

## **Consumer Medicine Information (CMI) summary**

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### **1. Why am I taking Ebixa?**

Ebixa contains the active ingredient memantine hydrochloride. Ebixa is used to treat moderately severe to severe Alzheimer's disease (AD). AD can be described as a general decline in all areas of mental ability.

For more information, see Section [1. Why am I taking Ebixa?](#) in the full CMI.

### **2. What should I know before I take Ebixa?**

Do not use if you have ever had an allergic reaction to Ebixa or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions (such as epileptic seizures, heart attack, heart failure, high blood pressure, kidney problems, severe bladder infection, severe liver problems**

and if you smoke), take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take Ebixa?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Ebixa and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take Ebixa?

- Take Ebixa as a single dose either in the morning or in the evening.
- Swallow the tablets with water, with or without food.

More instructions can be found in Section [4. How do I take Ebixa?](#) in the full CMI.

### 5. What should I know while taking Ebixa?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking Ebixa.</li></ul>
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	<ul style="list-style-type: none"> <li>• Tell your doctor if you become pregnant while taking Ebixa, are breastfeeding, or are experiencing serious side effects such as feeling depressed or have any suicidal thoughts.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop taking Ebixa, or lower the dosage, without checking with your doctor.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• If you drive a motor vehicle or operate machinery, ask your doctor whether you should continue to do so.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store Ebixa below 30°C and keep the tablets in the blister pack until it is time to take them.</li> </ul>

For more information, see Section [5. What should I know while taking Ebixa?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include headache, drug hypersensitivity, increased blood pressure, constipation, shortness of breath, tiredness, sleepiness, sleeplessness, or problems sleeping, dizziness or feeling off balance, feeling anxious, diarrhoea, vomiting, or nausea, loss of appetite, changes in liver function tests, conjunctivitis. Serious side effects include serious allergic reaction; swelling of the hands, ankles or feet, headache, feeling confused, seeing, feeling or hearing things that are not there, having fixed, irrational ideas that are not shared by others. For epileptic patients, Ebixa could increase the chance of a fit occurring.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# **Ebixa®** (Ee-BIC-sa)

**Active ingredient(s):** *memantine hydrochloride (meh-MAN-teen high-dro-CLOR-ride)*

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## **Consumer Medicine Information (CMI)**

This leaflet provides important information about taking Ebixa. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Ebixa.**

**Where to find information in this leaflet:**

- [1. Why am I taking Ebixa?](#)
- [2. What should I know before I take Ebixa?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Ebixa?](#)
- [5. What should I know while taking Ebixa?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I taking Ebixa?**

**Ebixa contains the active ingredient memantine hydrochloride.** 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

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degeneration. NMDA receptors are involved in the transmission of nerve signals within the brain, e.g. in learning and memory.

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

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

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

Ebixa is not addictive.

## **2. What should I know before I take Ebixa?**

### **Warnings**

#### **Do not use Ebixa if:**

- you are allergic or hypersensitive to memantine hydrochloride, or any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can use this medicine.
  - Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, or rash, itching or hives on the skin.

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

### **Check with your doctor if you:**

- **have allergies to any other substances such as foods, preservatives or dyes**
- **have, or have had, any other medical conditions including the following:**
  - a history of epileptic seizures or convulsions
  - kidney problems
  - severe bladder infection
  - severe liver problems
  - heart or blood vessel problems
  - high blood pressure
- **smoke**
- take any medicines for any other condition

**Also tell your doctor if you have recently changed your diet, intend to change your diet substantially or have had drastic changes in diet, or massive ingestions of gastric buffers, for example if you wish to become a vegetarian.**

- Your doctor may need to adjust the dose.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

- Ebixa is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.  
Talk to your doctor if you are breastfeeding or intend to breastfeed.
- It is not known whether Ebixa passes into breast milk. Due to the possibility that their baby might be affected, women taking Ebixa should not breast-feed.

