

# EBIXA(R)

**Ebixa(R) Film-coated Tablets 10mg**

**Ebixa(R) Oral Drops 10mg/mL**

*Memantine hydrochloride*

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## Consumer Medicine Information

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### What is in this leaflet

This leaflet contains answers to some common questions about EBIXA.

It does not contain all the information that is known about EBIXA. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking EBIXA against the benefits he/she expects it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What EBIXA is used for

EBIXA is used to treat the symptoms of moderately severe to severe Alzheimer's disease (AD). AD can be described as a general decline in all areas of mental ability.

EBIXA belongs to a group of medicines called N-methyl-D-aspartate (NMDA) receptor antagonists. It is thought to work by protecting NMDA receptors in the brain against high levels of the chemical glutamate, which could be the cause of brain degeneration. NMDA receptors are involved in the transmission of nerve signals within the brain e.g. in learning and memory.

EBIXA should improve your thinking capacity and your ability to remember.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

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### Before you take EBIXA

#### ***When you must not take it***

**Do not take EBIXA if you:**

**1. have an allergy to:**

- \* EBIXA or any related medicines.
- \* Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include asthma, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or swelling of other parts of the body, or rash, itching or hives on the skin.

**2. have kidney disease.**

**3. have a seizure disorder or any history of seizures (fits or epilepsy).**

**Do not give EBIXA to children.**

The safety and effectiveness of EBIXA with children has not been established.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking EBIXA, talk to your doctor or pharmacist.**

#### ***Before you start to take it***

**Tell your doctor if:**

- \* **You have allergies to any other medicines, foods, preservatives or dyes.**
- \* **You are pregnant, or plan to become pregnant.**
- \* **If you are breast-feeding, or plan to breast-feed.**  
Your doctor will discuss the risks and benefits of using EBIXA if you are pregnant or breast-feeding.
- \* **You have epilepsy, kidney disease and/or problems with the heart or blood vessels.**
- \* **You have recently changed or intend to change your diet substantially, for example if you wish to become a vegetarian.**  
Your doctor may need to adjust the dose.
- \* **You smoke.**

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking EBIXA.**

## **Taking other medicines**

**Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you get without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines and EBIXA may interfere with each other. These include some medicines used for:

- \* Stomach cramps or spasms, or travel sickness
- \* Stomach ulcers or reflux (cimetidine, ranitidine)
- \* Parkinson's disease
- \* Epilepsy or fits
- \* Certain mental and emotional conditions (psychoses or schizophrenia)
- \* Irregular beating of your heart
- \* Leg cramps or to relax muscles
- \* Cough, cold and flu (preparations containing dextromethorphan)
- \* Smoking addiction (nicotine patches or gum)
- \* Urinary tract infection (urinary alkalinisers)
- \* Anaesthetic agents (ketamine)
- \* Treatment of malaria (quinine)
- \* Prevention of blood clots (warfarin)

These medicines may be affected by EBIXA, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking EBIXA.

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## **How to take EBIXA**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your**

**doctor or pharmacist for help.**

### **How much to take**

- \* The usual starting dose for EBIXA is 5mg (half a tablet or 10 drops) once a day for the first week.
- \* In the second week this is increased to 5mg (half a tablet or 10 drops) twice a day.
- \* In the third week the dose is increased to 10mg (one tablet or 20 drops) in the morning and 5mg (half a tablet or 10 drops) in the evening (total 15mg).
- \* From the fourth week on, the recommended dose is 10mg (one tablet or 20 drops) in the morning, and 10mg (one tablet or 20 drops) at night (total 20mg).

However, depending on your condition and how you react to the medicine, your doctor may ask you to take some other dose.

### **How to take it**

EBIXA can be taken with or without food.

#### **Tablets**

Tablets should be swallowed whole with a little liquid.

#### **Drops**

The drops should be taken with a little liquid.

