



Package leaflet: Information for the user
Memantine Hydrochloride Medley 10 mg/ml oral solution

memantine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Memantine Hydrochloride Medley
3. How to take Memantine Hydrochloride Medley
4. Possible side effects
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1. What Memantine Hydrochloride Medley is and what it is used for

The name of this medicine is Memantine Hydrochloride Medley 10 mg/ml oral solution, and is referred to as Memantine Hydrochloride Medley throughout this leaflet.

Memantine Hydrochloride Medley contains the active substance memantine hydrochloride. It belongs to a group of medicines known as anti-dementia medicines.

Memory loss in Alzheimer's disease is due to a disturbance of message signals in the brain. The brain contains so-called N-methyl-D-aspartate (NMDA)-receptors that are involved in transmitting nerve signals important in learning and memory. Memantine Hydrochloride Medley belongs to a group of medicines called NMDA-receptor antagonists. This medicine acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

This medicine is used for the treatment of patients with moderate to severe Alzheimer's disease.

2. What you need to know before you take Memantine Hydrochloride Medley

Do not take Memantine Hydrochloride Medley

- if you are allergic to memantine, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Memantine Hydrochloride Medley

- if you have a history of epileptic seizures
- if you have recently experienced a myocardial infarction (heart attack), or if you are suffering from congestive heart failure or from an uncontrolled hypertension (high blood pressure).

In these situations the treatment should be carefully supervised, and your doctor will regularly reassess the benefits of Memantine Hydrochloride Medley for you.

If you suffer from renal impairment (kidney problems), your doctor should closely monitor your kidney function and if necessary adapt the memantine doses accordingly.

If you are suffering from states of renal tubular acidosis (RTA, an excess of acid-forming substances in the blood due to renal dysfunction (poor kidney function)) or severe infections of the urinary tract (structure that carries urine), your doctor may need to adjust the dose of your medicine.

The use of medicines called amantadine (for the treatment of Parkinson's disease), ketamine (a substance generally used as an anaesthetic), dextromethorphan (generally used to treat cough) and other NMDA-antagonists at the same time should be avoided.

Children and adolescents

This medicine is not recommended for children and adolescents under the age of 18 years.

Other medicines and Memantine Hydrochloride Medley

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, Memantine Hydrochloride Medley may change the effects of the following medicines and their dose may need to be adjusted by your doctor:

- amantadine (used for Parkinson's disease),
- ketamine (used as an anaesthetic, for pain relief, and depression treatment),
- dextromethorphan (used for colds and respiratory conditions),
- dantrolene (used for muscle spasms and serious reactions to anaesthesia), baclofen (used for muscle stiffness),
- cimetidine, ranitidine (used for acid reflux and heartburn),
- procainamide, quinidine (used for irregular heartbeats),
- quinine (used to treat malaria),
- nicotine (used to stop smoking)
- hydrochlorothiazide (used for high blood pressure and reducing swelling) or any combination with hydrochlorothiazide
- anticholinergics (generally used to treat movement disorders or intestinal cramps)
- anticonvulsants used to prevent and relieve fits)
- barbiturates (generally used to induce sleep)
- dopaminergic agonists, such as L-dopa, bromocriptine (used to treat conditions like Parkinson's disease by improving movement and reducing symptoms like tremors and stiffness)
- neuroleptics (substances used in the treatment of mental disorders)
- oral anticoagulants (used to prevent blood clots)

If you go into hospital, let your doctor know that you are taking Memantine Hydrochloride Medley.

Memantine Hydrochloride Medley with food and drink

You should inform your doctor if you have recently changed or intend to change your diet substantially (e.g. from normal diet to strict vegetarian diet), as your doctor may need to adjust the dose of your medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take memantine hydrochloride if you are pregnant.

Breast-feeding

Do not take Memantine Hydrochloride Medley if you are breast-feeding.

Driving and using machines

Your doctor will tell you whether your illness allows you to drive and to use machines safely. Also, this medicine may affect your reactivity, making driving or operating machinery inappropriate.

Memantine Hydrochloride Medley contains sorbitol and potassium

This medicine contains 70 mg sorbitol (E420) in each ml. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine

Furthermore, this medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially 'potassium-free'.

3. How to take Memantine Hydrochloride Medley

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose of Memantine Hydrochloride Medley for adults and elderly patients is 2 ml, equivalent to 20 mg memantine hydrochloride, once a day. In order to reduce the risk of side effects this dose is achieved gradually by the following daily treatment scheme:

week 1	0.5 ml once a day
week 2	1 ml once a day
week 3	1.5 ml once a day
week 4 and beyond	2 ml once a day

The usual starting dose is 0.5 ml (1 x 5 mg) once a day for the first week. This dose is increased in the second week to 1 ml once a day (1 x 10 mg), and in the third week to 1.5 ml once a day (1 x 15 mg). From the fourth week the recommended dose is 2 ml once a day (1 x 20 mg).

Use in patients with kidney problems

If you have kidney function problems, your doctor will decide upon a dose that suits your condition. In this case, your doctor will monitor your kidney function at specified intervals.

Administration

- Memantine Hydrochloride Medley should be administered orally once a day.
- To benefit from your medicine you should take it regularly every day at the same time of the day. The solution should be taken with a little water.
- The solution can be taken with or without food.

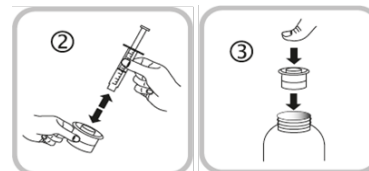
Instructions for use:

Open the bottle by turning it anti-clockwise (figure 1).



