Package leaflet: Information for the patient

Memantine 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.

What is in this leaflet

1. What Memantine 10mg film-coated Tablets is and what it is used for

How does Memantine10mg film-coated Tablets work

Memantine 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. Memantineacts on these NMDA-receptors improving the transmission of nerve signals and the memory.

What is Memantine 10mg film-coated Tablets used for

Memantine 10mg Film-Tablets is used for the treatment of patients with moderate to severe Alzheimer's disease.

2. What you need to know before you take Memantine 10mg film-coated Tablets

Do not take Memantine 10mg film-coated Tablets
- 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 10mg film-coated 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 ofMemantine 10mg film-coated Tablets 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.

You should inform your doctor 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.

Memantine 10mg film-coated Tablets is not recommended for children and adolescents under the age of 18 years.

Other medicines and Memantine 10mg film-coated Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, Memantine 10mg film-coated 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 10mg film-coated Tablets.

Memantine 10mg film-coated 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).

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.

The use of memantine in pregnant women is not recommended.

Women taking Memantine 10mg film-coated 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 10mg film-coated Tablets may change your reactivity, making driving or operating machinery inappropriate.

3. How to take Memantine 10mg Film-coated Tablets

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 10mg film-coated Tabletsfor adults and elderly patients 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.
For up-titration other tablet strengths are available.

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

The usual starting dose is half a 10 mg tablet once a day for the first week. This is increased to one 10 mg tablet once a day in the second week and to 1 and a half 10 mg tablet once a day in the third week. From the fourth week on, the usual dose is two 10 mg tablets or one 20 mg tablet once a day.

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.

Route and method of administration

Memantine 10mg film-coated 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.

Duration of treatment

Continue to take Memantine 10mg film-coated 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 10mg film-coated Tablets than you should

- In general, taking too much Memantine 10mg film-coated 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 10mg film-coated Tablets, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take Memantine 10mg film-coated Tablets

- If you find you have forgotten to take your dose of Memantine 10mg film-coated 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 (may affect up to 1 in 10people):
- 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 to 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 in10,000 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 10mg film-coated 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST
Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517

Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

5. How to store Memantine 10mg film-coated 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 after EXP. The expiry date refers to the last day of that month.

This medicinal product 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 10mg film-coated Tabletscontains

- The active substance is memantine hydrochloride.

Each film coated tablet contains 10 mg memantine hydrochloride equivalent to 8.31 mg memantine.
- The other ingredients are

Tablet core: microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, talc and magnesium stearate
Tablet coating: hypromellose, macrogol 400, titanium dioxide (E171) and talc.

What Memantine 10mg film-coated Tabletslooks like and contents of the pack

Memantine 10 mg film coated tablets are white to off white , capsule shaped , about 11.00 ± 0.5 mm long, 5.50 ± 0.5 mm wide, 3.95 ± 0.5 mm thick, film coated tablets, debossed with "M" and "12" on either side of breakline on one side and plain on other side.
The tablet can be divided into equal doses.

Memantine 10mg film coated tablets are available in blister packs of 28 tablets, 30 tablets, 42 tablets, 50 tablets, 56 tablets, 60 tablets, 98 tablets, 100 tablets, 112 tablets, or 1000 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Ranbaxy Ireland Ltd., Spafield, Cork Road, Cashel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

AT	Memantin Ranbaxy 10 mg Filmtabletten
CZ	Memantine Ranbaxy 10 mg potahovanétablety
DE	MEMANTIN BASICS 10 mg Filmtabletten
EE	MEMANTINE RANBAXY
EL	Memantine Minerva 10 mg Επικαλυμμένομελεπτό υμένιο δισκίο
ES	MEMANTINA RANBAXY 10 MG COMPRIMIDOS RECUBIERTOS CON PELÍCULA EFG
FR	MEMANTINE RANBAXY 10 mg, comprimé pelliculé sécable.
HU	Memantine Ranbaxy 10 mg filmtabletta
IE	Memantine 10mg film-coated Tablets
LT	Memantine Ranbaxy 10 mg plėvele dengtos tabletės
LV	Memantine Ranbaxy 10 mg apvalkotās tabletes
RO	Memantină Terapia 10 mg comprimate filmate
SK	Memantine Ranbaxy 10mg filmom obalenétablety

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Black

Memantine 10 mg PIL
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RLL/PKGDEV : AK21/08/13-V01, CG23/08/13-V02, AK24/08/13-V03 J23/09/13-V04

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