Version 4, 02/2016

PACKAGE LEAFLET

Package leaflet: Information for the user

Memantine hydrochloride Lupin 10mg film coated tablets
Memantine hydrochloride Lupin 20mg film-coated tablets
Memantine hydrochloride Lupin 5mg + 10mg + 15mg + 20mg film-coated tablets, titration pack

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 tablets are and what they are used for

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

- Memantine tablets are used for the treatment of patients with moderate to severe alzheimer's disease.

2. What you need to know before you take Memantine tablets.

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

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Warning and precautions
Talk to your doctor or pharmacist before taking Memantine tablets.

- 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 tablets should be 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.

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), 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 tablets is not recommended for children and adolescents under the age of 18 years.

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

In particular, Memantine tablets 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 tablets.

Memantine tablets 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 in pregnant women is not recommended.

Breast-feeding
Women taking Memantine tablets 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 tablets may change your reactivity, making driving or operating machinery inappropriate.

Memantine hydrochloride Lupin film-coated tablets contain Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Memantine Tablets.

The Memantine treatment initiation pack is only to be used for the beginning of the treatment with Memantine.

Always take this medicine exactly as your doctor has told you. 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 dose during the first 3 weeks of treatment. The treatment scheme is also indicated on the treatment initiation pack. Take one tablet once a day.

Week 1 (day 1-7):
Take one 5 mg tablet once a day (white to off-white, capsule shaped) for 7 days.

Week 2 (day 8-14):
Take one 10 mg tablet once a day (white to off-white, oval shaped) for 7 days.

Week 3 (day 15-21):
Take one 15 mg tablet once a day (mustard coloured, oval shaped) for 7 days.

Week 4 (day 22-28):
Take one 20 mg tablet per day (brownish pink coloured, oval shaped) for 7 days.

week 1	5 mg tablet
week 2	10 mg tablet
week 3	15 mg tablet
week 4 and beyond	20 mg tablet once a day

Maintenance dose
The recommended daily dose is 20mg once a day.
For continuation of the treatment please consult your doctor.

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 tablets 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.

The 10mg and 20mg tablet can be divided into equal doses.

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

If you take more Memantine tablets than you should

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

If you forget to take Memantine tablets

- If you find you have forgotten to take your dose of Memantine tablets, 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 (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 1000):

- 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 tablets.

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 www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the 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 tablets

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.

Do not store above 25°C. Protect from light. Store in the original package.

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 tablets contains

- The active substance is memantine hydrochloride. Each film-coated tablet contains either 5mg, 10mg, 15mg or 20mg memantine hydrochloride equivalent to 4.15mg, 8.31mg, 12.46mg or 16.62mg memantine.
- The other ingredients are microcrystalline cellulose, silica, colloidal anhydrous, croscarmellose sodium, talc, magnesium stearate all in the tablet core; and hypromellose, macrogol 400 and titanium dioxide (E171) all in the tablet coating.
- Additional for the 15mg tablets, Iron Oxide yellow (E172) in the tablet coating.
- Additional for the 20mg tablets, Red Iron Oxide (E172) in the tablet coating.

What Memantine tablets look like and contents of the pack

Memantine 5mg tablets are white to off white coloured, capsule shaped, biconvex, film-coated tablets, debossed with "5" on one side and plain on the other side.

Memantine 10mg tablets are white to off white coloured, oval shaped, film-coated tablets, debossed with "10" on one side and breakline on the other side.

Memantine 15mg tablets are mustard yellow coloured, oval shaped, film-coated tablets, debossed with "15" on one side and plain on the other side.

Memantine 20mg tablets are brownish pink coloured, oval shaped, film-coated tablets, debossed with "20" on one side and breakline on the other side

Memantine 10mg and 20mg tablets can be divided into equal doses.

Contents of the pack

Memantine 10mg and 20mg film-coated tablets are available in blister packs containing either 7, 10, 14 or 20 tablets per blister strip.

Pack sizes of 14, 28, 30, 42, 49 x 1, 50, 56, 56 x 1, 70, 84, 98, 98 x 1, 100, 100 x 1, 112, 840 (20 x 42), 980 (10 x 98) or 1000 (20 x 50) tablets are presented.

The pack sizes 49 x 1, 56 x1, 98 x 1 and 100 x 1 film-coated tablets are presented in unit dose blister.

Treatment initiation pack containing 5mg, 10mg, 15mg and 20mg tablets are available in blister packs contains 28 film-coated tablets in PVC/Al blisters with 7 film-coated tablets of 5mg, 7 film-coated tablets of 10mg, 7 film-coated tablets of 15mg and 7 film-coated tablets of 20mg tablets.

Not all pack sizes may be marketed.

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