

Package leaflet: Information for the user

Mantomed 5 mg, filmomhulde tabletten
Mantomed 10 mg, filmomhulde tabletten
Mantomed 15 mg, filmomhulde tabletten
Mantomed 20 mg, filmomhulde tabletten

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

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

1. What Mantomed is and what it is used for

Mantomed 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.

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

2. What you need to know before you take Mantomed

Do not take Mantomed:

- 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 Mantomed

- 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 Mantomed 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 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), 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

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

Other medicines and Mantomed

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

In particular, Mantomed 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 Mantomed.

Mantomed 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, breast-feeding and fertility

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 Mantomed 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, Mantomed may change your reactivity, making driving or operating machinery inappropriate.

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

3. How to take Mantomed

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

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 20 mg per day is achieved by a gradual increase of the Mantomed 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 5 mg tablet once a day for 7 days.

Week 2 (day 8-14):

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

Week 3 (day 15-21):

Take one 15 mg tablet once a day for 7 days.

Week 4 (day 22-28):

Take one 20 mg 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 20 mg 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

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

If you take more Mantomed than you should

In general, taking too much Mantomed should not result in any harm to you. You may experience increased symptoms as described in section 4.

If you take a large overdose of Mantomed, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take Mantomed

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

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

5. How to store Mantomed

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 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 Mantomed contains

- The active substance is memantine hydrochloride. Each tablet contains 5/10/15/20 mg of memantine hydrochloride equivalent to 4.15/8.31/12.46/16.62 mg memantine.
 - The other ingredients Mantomed 5/10/15 and 20 mg film-coated tablets are: cellulose microcrystalline, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate. For coating 5/10 and 20 mg: hypromellose, titanium dioxide (E171), macrogol 400, iron oxide yellow (E172)
For coating 15 mg: hypromellose, titanium dioxide (E171), macrogol 400, iron oxide red (E172)

What Mantomed looks like and contents of the pack

Mantomed 5 mg film-coated tablets are yellow, round, biconvex film coated tablets with diameter of nucleus 6mm

Mantomed 10 mg film-coated tablets are yellow, oblong, biconvex, scored on both side film coated tablets with dimensions of nucleus 5.6x11.1mm. The tablet can be divided into equal doses

Mantomed 15 mg film-coated tablets are pink, round, biconvex film coated tablets, with diameter of nucleus 9.5mm

Mantomed 20 mg film-coated tablets are yellow, round, biconvex film coated tablets with diameter of nucleus 10.3mm

All strengths of Mantomed are available in PVC/PE/PVDC-Alu transparent blisters or PA/Al/PVC-Al blisters in carton boxes of 14, 28, 30, 50, 56, 60, 70, 100, 112 and 1000 tablets.

Not all pack sizes may be marketed.

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Deze bijsluiter is voor het laatst gewijzigd in juli 2023.