

MARIXINO

Memantine hydrochloride film-coated tablets (10 mg)

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What *Marixino* is used for

Marixino contains the active substance memantine hydrochloride. It belongs to a group of medicines known as anti-dementia medicines.

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

How *Marixino* works

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

Before you use *Marixino*

- When you must not use it

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

Pregnancy and lactation

Do not take *Marixino* if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking *Marixino*, stop taking it immediately and contact your doctor.

The use of memantine in pregnant women is not recommended.

Do not take *Marixino* if you are breast-feeding. Women taking *Marixino* should not breast-feed. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Talk to your doctor or pharmacist before taking *Marixino*:

- 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 *Marixino* 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.

Children and adolescents

Marixino is not recommended for children and adolescents under the age of 18 years due to lack of data on safety and efficacy.

Marixino contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

In particular, *Marixino* may change the effects of the following medicines and their dose may need to be adjusted by your doctor:

- amantadine (a substance used to treat Parkinson's disease), ketamine (a substance used in anaesthesia), dextromethorphan (a substance used to treat cough)
- dantrolene, baclofen (substances used to relieve muscle spasms)
- cimetidine, ranitidine (substances to

treat stomach acid production), procainamide, quinidine (substances for treating irregular heartbeat), quinine (a substance used to treat malaria), nicotine

- hydrochlorothiazide (or any combination with hydrochlorothiazide)
- anticholinergics (substances generally used to treat movement disorders or intestinal cramps)
- phenytoin (a substances used to prevent and relieve seizures)
- barbiturates (substances generally used to induce sleep)
- dopaminergic agonists (substances such as L-dopa used to treat Parkinson's disease)
- neuroleptics (substances used in the treatment of mental disorders)
- oral anticoagulants (such as warfarin used to prevent blood clots).

If you go into hospital, let your doctor know that you are taking *Marixino*.

How to use *Marixino*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dose of *Marixino* for adults and older people 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	Two 10 mg tablets once a day

The usual starting dose is half a tablet once a day (1x 5 mg) for the first week. This is increased to one tablet once a day (1x 10 mg) in the second week and to 1 and a half tablets once a day (1x 15 mg) in the third week. From the fourth week on, the usual dose is 2 tablets once a day (1x 20 mg).

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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.

- When to use it

Use as directed by your doctor or pharmacist.

Marixino 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.

- How long to use it

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

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Taking too many tablets may cause side effects listed in section "Side effects" below.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking *Marixino*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Marixino* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. *Marixino* may change your reactivity, making driving or operating machinery inappropriate. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, *Marixino* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

In general, the observed side effects are mild to moderate.

Common:

Headache, sleepiness, constipation, elevated liver function tests, dizziness, balance disorders, shortness of breath, high blood pressure and drug hypersensitivity.

Alzheimer's disease has been associated with depression, suicidal ideation and suicide. These events have been reported in patients treated with *Marixino*.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of *Marixino*

- Storage

Keep out of the sight and reach of children.

Do not store above 30 °C.

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

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White, oval shaped, biconvex film-coated tablets scored on one side. The tablet can be divided into equal doses.

- Ingredients

Active ingredient

Each film-coated tablet contains 10 mg memantine hydrochloride.

Inactive ingredients

In the tablet core are: lactose monohydrate, microcrystalline cellulose, anhydrous colloidal silica, talc, magnesium stearate. In the film-coating are: methacrylic acid-ethyl acrylate copolymer (1:1), sodium laurilsulfate, polysorbate 80, talc, triacetin, simeticone.

- MAL number:

MAL18116142AZ

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai, 5 ½ Miles off
Jalan Meru, Klang, Selangor,
MALAYSIA.

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05/06/2018

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