

**PACKAGE LEAFLET**

## PACKAGE LEAFLET

### **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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### **In this leaflet:**

1. What Ebixa is and what it is used for
2. Before you take Ebixa
3. How to take Ebixa
4. Possible side effects
5. Storing Ebixa.

### **Ebixa 10 mg film-coated tablets Memantine hydrochloride**

The active substance is memantine hydrochloride.

The other ingredients are lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, talc and magnesium stearate, all in the tablet core; and methacrylic acid - ethyl acrylate copolymer (1:1), sodium lauryl sulphate, polysorbate 80, talc, triacetin and simethicone emulsion, all in the tablet coating.

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

## **1. WHAT EBIXA IS AND WHAT IT IS USED FOR**

### **What Ebixa is:**

Ebixa tablets are presented as white to off-white, long shaped, film-coated tablets with a single breakline on both sides. Each tablet contains 10 mg of memantine hydrochloride.

Ebixa tablets are available in blister packs of 30 tablets, 50 tablets or 100 tablets.

### **What Ebixa is used for:**

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

Memory loss in Alzheimer's disease is due to a disturbance of message signals in the brain. The brain contains so-called 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.

## **2. BEFORE YOU TAKE EBIXA**

Before taking Ebixa it is important that you read the following sections and discuss any questions you might have with your doctor. Your caregiver may be able to assist you with any details you wish to discuss.

**Do not take Ebixa:**

- if you are hypersensitive (allergic) to memantine hydrochloride or any of the other ingredients of Ebixa tablets listed above.

**Take special care with 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.

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 moderate renal impairment, your doctor should closely monitor your kidney function and adapt the memantine doses accordingly. For patients with severe renal impairment, the use of memantine is not recommended.

The use of medicinal products called amantadine, ketamine, dextromethorphan and other NMDA-antagonists at the same time should be avoided.

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

**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) or if you are suffering from states of renal tubular acidosis (RTA, an excess of acid-forming substances in the blood due to renal dysfunction) or severe infections of the urinary tract, as your doctor may need to adjust the dose of your medicine.

**Pregnancy:**

Tell your doctor if you are pregnant or planning to become pregnant. 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.

**Taking other medicines:**

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

In particular, the effects of the following medicines may be changed by Ebixa 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).

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

### 3. HOW TO TAKE EBIXA

Always take Ebixa exactly as your doctor has instructed you. To benefit from your medicine you should take it regularly every day. You should check with your doctor or pharmacist if you are unsure.

#### **Dosage:**

The recommended dose of Ebixa for adults and elderly patients is 20 mg (2x 1 tablet) daily. In order to reduce the risk of side effects this dose is achieved gradually by the following daily treatment scheme:

	morning	afternoon or evening
week 1	½ tablet	none
week 2	½ tablet	½ tablet
week 3	1 tablet	½ tablet
week 4 and beyond	1 tablet	1 tablet

The usual starting dose is half a tablet once daily (1x 5 mg) for the first week. This is increased to half a tablet twice a day (2x 5 mg) in the second week and to 1 tablet (1x 10 mg) and half a tablet (1x 5 mg) daily taken in separate doses in the third week. From the fourth week on, the usual dose is 1 tablet twice a day (2x 10 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 twice a day (except for the first week of treatment). 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 and you do not experience any unacceptable side effects. 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 the forgotten dose.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Ebixa can have side effects.

In general, observed side effects are mild to moderate. The most common side effects (frequency 2% and less) are hallucinations, confusion, dizziness, headache and tiredness. Uncommon side effects are anxiety, hypertonia (increased muscle tone), vomiting, bladder infections and increased sexual drive.

If you have experienced epileptic seizures, there is a slight possibility that Ebixa may increase the chances of one occurring.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **5. STORING EBIXA**

- Keep out of the reach and sight of children.
- There are no special storage instructions.

Do not use after the expiry date stated on the carton and the blister.

**This leaflet was last approved in {MM/YYYY}**

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

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### **Ebixa 10 mg/g oral drops, solution Memantine hydrochloride**

The active substance is memantine hydrochloride.

The other ingredients are: potassium sorbate, sorbitol, purified water.

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

## **1. WHAT EBIXA IS AND WHAT IT IS USED FOR**

### **What Ebixa is:**

Ebixa solution is presented as a clear, colourless to light yellowish solution. Each one gram of solution contains 10 mg of memantine hydrochloride.

Ebixa solution is available in bottles of 20 g, 50 g or 100 g.

### **What Ebixa is used for:**

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

Memory loss in Alzheimer's disease is due to a disturbance of message signals in the brain. The brain contains so-called 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.

## **2. BEFORE YOU TAKE EBIXA**

Before taking Ebixa it is important that you read the following sections and discuss any questions you might have with your doctor. Your caregiver may be able to assist you with any details you wish to discuss.

### **Do not take Ebixa:**

- if you are hypersensitive (allergic) to memantine hydrochloride or any of the other ingredients of Ebixa solution listed above.

**Take special care with 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.

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 moderate renal impairment, your doctor should closely monitor your kidney function and adapt the memantine doses accordingly. For patients with severe renal impairment, the use of memantine is not recommended.

The use of medicinal products called amantadine, ketamine, dextromethorphan and other NMDA-antagonists at the same time should be avoided.

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

**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) or if you are suffering from states of renal tubulary acidosis (RTA, an excess of acid-forming substances in the blood due to renal dysfunction) or severe infections of the urinary tract, as your doctor may need to adjust the dose of your medicine.

**Pregnancy:**

Tell your doctor if you are pregnant or planning to become pregnant. 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.

**Taking other medicines:**

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

In particular, the effects of the following medicines may be changed by Ebixa 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)
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- dopaminergic agonists (substances such as L-dopa, bromocriptine)
- neuroleptics (substances used in the treatment of mental disorders).

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

### 3. HOW TO TAKE EBIXA

Always take Ebixa exactly as your doctor has instructed you. To benefit from your medicine you should take it regularly every day. You should check with your doctor or pharmacist if you are unsure.

#### **Dosage:**

The recommended dose of Ebixa for adults and elderly patients is 20 mg (2x 20 drops) daily. In order to reduce the risk of side effects this dose is achieved gradually by the following daily treatment scheme:

	morning	afternoon or evening
week 1	10 drops	none
week 2	10 drops	10 drops
week 3	20 drops	10 drops
week 4 and beyond	20 drops	20 drops

The usual starting dose is 10 drops once daily (1x 5 mg) for the first week. This is increased to 10 drops twice a day (2x 5 mg) in the second week and to 20 drops (1x 10 mg) and 10 drops (1x 5 mg) daily taken in separate doses in the third week. From the fourth week on, the usual dose is 20 drops twice a day (2x 10 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 twice a day (except for the first week of treatment). The drops should be swallowed with some water. The drops can be taken with or without food.

#### **Duration of treatment:**

Continue to take Ebixa as long as it is of benefit to you and you do not experience any unacceptable side effects. 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 the forgotten dose.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Ebixa can have side effects.

In general, observed side effects are mild to moderate. The most common side effects (frequency 2% and less) are hallucinations, confusion, dizziness, headache and tiredness. Uncommon side effects are anxiety, hypertonia (increased muscle tone), vomiting, bladder infections and increased sexual drive.

If you have experienced epileptic seizures, there is a slight possibility that Ebixa may increase the chances of one occurring.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **6. STORING EBIXA**

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

Do not use after the expiry date stated on the carton and the bottle label.

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

This leaflet was last approved in {MM/YYYY}