### **How long to take it**

**Continue taking EBIXA as long as your doctor tells you to.**

EBIXA helps control your condition, but does not cure it. Your doctor should assess your treatment on a regular basis.

### **If you forget to take it**

**If you have forgotten to take your dose of EBIXA, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose that you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your doctor or pharmacist for some hints.**

### **If you take too much (overdose)**

**Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia and Tel: 0800 764 766 for New Zealand) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much EBIXA. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include feeling dizzy, tired or having a headache. You may also feel confused and see, hear or feel things that are not there. If you are an epileptic you could have a fit.

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## **While you are taking EBIXA**

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### **Things you must do**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking EBIXA.**

**Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.**

**If you become pregnant while taking EBIXA, tell your doctor immediately. If you are a woman of childbearing age, you should avoid becoming pregnant while taking EBIXA.**

**Tell your doctor immediately if you begin breast-feeding or wish to breast-feed while taking EBIXA.**

## Things you must not do

**Do not take EBIXA to treat any other complaint unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

## Things to be careful of

**If you drive a motor vehicle or operate machinery you should ask your doctor whether you should continue to do so.**

Your doctor will discuss whether your condition allows you to drive and use machines safely. EBIXA may also change your reactivity, thus making you less able to drive and use machines.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking EBIXA, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.**

This medicine helps most people with moderately severe to severe Alzheimer's disease, but it may have unwanted side effects in some people. All medicines can have side effects.

In general, the side effects of EBIXA are mild to moderate.

**Do not be alarmed by the following list of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

The most common side effects include:

- \* Seeing, hearing or feeling things that are not real

- \* Dizziness
- \* Headache
- \* Feeling confused
- \* Feeling tired

If you are an epileptic EBIXA could increase the chance of a fit occurring.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## After taking EBIXA

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### Storage

**If you are taking EBIXA tablets, keep them in the blister pack until it is time to take them.**

If you take them out of the blister pack they may not keep well.

**EBIXA drops should be discarded 3 months after opening.**

**Keep EBIXA in a cool dry place where the temperature stays below 30 degrees C.**

**Do not store EBIXA or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.**

Heat and dampness can destroy some medicines.

**Keep EBIXA where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## EBIXA description

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### What EBIXA tablets look like

EBIXA tablets are film-coated, white, oblong in shape and are scored on both sides of the tablet. It is available in boxes of 56 tablets.

### What EBIXA drops look like

EBIXA drops are a clear and colourless to pale yellow solution. It is available in bottles of 50mL (50g).

### Ingredients

#### Active ingredient(s)

EBIXA tablets contain 10mg memantine hydrochloride as the active ingredient.

EBIXA drops contain 10mg memantine hydrochloride per mL (20 drops) as the active ingredient.

#### Other ingredients

EBIXA tablets also contain:

- \* Lactose
- \* Cellulose - microcrystalline
- \* Silica - colloidal anhydrous
- \* Talc - purified
- \* Magnesium stearate
- \* Methacrylic acid copolymer
- \* Sodium lauryl sulphate
- \* Polysorbate 80
- \* Glycerol triacetate
- \* Simethicone

EBIXA drops also contain:

- \* Sorbitol solution 70% (non-crystallising)
- \* Potassium sorbate
- \* Water - purified

### Manufacturer/Distributor

EBIXA is supplied by H. Lundbeck A/S, Denmark.

**Distributed in Australia by:**

Lundbeck Australia Pty Ltd  
1/10 Inglewood Place  
Norwest Business Park  
Baulkham Hills NSW 2153  
Ph: +61 2 9836 1655

This leaflet was prepared in June  
2006.

Australian Registration Numbers:

Tablets: AUST R 82026

Drops: AUST R 82025

**"Ebixa" is the registered  
trademark of H. Lundbeck A/S.**

**Recommended maximum retail  
prices:**

Tablets, 56: AU\$180

Drops, 50 mL: AU\$161

**For information and support for  
dementia visit**

**[www.dementianet.com.au](http://www.dementianet.com.au)**