

Package leaflet: Information for the user

Memantine Grindeks 10 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

1. What Memantine Grindeks is and what it is used for
2. What you need to know before you take Memantine Grindeks
3. How to take Memantine Grindeks
4. Possible side effects
5. How to store Memantine Grindeks
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1. What Memantine Grindeks is and what it is used for

Memantine Grindeks contains the active substance memantine hydrochloride (further memantine). Memantine is an anti-dementia medicine. It helps to ease the symptoms of dementia in Alzheimer's disease.

How does Memantine Grindeks work

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'. It acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

What is Memantine Grindeks used for

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

2. What you need to know before you take Memantine Grindeks

Do not take Memantine Grindeks

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

Warnings and precautions

Talk to your doctor before taking Memantine Grindeks

- if you have ever had epileptic seizures;
- if you have recently had heart attack, or if you suffer from congestive heart failure or uncontrolled hypertension (high blood pressure).

In these cases, the treatment with memantine should be carefully supervised, and the clinical benefit of Memantine Grindeks regularly reassessed by your doctor.

If you have kidney disorders, your doctor should closely monitor your kidney function and if necessary adapt memantine doses accordingly.

Children and adolescents

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

Other medicines and Memantine Grindeks

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

You should not take Memantine Grindeks together with the following medicines:

- amantadine (medicine used to treat Parkinson's disease);
- ketamine (generally used as an anaesthetic);
- dextromethorphan (generally used to treat cough);
- other NMDA-antagonists.

Memantine Grindeks may change the effects of the following medicines and their dose may need to be adjusted by your doctor:

- dantrolene, baclofen;
- cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine;
- hydrochlorothiazide (or any combination with hydrochlorothiazide);
- anticholinergics (medicines generally used to treat movement disorders or intestinal cramps);
- anticonvulsants (used to prevent and relieve seizures);
- barbiturates (medicines generally used to induce sleep);
- dopaminergic agonists (substances such as L-dopa, bromocriptine);
- antipsychotics (used to treat mental disorders);
- oral anticoagulants (used to prevent blood clotting).

If you go into hospital, let your doctor know that you are taking Memantine Grindeks.

Memantine Grindeks 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 poor kidney function) or severe infections of the urinary tract, as your doctor may need to adjust the dose of your medicine.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. Memantine should not be used during pregnancy.

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

Memantine Grindeks 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 Grindeks

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

Dosage in adults and older people (over 65 years)

The recommended dose 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:

Week 1	Half a 10 mg tablet
Week 2	One 10 mg tablet
Week 3	One and a half 10 mg tablets
Week 4 and beyond	Two 10 mg tablets

The usual starting dose is half a tablet once a day for the first week. This is increased to one tablet once a day in the second week and to one and a half tablets once a day in the third week. From the fourth week on, the usual dose is two tablets once a day.

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

Tablets should be taken by mouth 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. The tablet can be divided into equal doses.

Duration of treatment

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

If you take more Memantine Grindeks than you should

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

If you forget to take Memantine Grindeks

If you find you have forgotten to take your dose of Memantine Grindeks 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)

- Drug hypersensitivity
- Sleepiness
- Dizziness
- Balance disorders
- High blood pressure
- Shortness of breath
- Constipation
- Elevated liver function tests
- Headache

Uncommon (may affect up to 1 in 100 people)

- Fungal infections
- Confusion
- Hallucinations
- Abnormal gait
- Heart failure
- Venous blood clotting (thrombosis/thromboembolism)
- Vomiting
- Tiredness

Very rare (may affect up to 1 in 10,000 people)

- Seizures

Not known (frequency cannot be estimated from the available data)

- Psychotic reactions
- Inflammation of the pancreas
- Inflammation of the liver (hepatitis)

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 HPRA Pharmacovigilance, Website: www.hpra.ie

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

5. How to store Memantine Grindeks

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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 Grindeks contains

- The active substance is memantine hydrochloride.

One film-coated tablet contains 10 mg memantine hydrochloride.

- The other ingredients are:

Tablets core: lactose monohydrate, cellulose, microcrystalline, talc, silica, colloidal anhydrous, magnesium stearate.

Tablets film-coat: Opadry II White 33G28707 (hypromellose (E 464), titanium dioxide (E 171), lactose monohydrate, macrogol 3000, triacetin), carnauba wax.

What Memantine Grindeks looks like and contents of the pack

White to off-white biconvex film-coated oblong tablets with rounded ends, concave in the middle and breakline on both sides. Tablet size: length approximately 12.7 mm, height 3.7 mm.

PVC/PVDC/Alu blisters containing either 7 or 10 tablets per blister.

Pack sizes: 10, 14, 20, 28, 30, 40, 50, 56, 60, 90, 98, 100 or 112 tablets are packed per cardboard box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

AS GRINDEKS (Site I)

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This medicinal product is authorised in the Member States of the EEA under the following names:

Estonia	Memantine Grindeks
Latvia	Memantine Grindeks 10 mg apvalkotās tabletes
Lithuania	Memantine Grindeks 10 mg plėvele dengtos tabletės
Hungaria	Memantine Grindeks 10 mg filmtabletta
Czech Republic	Memantine Grindeks
Romania	Memantină Grindeks 10mg comprimate filmate
Slovakia	Memantine Grindeks 10 mg filmom obalené tablet
Greece	Memantine Grindeks 10 mg, επικαλυμμένα με λεπτό υμένιο δισκία
Ireland	Memantine Grindeks 10 mg film-coated tablets
Austria	Memantin Grindeks 10 mg Filmtabletten
France	MEMANTINE GRINDEKS 10 mg, comprimé pelliculé sécable
Portugal	Memantina Grindeks 10 mg comprimidos revestidos por película
Poland	Memantine Grindeks
Croatia	Memantin Grindeks 10 mg filmom obložena tablet
Italy	Memantina Pharmexon

This leaflet was last revised in March 2021