

Memantine Hydrochloride 10mg/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:

1. What Memantine is and what it is used for
2. What you need to know before you take Memantine
3. How to take Memantine
4. Possible side effects
5. How to store Memantine
6. Contents of the pack and other information

1. WHAT MEMANTINE IS AND WHAT IT IS USED FOR

Memantine 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 belongs to a group of medicines called NMDA-receptor antagonists. Memantine acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

Memantine is used for the treatment of patients with moderate to severe Alzheimer’s disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MEMANTINE

Do not take Memantine- if you are allergic to memantine hydrochloride or any of the other ingredients of this medicine. (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Memantine

- 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 the clinical benefit of Memantine reassessed by your doctor on a regular basis.

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

The use of medicinal products 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

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

Other medicines and Memantine

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

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

- amantadine, ketamine, dextromethorphan
- dantrolene, baclofen
- cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine
- hydrochlorothiazide (or any combination with hydrochlorothiazide)
- anticholinergics (substances generally used to treat movement disorders or intestinal cramps)
- anticonvulsants (substances used to prevent and relieve seizures)
- barbiturates (substances generally used to induce sleep)
- dopaminergic agonists (substances such as L-dopa, bromocriptine)
- neuroleptics (substances used in the treatment of mental disorders)
- oral anticoagulants

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

Memantine 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) or if you are suffering from states of renal tubulary 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), 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 planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

The use of memantine in pregnant women is not recommended.

Breast-feeding

Women taking Memantine should not breast-feed.

Driving and using machines

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

Memantine contains Sorbitol

This medicinal product contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Your doctor will advise you.

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

3. HOW TO TAKE MEMANTINE

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

Dosage

(a)Pump pack of 5mg/pump actuation:

One pump actuation contains 5 mg memantine hydrochloride.

The recommended dose of Memantine for adults and older people is four pump actuations, equivalent to 20 mg 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	one pump actuation (equivalent to 0.5 ml)
week 2	Two pumps actuation (equivalent to 1ml)
week 3	Three pumps actuation (equivalent to 1.5ml)
week 4 and beyond	Four pumps actuation (equivalent to 2ml)

The usual starting dose is one pump actuation once daily (1x 5 mg) for the first week. This dose is increased in the second week to two pump actuations once daily (1 x 10 mg), and in the third week to three pump actuations once daily (1 x 15 mg). From the fourth week the recommended dose is four pump actuations once daily (1x 20 mg).

(b)Dosing Pipette:

week 1	0.5 ml
week 2	1 ml
week 3	1.5 ml
week 4 and beyond	2 ml

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

Dosage in patients with impaired kidney function

If you have impaired kidney function, your doctor will decide upon a dose that suits your condition. In this case, monitoring of your kidney function should be performed by your doctor at specified intervals.

Administration

Memantine 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. For detailed instructions on the preparation and handling of the product see end of this leaflet.

Duration of treatment

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

If you take more Memantine than you should

In general, taking too much Memantine 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, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take Memantine

If you find you have forgotten to take your dose of Memantine, 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 product, 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 (affects 1 to 10 users in 100):

- Headache, sleepiness, constipation, elevated liver function tests, dizziness, balance disorders, shortness of breath, high blood pressure and drug hypersensitivity

Uncommon (affects 1 to 10 users in 1,000):

- Tiredness, fungal infections, confusion, hallucinations, vomiting, abnormal gait, heart failure and venous blood clotting (thrombosis/ thromboembolism)

Very Rare (affects less than 1 user in 10,000):

- Seizures


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

Inflammation of the pancreas, inflammation of the liver (hepatitis) and psychotic reactions

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

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 national reporting system.

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Description		Memantine Hydrochloride 10mg/ml 50/100ml		No. of colours	1	Page Count	1/2	
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Superceded Affiliate Item Code	577176L00	Vendor Job No.	253972					
TrackWise PR No.	606325	Proof No.	2					
MA No.	PA 577/176/1	Client Market	Ireland	Equate CMYK with				
Packing Site/Printer	Chanelle Medical	Keyline/Drawing No.	N/A					
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Sign-offs				Dimensions	156 x 487 mm		Min Text Size used	9 pt

