

PACKAGE LEAFLET: INFORMATION FOR THE USER

Memantine hydrochloride Pinewood 10 mg Film-Coated Tablets **Memantine hydrochloride Pinewood 20 mg Film-Coated Tablets** 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 hydrochloride Pinewood is and what it is used for
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1. What Memantine hydrochloride Pinewood is and what it is used for

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

Memantine hydrochloride 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 Pinewood

Do not take Memantine hydrochloride Pinewood:

- 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 hydrochloride Pinewood if you:

- have a history of epileptic seizures

- 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 hydrochloride 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 hydrochloride Pinewood 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 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 hydrochloride Pinewood is not recommended for children and adolescents under the age of 18 years.

Other medicines and Memantine hydrochloride Pinewood

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

In particular, Memantine hydrochloride Pinewood 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 hydrochloride Pinewood.

Memantine hydrochloride Pinewood 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

The use of Memantine hydrochloride Pinewood in pregnant women is not recommended.

Breast-feeding

Women taking Memantine hydrochloride Pinewood 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 hydrochloride Pinewood may change your reactivity, making driving or operating machinery inappropriate.

3. How to take Memantine hydrochloride Pinewood

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

The recommended treatment dose of 20 mg per day is achieved by a gradual increase of the Memantine hydrochloride Pinewood dose during the first 3 weeks of treatment. In order to reduce the risk of side effects this dose is achieved gradually by the following daily treatment scheme:

Week 1	half a 10 mg tablet
Week 2	one 10 mg tablet
Week 3	one and a half 10 mg tablets
Week 4 and beyond	two 10 mg tablets once a day or one 20 mg tablet once a day

The usual starting dose is half a 10 mg tablet once a day (1x 5 mg) for the first week. This is increased to one 10 mg tablet once a day (1x 10 mg) in the second week and to one and a half 10 mg tablets (1 x 15 mg) once a day in the third week. From the fourth week on, the usual dose is two 10 mg tablets once a day (1x 20 mg) or one 20 mg tablet once a day (1 x 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 hydrochloride 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 tablets should be swallowed with some water. The tablets can be taken with or without food.

Duration of treatment

Continue to take Memantine hydrochloride Pinewood 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 Pinewood than you should

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

If you forget to take Memantine hydrochloride Pinewood

- If you find you have forgotten to take your dose of Memantine hydrochloride Pinewood, 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 up to 1 in 10 people

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

Uncommon: may affect up to 1 in 100 people

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

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

- 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 thoughts 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: + 353 1 6764971; Fax; +353 1 6762517. Website: www.hpra.ie; email: medsafety@hpra.ie.

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

5. How to store Memantine hydrochloride Pinewood

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 the blister after EXP. The expiry date refers to the last day of that month.

Store below 25°C for the 10mg tablet and store below 30°C for the 20mg tablet.

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 to protect the environment.

6. Contents of the pack and other information

What Memantine hydrochloride Pinewood contains

The active substance is memantine hydrochloride. The 10 mg film-coated tablet contains 10 mg memantine hydrochloride equivalent to 8.31 mg memantine. The 20 mg film-coated tablet contains 20 mg memantine hydrochloride equivalent to 16.62 mg memantine.

The other ingredients are microcrystalline cellulose, crospovidone, povidone K 29/32, colloidal anhydrous silica, purified talc and magnesium stearate, all in the tablet core; and hypromellose, macrogol 4000 and titanium dioxide (E171), all in the tablet coating.

What Memantine hydrochloride Pinewood looks like and contents of the pack

The 10 mg film-coated tablets are presented as off white capsule shaped biconvex, film-coated tablets debossed with “M” and “10” on either side of the breakline on one side and breakline on the other side.

The 20 mg film-coated tablets are presented as off white oval shaped film-coated tablets with “U” debossed on one side and plain on the other side.

Memantine hydrochloride Pinewood 10 mg and 20 mg film-coated tablets are supplied in cartons containing 14, 28, 42, 56, 70, 84, 98 or 112 film-coated tablets in blisters of PVC/PE/PVdC and aluminium foil.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pinewood Laboratories Limited,
Ballymacarbry,
Clonmel,
Co. Tipperary,
Ireland

Manufacturer:

Niche Generics Ltd.
Unit 5,
151 Baldoyle Industrial Estate
Dublin 13
Ireland

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