## **Children and adolescents**

**Do not give Ebixa to a child or adolescent under 18 years old.**

### **3. What if I am taking other medicines?**

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

**Some medicines may interfere with Ebixa and affect how it works. These include:**

- medicines used to treat stomach cramps or spasms, or travel sickness (anticholinergics)
- atropine, a medicine used in some eye drops



- levodopa, bromocriptine, amantadine and other medicines for the treatment of Parkinson's disease
- anticonvulsants and barbiturates, used to treat epilepsy or fits
- ketamine, an anaesthetic agent
- medicines used to treat certain mental and emotional conditions (psychoses or schizophrenia)
- dantrolene and baclofen, used to treat leg cramps or to relax muscles
- dextromethorphan, contained in cough, cold and flu medicines
- quinidine and procainamide, used to treat irregular heart beat
- nicotine, contained in patches or gums to treat smoking addiction
- cimetidine and ranitidine, used to treat stomach ulcers or reflux
- urinary alkalinisers, used to treat urinary tract infection
- quinine, a medicine used to treat malaria
- warfarin, used to prevent blood clots
- hydrochlorothiazide (or any combination with hydrochlorothiazide) used to treat hypertension and oedema

## **4. How do I take Ebixa?**

### **How much to take**

- The standard dose for this medicine is 20 mg per day.

- Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and your response to the medicine.
- Your doctor will start you on smaller doses which will be gradually increased for three weeks until the dose is reached where Ebixa works best for you.
  - **Week 1 (5 mg per day)**
    - Take half a 10 mg tablet (pale yellow to yellow).
  - **Week 2 (10 mg per day)**
    - Take one 10 mg tablet (pale yellow to yellow).
  - **Week 3 (15 mg per day)**
    - Take one and a half 10 mg tablets (pale yellow to yellow).
  - **From week 4 onwards (20 mg per day)**
    - Take two 10 mg tablets (pale yellow to yellow) or one 20 mg tablet (pink to grey-red).
- **Follow the instructions provided and take Ebixa until your doctor tells you to stop.**

### **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.

### **When to take Ebixa**

- Take Ebixa as a single dose at the same time every day.
- Take Ebixa with or without food.

## How to take Ebixa

- Swallow the tablets with water..

## How long should you take Ebixa

- **Continue taking your medicine for as long as your doctor tells you to.**
  - Ebixa helps control your condition. Your doctor will assess your treatment on a regular basis.

## If you forget to take Ebixa

Ebixa should be taken regularly at the same time each day.

If you miss your dose at the usual time, and it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

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

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

## **If you take too much Ebixa**

If you think that you have taken too much Ebixa, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre in Australia (**by calling 13 11 26**, or the National Poisons Centre in New Zealand (by calling **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

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

## **5. What should I know while taking Ebixa?**

### **Things you should do**

- **Remind any doctor, dentist or pharmacist you visit that you are taking Ebixa.**

## **Call your doctor straight away if you:**

- **become pregnant while taking Ebixa**
- **are feeling depressed or have any suicidal thoughts.**
  - Alzheimer's disease has been associated with depression and thoughts of suicide. All mentions of suicide or violence by a patient must be taken seriously.

**If you or someone you know demonstrates suicide-related behaviour while taking Ebixa, contact a health care provider immediately, or even go to the nearest hospital for treatment.**

## **Things you should not do**

- **Do not stop taking Ebixa, or lower the dosage, without checking with your doctor.**
- **Do not give the tablets to anyone else, even if they have the same condition as you.**
- **Do not take Ebixa to treat any other complaints unless your doctor tells you to.**

## **Driving or using machines**

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

Your doctor will discuss with you whether your condition allows you to drive or operate machinery safely. Furthermore, Ebixa may change your reactivity which may make driving or using machinery inappropriate.

## **Looking after your medicine**

- **Store Ebixa below 30°C and keep the tablets in the blister pack until it is time to take them.**
  - If you take the tablets out of the box or the blister pack they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

- If you take it after the expiry date has passed, it may not work as well. The expiry date refers to the last day of the month.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ebixa.**

It helps most people with moderately severe to severe Alzheimer's disease, but it may have unwanted side effects in a few people.

