

Package leaflet: Information for the patient

Memantine hydrochloride 20 mg Film-coated Tablets

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* is and what it is used for
2. What you need to know before you take *Memantine hydrochloride*
3. How to take *Memantine hydrochloride*
4. Possible side effects
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6. Contents of the pack and other information

1. What *Memantine hydrochloride* is and what it is used for

How does *Memantine hydrochloride* work

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.

What is *Memantine hydrochloride* used for

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*

Do not take *Memantine hydrochloride*:

- if you are allergic to memantine hydrochloride, peanut or soya 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*:

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

Other medicines and *Memantine hydrochloride*

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

In particular, *Memantine hydrochloride* 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*.

***Memantine hydrochloride* 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 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), 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 in pregnant women is not recommended.

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

***Memantine hydrochloride* contains lactose and soya lecithin**

This medicine contains 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.

This medicine contains soya lecithin. If you are allergic to peanut or soya, do not take this medicinal product.

3. How to take *Memantine hydrochloride*

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 hydrochloride* for 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.

At the beginning of treatment you will start by using 5 mg once a day. This dose will be increased weekly by 5 mg until the recommended (maintenance) dose is reached. The recommended maintenance dose is 20 mg once a day, which is reached at the beginning of the 4th week.

The tablet can be divided into equal doses.

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* 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* than you should

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

If you forget to take *Memantine hydrochloride*

- If you find you have forgotten to take your dose of *Memantine hydrochloride*, 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 1,000):

- 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.

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 at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Memantine hydrochloride

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

Blister packs

Do not store above 25°C

HDPE bottles

Shelf life after first opening of the container: 6 months.

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 contains

The active substance is memantine hydrochloride.

Each film-coated tablet contains 20 mg memantine hydrochloride equivalent to 16.62 mg memantine.

The other ingredients are:

Tablet core

Cellulose microcrystalline, starch pregelatinised, lactose anhydrous, colloidal anhydrous silica, magnesium stearate.

Coating

Polysorbate 80, polyvinyl alcohol, titanium dioxide, talc, soya lecithin, xanthan gum.

What Memantine hydrochloride looks like and contents of the pack

White to off-white, capsule shaped (15.6 x 8.0 mm), biconvex tablets with a break score on one side and embossed with "20" on the other side.

Memantine hydrochloride is available in packs of 7, 10, 14, 21, 28, 30, 42, 56, 98 and 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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APPROVALS

Signed by	Meaning of Signature	Server Date
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