

Package leaflet: information for the user

Ebixa 5 mg film-coated tablets
Ebixa 10 mg film-coated tablets
Ebixa 15 mg film-coated tablets
Ebixa 20 mg film-coated tablets
Memantine hydrochloride

Read the entire 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.
- Do you have any questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Ebixa and what is it used for?

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

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 the transmission of nerve signals important for learning and memory. Ebixa belongs to the group of medicines known as NMDA receptor antagonists. Ebixa acts on these NMDA receptors and improves the transmission of nerve signals and memory.

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

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine:

- if you have a history of epileptic seizures
- if you have recently had a myocardial infarction (heart attack) or if you suffer from congestive heart failure or from hypertension (high blood pressure) that is not under control.

In these cases, treatment should be under careful supervision and the clinical benefits of Ebixa should be regularly reassessed by your doctor.

If you suffer from impaired kidney function, your doctor should carefully monitor your kidney function and adjust the memantine dosage if necessary.

If you suffer from a form of renal tubular acidosis (RTA, an excess of acid-forming substances in the blood due to impaired kidney function) or severe urinary tract infections, your doctor may need to adjust the dosage of your medicine.

The simultaneous use of medicines such as amantadine (for the treatment of Parkinson's disease), ketamine (a substance commonly used for anesthesia), dextromethorphan (commonly used for cough) and other NMDA antagonists should be avoided.

Children and adolescents under 18 years

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

Are you taking any other medicines?

Are you taking any other medicines besides Ebixa, or have you recently taken any or is there a possibility that you will take other medicines in the near future? If so, inform your doctor or pharmacist.

The effects of the following medicines in particular may be influenced by Ebixa, and their dosage may need to be adjusted by your doctor:

- amantadine, ketamine, dextromethorphan
- dantrolene, baclofen
- cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine
- hydrochlorothiazide (or a combination with hydrochlorothiazide)
- anticholinergics (substances usually used for the treatment of movement disorders or intestinal cramps)
- antiepileptics (substances used to prevent and reduce seizures)
- barbiturates (substances usually used to induce sleep)
- dopaminergic agonists (substances such as L-dopa or bromocriptine)
- neuroleptics (substances used for the treatment of mental disorders)
- oral anticoagulants

If you need to be hospitalized, let the doctor know that you are taking Ebixa.

What should you pay attention to with food and drink?

You should inform your doctor if you have recently changed your diet drastically or plan to do so (e.g., from a normal diet to a strict vegetarian diet), as your doctor may need to adjust the dosage of your medicine.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? If so, contact your doctor or pharmacist before using this medicine.

Pregnancy

The use of memantine is not recommended for pregnant women.

Breastfeeding

Women taking Ebixa should not breastfeed.

Driving and using machines

Your doctor can tell you whether you can drive or operate machines safely with your condition. Ebixa can impair your reaction time. Therefore, it is advised not to drive vehicles or operate machines.

Ebixa contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How to use this medicine?

The Ebixa starter pack is only used to initiate treatment with Ebixa.

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The recommended Ebixa treatment dose of 20 mg per day is gradually increased over the first 3 weeks of treatment. The treatment schedule is also indicated on the starter pack. Take one tablet once a day.

Week 1 (days 1-7):

Take a 5 mg tablet once a day (white to off-white, oval, oblong) for 7 days.

Week 2 (days 8-14):

Take a 10 mg tablet once a day (light yellow to yellow, oval) for 7 days.

Week 3 (days 15-21):

Take a 15 mg tablet once a day (grey-orange, oval and convex on both sides) for 7 days.

Week 4 (day 22-28):

Take a 20 mg tablet once daily (gray-red, oval and convex on both sides) for 7 days.

week 1	5 mg tablet
week 2	10 mg tablet
week 3	15 mg tablet

week 4 and thereafter 20 mg tablets once daily

Maintenance dosage

The recommended daily dose is 20 mg once daily.
To continue the treatment, please consult your doctor.

Dosage for patients with impaired renal function

If you suffer from impaired renal function, your doctor will determine the appropriate dosage for your condition. In this case, your renal function should be regularly monitored by your doctor.

Administration

Ebixa should be administered once a day orally. For the best possible result of your treatment, you should take the tablets regularly, every day at the same time of day. The tablets should be swallowed with a little water. The tablets can be taken with or without food.

Duration of treatment

You can take Ebixa as long as you benefit from it. Your doctor should evaluate your treatment at regular intervals.

Have you used too much of this medicine?

- In general, using too much Ebixa does not have harmful consequences. You may experience the symptoms described in section 4 "Possible side effects" to a greater extent.
- If you have taken a large overdose of Ebixa, you should contact your doctor or seek medical help, as it may be necessary.

Have you forgotten to use this medicine?

- If you notice that you have forgotten to take a 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.

Do you have any other questions about the use of this medicine? Then contact 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 (in 1 to 10 users out of 100):

headache, drowsiness, constipation, elevated liver function test values, dizziness, balance disorders, shortness of breath, high blood pressure, and hypersensitivity to the medicine.

Uncommon (in 1 to 10 users out of 1,000):

fatigue, fungal infections, confusion, hallucinations, vomiting, abnormal gait, heart failure, and blood clotting in the veins (thrombosis/thromboembolism).

Very rare (in less than 1 user out of 10,000):

seizures/convulsions.

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

pancreatitis, liver inflammation (hepatitis), and psychotic reactions

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

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to any side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in Appendix V.

By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the box and the blister pack after EXP. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is memantine hydrochloride. Each tablet contains 5/10/15/20 mg memantine hydrochloride, equivalent to 4.15/8.31/12.46/16.62 mg memantine.
- The other substances in this medicine for Ebixa 5, 10, 15, and 20 mg film-coated tablets are microcrystalline cellulose, sodium croscarmellose, colloidal anhydrous silica, and magnesium stearate (all in the core of the tablet), and hypromellose, macrogol 400, titanium dioxide (E171). Additionally, for Ebixa 10 mg film-coated tablets, iron oxide yellow (E 172) and for Ebixa 15 mg and Ebixa 20 mg film-coated tablets, iron oxide yellow and red (E172) (all in the coating of the tablet).

What Ebixa looks like and contents of the pack

Ebixa 5 mg film-coated tablets are white to off-white, oval, oblong film-coated tablets with the engraving '5' on one side and 'MEM' on the other side.

Ebixa 10 mg film-coated tablets are light yellow to yellow, oval, film-coated tablets with a score line and the inscriptions '1 0' on one side and 'M M' on the other side. The tablet can be divided into equal doses.

Ebixa 15 mg film-coated tablets are orange to grey-orange, oval, oblong film-coated tablets with the engraving '15' on one side and 'MEM' on the other side.

Ebixa 20 mg film-coated tablets are light red to grey-red, oval, oblong film-coated tablets engraved with '20' on one side and 'MEM' on the other side.

A treatment initiation pack contains 28 tablets in 4 blister strips with 7 tablets of Ebixa 5 mg, 7 tablets of Ebixa 10 mg, 7 tablets of Ebixa 15 mg, and 7 tablets of Ebixa 20 mg.

Marketing Authorization Holder and Manufacturer

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Other sources of information

More information about this medicine is available on the website of the European Medicines Agency (<http://www.ema.europa.eu>).