Package leaflet: Information for the user

Ebixa 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 Ebixa is and what it is used for

Ebixa 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. 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.

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

2. What you need to know before you take Ebixa

Do not take Ebixa

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

Warning and precautions

Talk to your doctor or pharmacist before taking Ebixa:

- 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 Ebixa 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.

If you are suffering from states of renal tubulary 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

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

Other medicines and Ebixa

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

In particular, Ebixa 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 Ebixa.

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.

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 memantine in pregnant women is not recommended.

Breast-feeding

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.

Ebixa contains Sodium

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

3. How to take Ebixa

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

The recommended dose of Ebixa 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 and beyond	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 in the third week. From the fourth week on, the usual dose is 2 tablets once a day (1x 20 mg).

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

Ebixa 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.

Duration of treatment

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

If you take more Ebixa than you should

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

If you forget to take Ebixa

- 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 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 Ebixa.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacis. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom (Northern Ireland)
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 Ebixa

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 Ebixa contains

- The active substance is memantine hydrochloride. Each film-coated tablet contains 10 mg memantine hydrochloride equivalent to 8.31 mg memantine.

- The other ingredients are microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica and magnesium stearate, all in the tablet core; and hypromellose, macrogol 400, titanium dioxide (E171) and iron oxide yellow (E172), all in the tablet coating.

What Ebixa looks like and contents of the pack

Ebixa film-coated tablets are presented as pale yellow to yellow, oval shaped film-coated tablet with breaking line and engravings “1 0” on one side and “M M” on the other side. The tablet can be divided into equal doses.

Ebixa film-coated tablets are available in blister packs of 14 tablets, 28 tablets, 30 tablets, 42 tablets, 49 x 1 tablets, 50 tablets, 56 tablets, 56 x 1 tablets, 70 tablets, 84 tablets, 98 tablets, 98 x 1 tablets, 100 tablets, 100 x 1 tablets, 112 tablets, 980 (10 x 98) tablets or 1000 (20 x 50) tablets. The pack sizes 49 x 1, 56 x 1, 98 x 1 and 100 x 1 film-coated tablets are presented in unit dose blister.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

H. Lundbeck A/S
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Denmark.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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Other sources of information

Based on REG_002625 V 41.0

Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu