Package leaflet: Information for the user

Memantine hydrochloride 5mg orodispersible tablets
Memantine hydrochloride 10mg orodispersible tablets
Memantine hydrochloride 15mg orodispersible tablets
Memantine hydrochloride 20mg orodispersible tablets

memantine hydrochloride

Pharmacode

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 orodispersible tablets are and what they are used for

The name of your medicine is Memantine hydrochloride 5mg, 10mg, 15mg and 20mg orodispersible tablets (called Memantine hydrochloride tablets in the rest of this leaflet).

This medicine 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 hydrochloride tablets belong to a group of medicines called NMDA-receptor antagonists. Memantine hydrochloride tablets act on these NMDA-receptors improving the transmission of nerve signals and the memory.

Memantine hydrochloride 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 hydrochloride orodispersible tablets

Do not take Memantine hydrochloride tablets
- 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 hydrochloride 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 uncontrolled hypertension (high blood pressure).

In these situations, the treatment should be carefully supervised, and the clinical benefit of Memantine hydrochloride 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.

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 hydrochloride tablets are not recommended for children and adolescents under the age of 18 years.

Other medicines and Memantine hydrochloride tablets

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

In particular, Memantine hydrochloride 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 hydrochloride tablets.

Memantine hydrochloride 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.

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

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

Memantine hydrochloride tablets contain Sodium

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

Memantine hydrochloride tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Memantine hydrochloride tablets contain aspartame

Each 5mg, 10mg, 15mg and 20mg orodispersible tablets contain 1.25mg, 2.5mg, 3.75mg and 5mg of aspartame, respectively.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3 How to take Memantine hydrochloride orodispersible tablets

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 20mg per day is achieved by a gradual increase of the Memantine hydrochloride tablet dose during the first 3 weeks of treatment. Take one tablet once a day.

Week 1 (day 1 - 7)	Take one 5mg tablet once a day (light pink round, flat, speckled tablets with bevelled edges, a diameter of 7mm and engraved with "5" on one side) for 7 days.
Week 2 (day 8 - 14)	Take one 10mg tablet once a day (light pink, round, flat, speckled tablets with bevelled edges, a diameter of 9mm and engraved with "10" on one side) for 7 days.
Week 3 (day 15 - 21)	Take one 15mg tablet once a day (light pink, round, flat, speckled tablets with bevelled edges, a diameter of 11mm and engraved with "15" on one side) for 7 days.
Week 4 and beyond	Take one 20mg tablet once a day (light pink, round, flat, speckled tablets with bevelled edges, a diameter of 12mm and engraved with "20" on one side) for 7 days.

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 hydrochloride 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 tablet can be taken with or without food.

Memantine hydrochloride tablets break easily, so you should handle the tablets carefully. Do not handle the tablets with wet hands as the tablets may break up.
- Hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
- Carefully peel off the backing.
- Place the tablet on your tongue. The tablet will rapidly disintegrate and can be swallowed without water.

Duration of treatment

Continue to take Memantine hydrochloride 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 hydrochloride tablets than you should
- In general, taking too many Memantine hydrochloride 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 hydrochloride tablets, contact your doctor, or get medical advice, as you may need medical attention.

If you forget to take Memantine hydrochloride tablets
- If you find you have forgotten to take your dose of Memantine hydrochloride 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 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.

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 Yellow Card Scheme Website: 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 hydrochloride orodispersible 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 day 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 hydrochloride tablets contain
- The active substance is memantine hydrochloride. Each orodispersible tablet contains 5mg, 10mg, 15mg or 20mg of memantine hydrochloride equivalent to 4.15mg, 8.31mg, 12.46mg or 16.62mg memantine.
- The other ingredients are polacriline, lactose monohydrate, cellulose microcrystalline, mannitol, croscarmellose sodium, aspartame (E951), silica colloidal anhydrous, iron oxide red (E172), flavour peppermint (containing Maltodextrin (maize), Modified starch E1450 (waxy maize), Peppermint oil (mentha arvensis)), magnesium stearate.

What Memantine hydrochloride tablets look like and contents of the pack

Memantine hydrochloride 5mg orodispersible tablets are presented as light pink, round, flat, speckled tablets with bevelled edges and engraved with "5" on one side.

Memantine hydrochloride 10mg orodispersible tablets are presented as light pink, round, flat, speckled tablets with bevelled edges and engraved with "10" on one side.

Memantine hydrochloride 15mg orodispersible tablets are presented as light pink, round, flat, speckled tablets with bevelled edges and engraved with "15" on one side.

Memantine hydrochloride 20mg orodispersible tablets are presented as light pink, round, flat, speckled tablets with bevelled edges and engraved with "20" on one side.

Memantine hydrochloride 5mg and 15mg tablets are available in blister packs of 7 and 28 orodispersible tablets.

Memantine hydrochloride 10mg and 20mg tablets are available in blister packs of 7, 14, 28, 30, 50, 42, 56, 60, 98, 100, 420 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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