

Ebixa[®]

(Ee-BIC-sa)

Memantine hydrochloride (meh-MAN-teen high-dro-CLOR-ride)

Consumer Medicine Information (CMI)

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 risk of you using this medicine against the benefits he/she expects it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Ebixa is used for

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 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.

Your doctor, however, may prescribe Ebixa for another purpose.

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

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

Ebixa is not addictive.

Before you take it

When you must not take it

Do not take Ebixa if you are allergic to it or any of the ingredients listed at the end of this leaflet.

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.

Do not take Ebixa if you have a seizure disorder or any history of seizures (fits or epilepsy).

Do not take it after the expiry date printed on the pack.

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.

Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if:

- 1. you have allergies to any other substances such as foods, preservatives or dyes.**

- 2. 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.

- 3. you are breast-feeding or planning to breast-feed.**

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.

- 4. you have, or have had, the following medical conditions:**

- a history of epileptic seizures or convulsions
- kidney problems
- severe bladder infection
- severe liver problems
- heart or blood vessel problems
- high blood pressure.

- 5. you smoke.**

Also tell your doctor if you have recently changed your diet or intend to change your diet substantially, for example if you wish to become a vegetarian.

Your doctor may need to adjust the dose.

If you are lactose intolerant, contact your doctor before taking Ebixa 10 mg tablets.

Ebixa 10 mg tablets contain lactose.

Tell your doctor if you are hypersensitive to memantine, the active substance in Ebixa.

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

If you have not told your doctor about any of the above, tell them before you use Ebixa.

Taking other medicines

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

Some medicines and Ebixa may interfere with each other. 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.

These medicines may be affected by Ebixa, or may affect how well it works. You may need to use different amounts of your medicines, or take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Ebixa.

How to take it

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 (white) or 10 drops once a day.

Week 2 (10 mg per day)

Take one 10 mg tablet (white) or 20 drops once a day.

Week 3 (15 mg per day)

Take one and a half 10 mg tablets (white) or 30 drops once a day.

From week 4 onwards (20 mg per day)

Take two 10 mg tablets (white) or one 20 mg tablet (pink to grey-red) or 40 drops once a day.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Ebixa may not work as well and your condition may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew them.

Take the drops with a little liquid.

When to take it

Take Ebixa as a single dose either in the morning or in the evening.

Take Ebixa with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

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

If you forget to take it

If 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 (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (Tel: 13 11 26 for Australia and Tel: 0800 764 766 for New Zealand), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have 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 feel confused and see, feel or hear things that are not there. You could also have a seizure.

While you are taking it

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.

Tell your doctor immediately if you 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 must not do

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.

Do not stop taking Ebixa, or lower the dosage, without checking with your doctor.

Things to be careful of

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.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he/she expects it will have for you.

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.

Tell your doctor if you notice any of the following and they worry you:

- tiredness, sleepiness, sleeplessness, or problems sleeping
- dizziness
- diarrhoea, vomiting, or nausea
- loss of appetite
- feeling anxious
- conjunctivitis.

These are mild side effects of the medicine.

Tell your doctor as soon as possible if you notice any of the following:

- swelling of 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.

These may be serious side effects of Ebixa. You may need urgent medical attention.

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

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- 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).

This is a very serious side effect. You may need urgent medical attention or hospitalisation.

This side effect is very rare.

Tell your doctor if you notice anything else that is making you feel unwell.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep Ebixa 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.

Discard Ebixa oral drops 3 months after first opening.

Keep the medicine in a cool dry place where the temperature stays below 30°C.

Do not store Ebixa or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it 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 the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Ebixa comes in two types of tablets and as oral drops:

- Ebixa 10 mg film-coated tablets - oblong, white, scored on both sides of the tablet
- Ebixa 20 mg film-coated tablets - oval, pink to grey-red, embossed with '20' on one side and 'MEM' on the other side
- Ebixa 10 mg/g oral drops - clear, colourless to pale yellow solution.

A box contains 56 tablets (Ebixa 10 mg) or 28 tablets (Ebixa 20 mg), respectively, and a bottle contains 50 g (50 mL).

Ingredients

Active ingredient(s):

- Ebixa 10 mg tablets - 10 mg memantine hydrochloride (equivalent to 8.31 mg memantine) per tablet
- Ebixa 20 mg tablets - 20 mg memantine hydrochloride (equivalent to 16.62 mg memantine) per tablet
- Ebixa 10 mg/g oral drops - 10 mg memantine hydrochloride (equivalent to 8.31 mg memantine) per 1 mL.

Inactive ingredients (10 mg tablets):

- cellulose - microcrystalline
- glycerol triacetate

- lactose
- magnesium stearate
- methacrylic acid copolymer
- polysorbate 80
- silica - colloidal anhydrous
- simethicone
- sodium lauryl sulphate
- talc - purified.

Ebixa 10 mg tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Inactive ingredients (20 mg tablets):

- cellulose - microcrystalline
- croscarmellose sodium
- hypromellose
- iron oxide red CI77491
- iron oxide yellow CI77492
- macrogol 400
- magnesium stearate
- silica - colloidal anhydrous
- titanium dioxide.

Ebixa 20 mg tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Inactive ingredients (oral drops):

- potassium sorbate
- sorbitol solution 70% (non-crystallising)
- water - purified.

Ebixa oral drops do not contain lactose, gluten, sucrose, tartrazine or any other azo dyes.

Manufacturer/Sponsor

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

Distributed in Australia by:

Lundbeck Australia Pty Ltd

1 Innovation Road

North Ryde

NSW 2113

Ph 02 8669 1000

Distributed in New Zealand by:

Healthcare Logistics

PO Box 62-027

Mt Wellington, Auckland

Ph: +64 9 966 0000

This leaflet was prepared in March 2011.

Australian Registration Numbers:

Ebixa tablets

10 mg - AUST R 82026

20 mg - AUST R 156299

Ebixa oral drops

10 mg/g - AUST R 82025

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

For information and support for dementia visit

www.dementianet.com.au

AU-NZ-628308-PIL