

Package leaflet: Information for the user

Mentino 5 mg Orodispersible Tablets
Mentino 10 mg Orodispersible Tablets
Mentino 15 mg Orodispersible Tablets
Mentino 20 mg Orodispersible 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

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

1. What Mentino is and what it is used for

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

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

2. What you need to know before you take Mentino

Do not take Mentino

- if you are allergic to Mentino or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Mentino:

- 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 Mentino 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 Mentino 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

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

Other medicines and Mentino

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

In particular, Mentino 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 Mentino.

Mentino 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.

Pregnancy

The use of Mentino in pregnant women is not recommended.

Breast-feeding

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

Mentino contains Sodium

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

Mentino 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.

Mentino contains Aspartame

Mentino 5 mg Orodispersible tablets contains 1.25 mg aspartame in each tablet.

Mentino 10 mg Orodispersible tablets contains 2.5 mg aspartame in each tablet.

Mentino 15 mg Orodispersible tablets contains 3.75 mg aspartame in each tablet.

Mentino 20 mg Orodispersible tablets contains 5 mg aspartame in each tablet.

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 Mentino

Always take Mentino 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 Mentino dose during the first 3 weeks of treatment. Take one tablet once a day.

Week 1 (day 1-7):

Take one 5 mg tablet once a day (light pink round, flat, speckled tablets with beveled edges, a diameter of 7 mm and engraved with “5” on one side) for 7 days.

Week 2 (day 8-14):

Take one 10 mg tablet once a day (light pink, round, flat, speckled tablets with beveled edges, a diameter of 9 mm and engraved with “10” on one side) for 7 days.

Week 3 (day 15-21):

Take one 15 mg tablet once a day (light pink, round, flat, speckled tablets with beveled edges, a diameter of 11 mm and engraved with “15” on one side) for 7 days.

Week 4 (day 22-28):

Take one 20 mg tablet per day (light pink, round, flat, speckled tablets with beveled edges, a diameter of 12 mm and engraved with “20” on one side) for 7 days.

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

Mentino 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 can be taken with or without food.

The tablet should be placed on the tongue and allowed to disintegrate before swallowing with or without water, according to patient preference.

Duration of treatment

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

If you take more Mentino than you should

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

If you forget to take Mentino

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

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:

United Kingdom

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 Mentino

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 Mentino contains

- The active substance is memantine hydrochloride.
Each tablet contains 5 mg of memantine hydrochloride equivalent to 4.15 mg memantine.
Each tablet contains 10 mg of memantine hydrochloride equivalent to 8.31 mg memantine.
Each tablet contains 15 mg of memantine hydrochloride equivalent to 12.46 mg memantine.
Each tablet contains 20 mg of memantine hydrochloride equivalent to 16.62 mg memantine.
- The other ingredients for Mentino 5 mg, 10 mg, 15 mg and 20 mg Orodispersible tablets are Polacrillin, Sodium hydroxide (E 524), Water purified, Lactose monohydrate, Cellulose microcrystalline (E 460), Mannitol (E 421), Croscarmellose sodium (E 468), Aspartame (E 951), Silica colloidal anhydrous, Iron oxide red (E 172), Flavor peppermint, Magnesium stearate (E 572)

What Mentino looks like and contents of the Pack

Mentino 5 mg Orodispersible tablets are presented as light pink round, flat, speckled tablets with beveled edges, a diameter of 7 mm and engraved with “5” on one side.

Mentino 10 mg Orodispersible tablets are presented as light pink, round, flat, speckled tablets with beveled edges, a diameter of 9 mm and engraved with “10” on one side.

Mentino 15 mg Orodispersible tablets are presented as light pink, round, flat, speckled tablets with beveled edges, a diameter of 11 mm and engraved with “15” on one side.

Mentino 20 mg Orodispersible tablets are presented as Light pink, round, flat, speckled tablets with beveled edges, a diameter of 12 mm and engraved with “20” on one side.

5 mg:

Aluminium/ peelable Aluminium blisters

Each pack contains 7 orodispersible tablets.

10 mg:

Aluminium/ peelable Aluminium blisters

Pack sizes of 7, 14, 28, 30, 42, 50, 56, 70, 84, 98, 100,112 Orodispersible tablets.

Multipack containing 980 (10 packs of 98) and 1000 (20 packs of 50) Orodispersible tablets.

Perforated unit dose blister: Aluminium/ peelable Aluminium blisters

Pack sizes 49 x 1, 56 x1, 98 x 1 and 100 x 1 Orodispersible tablets

Not all pack sizes may be marketed.

15 mg:

Aluminium/ peelable Aluminium blisters

Each pack contains 7 orodispersible tablets.

20 mg:

Aluminium/ peelable Aluminium blisters

Pack sizes of 7, 14, 28, 42, 56, 70, 84, 98, 112 Orodispersible tablets.

Multipack containing 840 (20 x 42) Orodispersible tablets.

Perforated unit dose blister: Aluminium/ peelable Aluminium blisters

Pack sizes 49 x 1, 56 x1, 98 x 1 and 100 x 1 Orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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