to 77°F (20 to 25°C).

Keep memantine hydrochloride extended-release capsules and all medicines out of the reach of children.

What are the ingredients in memantine hydrochloride extended-release capsules?

Active ingredient: memantine hydrochloride USP

Inactive ingredients: ethyl cellulose, gelatin, hypromellose, maize starch, sucrose, talc, titanium dioxide and triethyl citrate in hard gelatin capsules. Additionally, 7 mg strength capsules contain D&C Yellow #10 and FD&C Red #40; 14 mg strength capsules contain D&C Yellow #10, FD&C Blue #1, FD&C Red #40 and iron oxide yellow; 21 mg and 28 mg strength capsules contain FD&C Blue #1 and iron oxide yellow. The capsules are printed with edible ink containing black iron oxide, potassium hydroxide, propylene glycol and shellac.

General information about the safe and effective use of memantine hydrochloride extended-release capsules:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not take memantine hydrochloride extended-release capsules for a condition for which it was not prescribed. Do not give memantine hydrochloride extended-release capsules 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 extended-release capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about memantine hydrochloride extended-release capsules that was written for healthcare professionals.

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

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