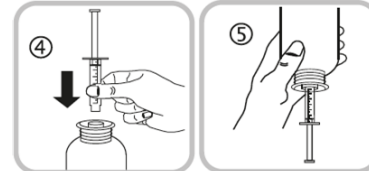
Follow these steps the first time you take Memantine Hydrochloride Medley:

- Take off the adaptor from the oral syringe (figure 2).
- Put the adaptor into the top of the bottle (figure 3). Make sure it is fixed well in place. You do not need to remove the adaptor after use.

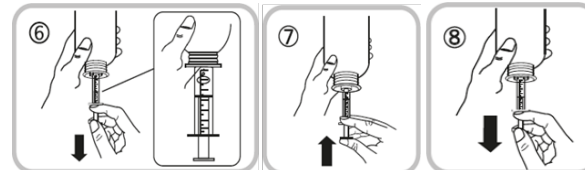


Follow these steps each time you take Memantine Hydrochloride Medley:

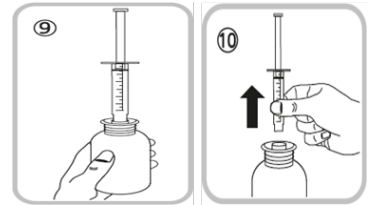
- Put the oral syringe into the adaptor opening (figure 4).
- Turn the bottle upside down (figure 5).



- Hold the bottle upside down in one hand and use the other hand to fill the oral syringe.
- Pull the piston down to fill the oral syringe with a small amount of solution (figure 6).
- Push the piston up to get rid of any bubbles (figure 7).
- Pull the piston down to the milliliter (ml) dose marker prescribed by your doctor (figure 8).

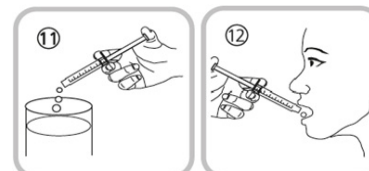


- Turn the bottle the right way up (figure 9).
- Take the oral syringe out of the adaptor (figure 10).

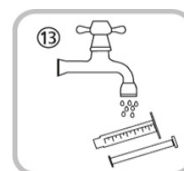


There are two ways in which you can choose to drink the medicine:

- Empty the contents of the oral syringe into a little water by pushing the piston to the bottom of the oral syringe (figure 11) – you will then need to drink all of the water (add just enough to make it easy to drink)
- or**
- Put the end of the syringe into your mouth and push the piston slowly back in to take the medicine (figure 12) – drink the whole contents of the oral syringe. Alternatively, dispense the solution onto a spoon or into a small glass of water and take your medicine straight away.



- Close the bottle with the child-resistant cap (you do not need to remove the adaptor).
- Wash the oral syringe with water and let it dry before you use it again (figure 13).



Duration of treatment

Continue to take Memantine Hydrochloride Medley as long as it is of benefit to you. Your doctor should assess your treatment on a regular basis.

If you take more Memantine Hydrochloride Medley than you should

- In general, taking too much Memantine Hydrochloride Medley should not result in any harm to you. You may experience increased symptoms as described in section 4. "Possible side effects".
- If you take a large overdose of Memantine Hydrochloride Medley, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take Memantine Hydrochloride Medley

- If you find you have forgotten to take your dose of Memantine Hydrochloride Medley, wait and take your next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In general, the observed side effects are mild to moderate.

Common (may affect more than 1 in 10 people):

- headache,
- sleepiness,
- constipation,
- elevated liver function tests,
- dizziness,
- balance disorders,
- shortness of breath,
- high blood pressure
- allergic reaction such as rash, itching, swelling and difficulty breathing.

Uncommon (may affect up to 1 in 100 people):

- tiredness,
- fungal infections,
- confusion,
- hallucinations,
- vomiting (being sick),
- abnormal gait (walking in an unusual or different way than normal),
- heart failure
- venous blood clotting, blood clot forms in a vein, which can block blood flow (thrombosis/ thromboembolism).

Very Rare (may affect up to 1 in 10,000 people):

- seizures (fits).

Not known (frequency cannot be estimated from the available data):

- inflammation of the pancreas,
- inflammation of the liver (hepatitis)
- psychotic reactions (extreme changes in thinking or perception, like seeing or hearing things that aren't real or having delusions).

Alzheimer's disease has been associated with depression, suicidal ideation and suicide. These events have been reported in patients treated with memantine hydrochloride.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Memantine Hydrochloride Medley

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30°C.

Once opened, the contents of the bottle should be used within 3 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Memantine Hydrochloride Medley contains

- The active substance is memantine hydrochloride. 1 ml of oral solution contains 10 mg memantine hydrochloride which is equivalent to 8.32 mg memantine.
- The other ingredients are sorbitol (E420), potassium sorbate and purified water.

What Memantine Hydrochloride Medley looks like and contents of the pack

Memantine Hydrochloride Medley solution is a clear and colorless to light yellowish solution.

It is presented in 50 ml or 100 ml amber coloured glass bottle closed with a polypropylene (PP) cap fitted with expanded polyethylene (EPE) wad.

The bottle is supplied with a 2 ml syringe (graduations of 0.5 ml each) with a body of polypropylene (PP), pusher of high-density polyethylene (HDPE) and an adapter of linear low-density polyethylene (LLDPE).

Marketing Authorisation Holder and Manufacturer

Medley Pharma Limited
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This leaflet was last revised in October 2025

Other sources of information.

To request a copy of this leaflet in braille, large print or audio, please call +441515214527 (UK only).

Please be ready to give the following information.

Product Name	Reference Number
Memantine Hydrochloride Medley 10 mg/ml Oral Solution	PL 43870/0053

XXX/XX
P0XXXXX