

Patient Information
Memantine Hydrochloride (mem' an teen hye'' droe klor' ide)
Oral Solution

Read this Patient Information that comes with memantine hydrochloride oral solution 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 is memantine hydrochloride oral solution?

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

It is not known if memantine hydrochloride oral solution is safe and effective in children.

Who should not take memantine hydrochloride oral solution?

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

What should I tell my doctor before taking memantine hydrochloride oral solution?

Before you take memantine hydrochloride oral solution, 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 oral solution will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if memantine hydrochloride oral solution passes into your breast milk. You and your doctor should decide if you will take memantine hydrochloride oral solution or breastfeed.

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

Taking memantine hydrochloride oral solution with certain other medicines may affect each other. Taking memantine hydrochloride oral solution 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 oral solution?

- **See the step-by-step instructions for taking memantine hydrochloride oral solution at the end of this Patient Information.**
- Your doctor will tell you how much memantine hydrochloride oral solution to take and when to take it.
- Your doctor may change your dose if needed.
- Memantine hydrochloride oral solution can be taken with food or without food.
- If you forget to take one dose of memantine hydrochloride oral solution, 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 oral solution for several days, you should not take the next dose until you talk to your doctor.
- If you take too much memantine hydrochloride oral solution, 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 oral solution?

Memantine hydrochloride oral solution may cause side effects, including:

The most common side effects of memantine hydrochloride oral solution include:

- dizziness
- headache
- confusion
- constipation

These are not all the possible side effects of memantine hydrochloride oral solution. 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 oral solution?

Store memantine hydrochloride oral solution at room temperature between 68°F to 77°F (20°C to 25°C).

What are the ingredients in memantine hydrochloride oral solution?

Active ingredients: memantine hydrochloride

Inactive ingredients: sucralose, methylparaben, propylparaben, propylene glycol, glycerin, peppermint flavor PFC 9927, citric acid, sodium citrate, and purified water

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

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

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

PATIENT INSTRUCTION FOR MEMANTINE HYDROCHLORIDE ORAL SOLUTION

Read these instructions before taking memantine hydrochloride oral solution 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.

Follow the directions below to use your Memantine Hydrochloride Oral Solution dosing device

IMPORTANT: Read these instructions before using Memantine Hydrochloride Oral Solution.

INSTRUCTIONS FOR USE

Memantine Hydrochloride (mem' an teen hye'' droe klor' ide) Oral Solution

Directions for Using your Memantine Hydrochloride Oral Solution



Figure 1

1. Remove cap by pressing down and turning it counter-clockwise. See Figure 1.



Figure 2

2. While holding the bottle firmly, insert plastic bottle adapter completely into neck of the open bottle. See Figure 2.
Do not remove the plastic bottle adapter once it has been inserted into the neck of the bottle.

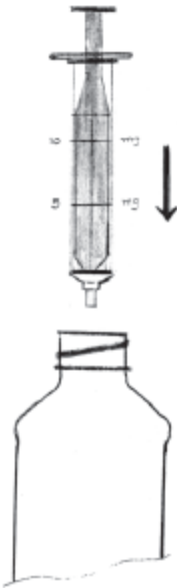


Figure 3



Figure 4

3. Insert the tip of syringe firmly into opening of plastic bottle adapter. See Figure 3.

4. Invert the entire unit (bottle with syringe) upside down as shown in Figure 4.

5. While holding the bottle and outer barrel of syringe, pull the plunger down slowly to the level (see markings on side) that equals the dosage prescribed by your doctor. (See Figure 4)

6. Remove the syringe from the bottle and swallow the Oral Solution directly from the syringe. Do not mix with any other liquid.

7. After use, place the child-resistant cap with the plastic bottle adapter on the bottle, rinse the empty syringe by inserting the open end of the syringe into a glass of water, pulling the plunger out to draw in water, and pushing the plunger in to remove the water. Allow the syringe to air dry.

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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