

Memantine 20 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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2. What you need to know before you take Memantine
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1. What Memantine is and what it is used for

How does Memantine work

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

What is Memantine used for

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

2. What you need to know before you take Memantine

Do not take Memantine

- 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

Take special care with Memantine:

- 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 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 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.

Children and adolescents

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

Other medicines and Memantine

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

Memantine 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.

Memantine 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.

Pregnancy

The use of Memantine in pregnant women is not recommended.

Breast-feeding

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

Memantine 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.

3. How to take Memantine

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

Dose

The recommended dose of Memantine 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.

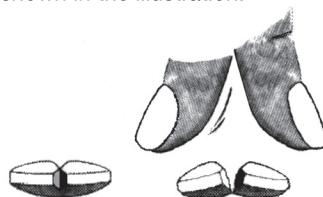
At the beginning of treatment you will start by using Memantine 5 mg film-coated tablets once a day. This dose will be increased weekly by 5 mg until the recommended (maintenance) dose is reached. The recommended maintenance dose is 20 mg once a day, which is reached at the beginning of the 4th week.

Renal impairment

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.

Breaking the tablet

Place the tablet with the round side on a hard surface, the score line should face upwards. Press with the forefinger and thumb of the same hand on either side of the score line and push down until the tablet breaks as shown in the illustration.



Administration

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

If you take more Memantine than you should

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

If you forget to take Memantine

If you find you have forgotten to take your dose of Memantine, 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.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Zentiva Pharma UK Limited
12 New Fetter Lane
London EC4A 1JP
United Kingdom

Manufacturer(s):

Synthon Hispania S.L.
Castelló, 1
Polígono Las Salinas
08830 Sant Boi de Llobregat
Spain

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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
- high blood pressure • shortness of breath • drug hypersensitivity

Uncommon (may affect up to 1 in 100 people)

- Tiredness • fungal infections • confusion
- hallucinations • vomiting • abnormal gait
- heart failure • 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) • 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 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

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 blister and 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 contains

- The active substance is memantine hydrochloride. Each film-coated tablet contains 20 mg of memantine hydrochloride equivalent to 16.62 mg memantine.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, talc and magnesium stearate, all in the tablet core; and lactose monohydrate, hypromellose, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172) and macrogol 4000, all in the tablet coating.

What Memantine looks like and contents of the pack

Memantine 20 mg film-coated tablets are presented as pink, oval, biconvex tablets (13.5 x 6.6 mm) with a score line on one side and debossed with 'M9MN 20' on the other side. The tablet can be divided into equal halves.

Memantine film-coated tablets are available in blister packs of:

blisters containing 10, 14, 20, 28, 30, 42, 50, 56, 60, 90, 98, 100, 112 or 120 tablets and a Unit dose blister containing 30x1 tablet

Not all pack sizes may be marketed.