### Less serious side effects

Less serious side effects	What to do
<p><b>General disorders:</b></p> <ul style="list-style-type: none"><li>• tiredness, sleepiness, sleeplessness, or problems sleeping</li><li>• dizziness or feeling off balance</li><li>• feeling anxious</li></ul> <p><b>Gastrointestinal disorders:</b></p> <ul style="list-style-type: none"><li>• diarrhoea, vomiting, or nausea</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• loss of appetite</li> <li>• constipation</li> </ul> <b>Eye disorders:</b> <ul style="list-style-type: none"> <li>• conjunctivitis</li> </ul> <b>Infections and infestations:</b> <ul style="list-style-type: none"> <li>• fungal infections</li> </ul> <b>Vascular disorders:</b> <ul style="list-style-type: none"> <li>• high blood pressure</li> </ul> <b>Respiratory disorders:</b> <ul style="list-style-type: none"> <li>• Shortness of breath</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<b>General disorders:</b> <ul style="list-style-type: none"> <li>• swelling of hands, ankles or feet</li> <li>• headache</li> <li>• feeling confused</li> </ul> <b>Psychiatric disorders:</b> <ul style="list-style-type: none"> <li>• seeing, feeling or hearing things that are not there</li> </ul>	<b>Tell your doctor as soon as possible if you notice any of these serious side effects.</b>



<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• having fixed, irrational ideas that are not shared by others.</li> </ul> <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>• if you are an epileptic, Ebixa could increase the chance of a fit occurring</li> </ul> <p><b>Hepatobiliary disorders:</b></p> <ul style="list-style-type: none"> <li>• inflammation of the liver and/or changes in liver function tests</li> </ul>	

## **Very serious side effects**

<b>Very serious side effects</b>	<b>What to do</b>
<p><b>Immune system disorders:</b></p> <ul style="list-style-type: none"> <li>• serious allergic reaction symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, or hives.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Very serious side effects	What to do
<p>This is a very serious side effect. You may need urgent medical attention or hospitalisation.</p> <p>This side effect is very rare.</p>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) for Australia, and to consumer reporting at <https://pophealth.my.site.com/carmreportnz/s/> for New Zealand. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Ebixa contains

<b>Active ingredient (main ingredient)</b>	<b>Ebixa 10 mg tablets</b> <ul style="list-style-type: none"><li>• 10 mg memantine hydrochloride (equivalent to 8.31 mg memantine) per tablet</li></ul> <b>Ebixa 20 mg tablets</b> <ul style="list-style-type: none"><li>• 20 mg memantine hydrochloride (equivalent to 16.62 mg memantine) per tablet</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<b>Ebixa 10 mg tablets</b> <ul style="list-style-type: none"><li>• microcrystalline cellulose</li><li>• croscarmellose sodium</li><li>• hypromellose</li><li>• iron oxide yellow</li><li>• macrogol 400</li><li>• magnesium stearate</li><li>• colloidal anhydrous silica</li><li>• titanium dioxide</li></ul>

	<b>Ebixa 20 mg tablets</b> <ul style="list-style-type: none"> <li>• microcrystalline cellulose</li> <li>• croscarmellose sodium</li> <li>• hypromellose</li> <li>• iron oxide red</li> <li>• iron oxide yellow</li> <li>• macrogol 400</li> <li>• magnesium stearate</li> <li>• colloidal anhydrous silica</li> <li>• titanium dioxide</li> </ul>
<b>Potential allergens</b>	Ebixa 10 mg and 20mg tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Ebixa looks like**

- Ebixa 10 mg film-coated tablets - oval, pale yellow to yellow, embossed with 'M' on both sides of the break line; on the other side, '1' and '0' left and right of the break line (AUST R 180400).
- Ebixa 20 mg film-coated tablets - oval, pink to grey-red, embossed with '20' on one side and 'MEM' on the other side (AUST R 156299).

A box contains 56 tablets (Ebixa 10 mg) or 28 tablets (Ebixa 20 mg), respectively.

Note: Ebixa 20 mg tablets are not registered for supply in NZ.

## **Who distributes Ebixa**

### **Distributed in Australia by:**

Lundbeck Australia Pty Ltd

1 Innovation Road

North Ryde NSW 2113

Ph: +61 2 8669 1000

### **Distributed in New Zealand by:**

Healthcare Logistics

PO Box 62027

Mt Wellington, Auckland

Ph: +64 9 918 5100

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