

EBIXA® FILM COATED TABLET

Memantine Hydrochloride (10mg , 20mg)

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What Ebixa is used for

Ebixa is used for the treatment of moderate to severe Alzheimer's disease.

How Ebixa works

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

Before you use Ebixa

- When you must not use it

Do not take Ebixa

- if you are allergic (hypersensitive) to memantine hydrochloride or any of the other ingredients of Ebixa film-coated tablets (see section Ingredients).

- Before you start to use it

Take special care with Ebixa

- if you have a history of seizures
- if you have recently experienced a heart attack, or if you are suffering from congestive heart failure or from an uncontrolled high blood pressure.
- If you suffer from kidney impairment, your doctor should closely monitor your kidney function and if necessary, adapt the memantine doses accordingly.
- if you suffer from severe infections of the urinary tract.

In these situations, the treatment should be carefully supervised, and the clinical benefit of Ebixa reassessed by your doctor on a regular basis.

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

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

- Medicines used to treat travel sickness or stomach cramps (anticholinergics)
- Medicines generally used to induce sleep (barbiturates),
- Medicines used in the treatment of mental disorders (neuroleptics)
- Anaesthetic agents (ketamine)
- Medicines used to treat muscle cramps or to relax muscles (dantrolene and baclofen)
- Medicines for cough, cold and flu (dextromethorphan)
- Medicines used for the treatment of Parkinsons disease (Amantadine)
- Medicines used to treat irregular heartbeat (quinidine and procainamide)
- Medicines used to treat smoking addiction, contained in patches or gums (nicotine)
- Medicines used to treat stomach ulcers or reflux (cimetidine and ranitidine)
- Medicines used to treat malaria (quinine)
- Medicines used to prevent blood clots (oral anticoagulants)
- Medicines used to treat high blood pressure and swelling due to fluid build-up (Hydrochlorothiazide)

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

- Taking Ebixa 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.

How to use Ebixa

Always take Ebixa exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- How much to use

The recommended dose of Ebixa for adults and elderly 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	One 20 mg tablet once a day

Dosage in people 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

Ebixa should be taken 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

Take Ebixa for the duration as your doctor recommends. Your doctor should assess your treatment on a regular basis.

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- If you forget to use it

If you find you have forgotten to take your dose of Ebixa, 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 use too much (overdose)

You may experience increased symptoms as described in section "Side effects".

If you overdose of Ebixa, contact your doctor or get medical advice, as you may need medical attention.

While you are using it

- Things you must do

Read all of this leaflet carefully before you start taking this medicine

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

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

Side effects

Like all medicines, Ebixa 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 hypersensitivity

Uncommon (affects 1 to 10 users in 1,000):

- Tiredness, fungal infections, confusion, hallucinations, vomiting, abnormal gait, heart failure and blood clotting

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 people treated with Ebixa.

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.

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.gov.my ([Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]) **Storage and Disposal of Ebixa**

Storage

Keep out of the reach and sight of children. Do not store above 30°C

Disposal

Do not use Ebixa 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. 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

Ebixa 10mg:

Ebixa 10mg film-coated tablets are presented as pale yellow to yellow, oval shaped with breaking line and engravings "1 0" on one side and "M M" on the other side.

Ebixa 20mg:

Ebixa 20mg film-coated tablets are presented as pale red to grey-red, oval-oblong shaped with imprint '20' on one side and imprint 'MEM' on the other side.

Ingredients

- Active ingredient:

The active substance is memantine hydrochloride.

Ebixa 10mg:

Each film-coated tablet contains 10 mg memantine hydrochloride

Ebixa 20mg:

Each film-coated tablet contains 20 mg memantine hydrochloride.

- Inactive ingredient:

Tablet cores for 10mg and 20mg

film-coated tablets:

Microcrystalline cellulose
Croscarmellose sodium
Colloidal anhydrous silica
Magnesium stearate

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Tablet coat for 10mg and 20mg film-coated tablets:

Hypromellose
Macrogol 400
Titanium dioxide

Color for 10mg film-coated tablets:

Iron oxide yellow (E172)

Color for 20mg film-coated tablets:

Iron oxide yellow and red (E172)

- MAL Number

Ebixa 10mg: MAL20061488ACRZ

Ebixa 20mg: MAL10120014ACRZ

Manufacturer:

Rottendorf Pharma GmbH
Ostenfelder Strasse 51-61
D-59320 Ennigerloh
Germany

Packed by:

Merz Pharma GmbH & Co. KgaA,

Product Registration Holder

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