**Patient Package Leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed by a doctor's prescription only

**Ebixa Tablets 10 mg**
**Ebixa Tablets 20 mg**

Composition:
Each film coated Ebixa 10 mg tablet contains the active substance:
Memantine Hydrochloride 10 mg.
Each film coated Ebixa 20 mg tablet contains the active substance:
Memantine Hydrochloride 20 mg.

Inactive ingredients: See section 6.

- **Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist.
- This medicine was prescribed for the treatment of your ailment. Do not pass it on to others. It can harm them even if it seems to you that their ailment is similar.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

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

**Therapeutic group:** NMDA receptor antagonist.

Ebixa belongs to a group of medicines for the treatment of dementia.
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 acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

## 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**
- You are sensitive (allergic) to the active ingredient or to any of the other ingredients which the medicine contains (for the list of inactive ingredients, see section 6).

**Special warnings regarding the use of the medicine**

**Before using Ebixa, tell the doctor if:**

- You have a history of epileptic seizures.
- 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 by the doctor, who will reassess the clinical benefit of Ebixa on a regular basis.

- If you suffer from renal impairment (kidney problems), the doctor should closely monitor

your kidney function and if necessary adapt the dosage 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.

**While using Ebixa, the use of the following medicinal products at the same time should be avoided:**

- amantadine (for the treatment of Parkinson's disease)
- ketamine (a substance generally used as an anaesthetic)
- dextromethorphan (generally used to treat cough)
- other NMDA-antagonists

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

**Drug interactions:**
**If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist.** It is especially important to inform the doctor or pharmacist if you are taking the following medicines since Ebixa may change the effects of them and their dose may need to be adjusted by your doctor:

- amantadine, ketamine, dextromethorphan (see section "Special warnings regarding use of the medicine")
- 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)
- medicines for the treatment of epilepsy (to prevent and relieve seizures)
- barbiturates (substances generally used to induce sleep)
- dopaminergic agonists such as L-dopa, bromocriptine
- neuroleptics (used in the treatment of mental disorders)
- oral anticoagulants

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

**Use of the medicine and food**
The medicine can be taken with or without food.
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 breastfeeding**
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 explain to 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 SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. You should check with the doctor or pharmacist if you are not sure about the dosage or the administration of the medicine. The dosage and treatment regimen will be determined by the doctor only. The usual dosage is:
The recommended dose for adults and elderly patients is 20 mg daily.
In order to reduce the risk of side effects, this dose is achieved gradually by the following treatment scheme:

| | |
|---|---|
| week 1 | 5 mg per day |
| week 2 | 10 mg per day |
| week 3 | 15 mg per day |
| week 4 and beyond | 20 mg per day |

The starting dose is half an Ebixa 10 mg tablet per day during the first week.
In the second week – one Ebixa 10 mg tablet daily.
In the third week - one and a half Ebixa 10 mg tablet daily.
From the fourth week onwards - one Ebixa 20 mg tablet or 2 Ebixa 10 mg tablets daily.

Dosage in patients with impaired kidney function:
Dosage in patients with mild impaired kidney function (Creatinine clearance 50-80 ml per minute): there is no need for dosage adjustment.
Dosage in patients with moderate impaired kidney function (Creatinine clearance 30-49 ml per minute), daily dosage is 10 mg. In case of tolerance to the medicine, after 7 days of treatment, dosage may be augmented to 20 mg daily.
Dosage in patients with severe impaired kidney function (Creatinine clearance 5-29 ml per minute): daily dosage is 10 mg.

**Do not exceed the recommended dose.**

Directions for use: Swallow the tablet with some water. The medicine can be taken with or without food. The medicine should be taken once daily, at the same time every day.
Ebixa 10 mg tablets can be cut in half (the tablet has a breaking line).

**- If you mistakenly took a higher dosage,** contact the doctor or seek medical help. Taking an overdose will usually not result in any harm, but you may experience increased side effects (see section "side effects"). If a child swallowed the medicine by mistake, refer immediately to the physician or to a hospital emergency room and bring the package of the medicine with you.

- **If you have forgotten to take the medicine** at the specified time, do not take a double dose. Take the next dose at the usual time and consult the physician.

- This medicine should be taken at the specific time intervals determined by the attending doctor.

You should continue with the treatment as instructed by the doctor. Even if there is an improvement in your health, do not discontinue use of this medicine without consulting the doctor.

**- Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have any further questions on the use of the medicine, consult the doctor or**

**pharmacist.**

## 4. SIDE EFFECTS

As with all medicines, use of Ebixa may cause side effects in some users. Do not be alarmed when reading the list of side effects; you may not experience any of them.
In general, the observed side effects are mild to moderate.

Common side effects (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 side effects (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 side effects (affects less than 1 user in 10,000):
Seizures.

Side effects with unknown frequency (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 also been reported in patients treated with Ebixa.

**If you notice side effects, if any of the side effects gets worse, or if you suffer from any side effect not listed in the leaflet, consult the doctor.**

**Reporting of side effects**
Side effects can be reported to the Ministry of Health by clicking on the link **"**Adverse Drug Reactions Report**"** that appears on the home page of the Ministry of Health website **(**www.health.gov.il**)**, which leads to an online form for reporting side effects. Alternatively you can use the following link:
https://sideeffects.health.gov.il/

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid Poisoning!
This medicine, and all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning.
Do not induce vomiting unless explicitly instructed to do so by a physician!
**-** Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

**- Storage conditions:** Store at a temperature below 30°C.
**-** Do not discard of medicines via wastewater or household waste. In order to protect the environment, consult the pharmacist how to dispose of medicines no longer required or expired.

## 6. ADDITIONAL INFORMATION

- **In addition to the active ingredient, the medicine also contains:**
**Ebixa 10mg:**
microcrystalline cellulose, croscarmellose sodium, hypromellose, titanium dioxide (E 171), colloidal anhydrous silica, magnesium stearate, macrogol 400, iron oxide yellow (E 172).

**Ebixa 20mg:**
microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium

stearate, hypromellose, titanium dioxide (E171), Macrogol 400, iron oxide red (E172), iron oxide yellow (E172).

**-What the medicine looks like and contents of the pack:**
**Ebixa 10 mg:** oval shaped film-coated tablet, pale yellow to yellow, with breaking line and engravings “1 0” on one side and “M M” on the other side.
**Ebixa 20 mg:** oval-oblong film-coated tablet, pale red to grey-red with imprint ‘20’ on one side and imprint ‘MEM’ on the other side.

The packs contain:
**Ebixa 10 mg:** 10, 14, 20, 30, 50, 56, 100, 112 tablets in blister packages.
**Ebixa 20 mg:** 14, 28, 42, 49, 56, 70, 84, 98, 100, 112, 840 tablets in blister packages.

Not all pack sizes may be marketed**.**

- **License Holder:** Lundbeck Israel Ltd., 11 Galgaley Haplada, P.O.B. 13105, Herzliya 4672211.
Fax: 03- 9100116, email address: Israel@lundbeck.com.

**- Manufacturer:** H.Lundbeck A/S, Ottiliavej 9, DK- 2500 Valby, Denmark

**- Revised in May 2021 according to MoH guidelines.**

**- Registration number of the medicine in the National Drug Registry of the Ministry of Health:**
Ebixa 10 mg tablets: 129.83.30891
Ebixa 20 mg tablets: 142.62.32007