

MEMANDO

10mg film-coated tablets, 20mg film-coated tablets

MEMANTINE HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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?

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1. WHAT MEMANDO IS AND WHAT IS IT USED FOR

How does Memando work

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

What is Memando used for

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

2. BEFORE YOU TAKE MEMANDO

Do not take Memando:

- if you are allergic to memantine hydrochloride or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Memando

- 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
- Accord assessed 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

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

Other medicines and Memando

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

In particular, Memando 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 Memando.

Memando 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

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor if you are pregnant or planning to become pregnant. The use of memantine in pregnant women is not recommended.

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

Memando contains lactose

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product. Your doctor will advise you.

3. HOW TO TAKE MEMANDO

The Memando treatment initiation pack is only to be used for the beginning of the treatment with Memando.

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

Dosage

The recommended treatment dose of 20mg per day is achieved by a gradual increase of the Memando dose during the first 3 weeks of treatment. The treatment scheme is also indicated on the treatment initiation pack. Take one tablet once a day.

Week 1 (day 1-7):

Take one 5mg tablet once a day for 7 days. Week 2 (day 8-14):

Take one 10mg tablet once a day for 7 days.

Week 3 (day 15-21):

Take one 15mg tablet once a day for 7 days. Week 4 (day 22-28):

Take one 20mg tablet per day for 7 days.

week 1	5 mg tablet
week 2	10 mg tablet
week 3	15 mg tablet
week 4 and beyond	20 mg tablets once a day

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

Memando 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 a little water. The tablets can be taken with or without food.

Duration of treatment

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

If you take more Memando than you should

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

If you forget to take Memando

- If you find you have forgotten to take your dose of Memando, 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 test, 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 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MEMANDO

Keep this medicine out of the sight and reach of children.

Do not use Memando after the expiry date which is stated on the carton and the blister 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.