Package leaflet: Information for the patient

Memantine Mylan 10 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

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1. What Memantine Mylan is and what it is used for

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

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

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

Do not take Memantine Mylan:
- 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 or pharmacist before taking Memantine Mylan
- 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 Mylan 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 Mylan is not recommended for children and adolescents under the age of 18 years.

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

In particular, Memantine Mylan 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 Mylan.

Memantine Mylan 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 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 Mylan 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 Mylan may change your reactivity, making driving or operating machinery inappropriate.

Memantine Mylan contains 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 Mylan

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

Dosage
The recommended dose of Memantine Mylan for adults and older people is 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	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

The usual starting dose is half a 10 mg tablet once a day (5 mg) for the first week. This is increased to one 10 mg tablet once a day (10 mg) in the second week and to 1 and a half 10 mg tablets once a day in the third week. From the fourth week on, the usual dose is two 10 mg tablets once a day (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 Mylan 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 divided into equal doses and can be taken with or without food.

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

If you take more Memantine Mylan than you should
- In general, taking too much Memantine Mylan 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 Mylan, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take Memantine Mylan
- If you find you have forgotten to take your dose of Memantine Mylan, 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 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 national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom (Northern Ireland)
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Memantine Mylan

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

This medicine does not require any special storage conditions.

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 Mylan contains

- The active substance is memantine. Each film-coated tablet contains 10 mg of memantine hydrochloride equivalent to 8.31 mg memantine.
- The other ingredients are microcrystalline cellulose, croscarmellose sodium (see section 2 'Memantine Mylan contains sodium'), magnesium stearate, talc and colloidal anyhdrous silica, all in the tablet core; polydextrose (E1200), titanium dioxide (E171), hypromellose 3cP (E464), hypromellose 6cP (E464), hypromellose 50cP (E464), iron oxide yellow (E172), macrogol 400 (E1521), macrogol 8000, indigo carmine aluminium lake (E132) and iron oxide red (E172), all in the tablet coating.

What Memantine Mylan looks like and contents of the pack

A dark yellow film-coated, tapered oblong shaped, biconvex tablet marked with “ME” on the left of the score and “10” on the right of the score on one side of the tablet and a score on the other side. The tablet can be divided into equal doses.

Memantine Mylan film-coated tablets are available in blister packs of 7, 10, 14, 28, 28 x 1, 30, 42, 50, 56, 56 x 1, 60, 70, 84, 98, 98 x 1, 100, 100 x 1 or 112 film-coated tablets.
The pack sizes 28 x 1, 56 x 1, 98 x 1 and 100 x 1 film-coated tablets are presented in unit dose blisters.

Not all pack sizes may be marketed.

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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.