Package leaflet: Information for the user

Ebixa 5 mg/pump actuation oral solution
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 sorbitol and Potassium

This medicine contains 100 mg sorbitol in each gram which is equivalent to 200 mg /4 pump actuation. Sorbitol is a source of fructose. If your doctor told you that you have an intolerance to some sugars, or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine. Your doctor will advise you.

Furthermore, this medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially potassium-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.

One pump actuation contains 5 mg memantine hydrochloride.
The recommended dose of Ebixa for adults and older people is four pump actuations, equivalent to 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	one pump actuation
week 2	two pump actuations
week 3	three pump actuations
week 4 and beyond	Four pump actuations

The usual starting dose is one pump actuation once daily (1x 5 mg) for the first week. This dose is increased in the second week to two pump actuations once daily (1 x 10 mg), and in the third week to three pump actuations once daily (1 x 15 mg). From the fourth week the recommended dose is four pump actuations once daily (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 solution should be taken with a little water. The solution can be taken with or without food.

For detailed instructions on the preparation and handling of the product see end of this leaflet.

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).

United Kingdom
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 bottle label after EXP. The expiry date refers to the last day of that month.

Do not store above 30ºC.

Once opened, the contents of the bottle should be used within 3 months.

The bottle with the mounted pump must be kept and transported in an upright position only.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer required. 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 pump actuation delivers 0.5 ml of solution which contains 5 mg of memantine hydrochloride which is equivalent to 4.16 mg memantine.

- The other ingredients are potassium sorbate, sorbitol E420 and purified water.

What Ebixa looks like and contents of the pack

Ebixa oral solution is presented as a clear, colourless to light yellowish solution.

Ebixa oral solution is available in bottles of 50 ml, 100 ml or 10 x 50 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

H. Lundbeck A/S
Ottiliavej 9
2500 Valby
Denmark.

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

United Kingdom
Lundbeck Limited
Tel: +44 1908 64 9966

This leaflet was last revised in July 2021.

Instruction for proper use of the pump

The solution must not be poured or pumped directly into the mouth from the bottle or pump. Measure the dose onto a spoon or into a glass of water, using the pump.

Take the screw cap off the bottle:

The cap must be turned anticlockwise, unscrewed completely and removed (fig. 1).

1.

Mounting the dosing pump on the bottle:

Take the dosing pump out of the plastic bag (fig. 2) and place it on top of the bottle. Slide the plastic dip tube carefully into the bottle. Hold the dosing pump onto the neck of the bottle and screw it clockwise until it fits firmly (fig. 3). The dosing pump is only screwed on once when starting the use, and should never be unscrewed.

2.

3.

How the dosing pump works:

The dosing pump head has two positions and is easy to turn:

- anticlockwise to unlock and
- clockwise to lock.

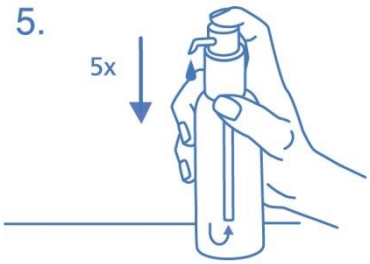
The dosing pump head should not be pushed down while in the locked position. The solution may only be dispensed in the unlocked position. To unlock, turn the pump head in the direction of the arrow until it cannot be turned any further (about one eighth of a turn, fig. 4). The dosing pump is then ready for use.

4.

Preparing the dosing pump:

When used for the first time, the dosing pump does not dispense the correct amount of oral solution. Therefore, the pump must be prepared (primed) by pushing the dosing pump head down completely five times in succession (fig. 5).

5.



The solution thus dispensed is discarded. The next time the dosing pump head is pushed downwards completely (equivalent to one pump actuation), it dispenses the correct dose (fig. 6).

6.

Correct use of the dosing pump:

Place the bottle on a flat, horizontal surface, for example a table top, and only use it in an upright position. Hold a glass with a little water or a spoon below the nozzle. Push down the dosing pump head in a firm but calm and steady manner - not too slowly (fig. 7, fig. 8).

7.

8.

The dosing pump head can then be released and is ready for the next pump actuation.

The dosing pump must only be used with the Ebixa solution in the bottle provided, not for other substances or containers. If the pump does not function properly, consult your doctor or a pharmacist. Lock the dosing pump after using Ebixa.