

EBIXA® (ALSO KNOWN AS MEMANTINE HYDROCHLORIDE)

The purpose of this medication:

Ebixa has been conditionally approved* by Health Canada to relieve the symptoms of people with moderate to severe Alzheimer's disease. It has been approved pending the results of further studies to verify its clinical benefit.

Ebixa is one of a group of drugs called NMDA (N-methyl-D-aspartate) receptor antagonists. Receptors are molecules on cells which "receive" other molecules, so allowing those molecules to initiate important chemical reactions. The NMDA receptors are the receiving targets of glutamate molecules released from nerves; when these molecules interact with NMDA receptors they function as "neurotransmitters", passing on messages from one nerve cell to another. In a disease like Alzheimer's disease, nerve cells get sick and then massive amounts of glutamate leak out of them. This excess of glutamate leads to excessive interaction with the NMDA receptors. The consequence is a toxic one; the "receiving" nerve cells get sick and may die. Ebixa and other Memantine-like drugs work by themselves interacting with the NMDA receptors, but all they do is block them and prevent glutamate from interacting with them, thereby reducing the toxicity of excess glutamate. The result is a normalization of the transmission of nerve messages between nerve cells, and a slowing in the decline of memory and cognition in Alzheimer's disease.

Ebixa can be used on its own or in combination with cholinesterase inhibitors (i.e., Aricept, Exelon, or ReminylER). Ongoing research is finding that combining cholinesterase inhibitors together with Ebixa seems to greatly improve outcomes, sometimes more than predicted from the sum of the effects of either drug alone. However, more and larger drug trials are needed to confirm these promising early results.

In controlled clinical trials, Ebixa has been used on its own and in combination with Aricept.

How does it help?

Ebixa is intended to treat symptoms in people with moderate to advanced Alzheimer's disease. In clinical trials, individuals who took the drug when compared to individuals who took a placebo (a substance which looks like the drug but has no effect), showed stabilization or slower decline in cognition (including memory, orientation, language) and function (including performance of daily activities).

The medication may take as long as 12 weeks to begin working and the type and length of response as well as the time it takes for patients to respond to this medication will vary from person to person.

Will this medication cure Alzheimer's disease?

Ebixa is not a cure for Alzheimer's disease as it does not affect the underlying degenerative process of the disease.

Who should take this medication?

The medication is for people who have been diagnosed with moderate to advanced Alzheimer's disease.

How do you obtain this medication?

Ebixa can only be obtained with a prescription from a doctor after a diagnosis of Alzheimer's disease has been made.

A reminder: This medication has been prescribed only for you or for the person you are caring for. It must not be given to anybody else or used for any other illness.

Important! Things to know before taking this medication:

Before taking Ebixa, give the doctor the following information:

- all medical conditions, including heart problems, uncontrolled hypertension (high blood pressure), history of seizures or kidney disease
- any medications, including prescriptions and non-prescriptions which you are currently taking or have taken within the last 14 days
- if you ever had an allergic reaction to any medication
- if you have a urinary tract infection, kidney problems, or if you have recently changed your diet substantially (e.g., from a diet including meat to a vegetarian diet)

How do you take this medication?

- Take the medication only as instructed by the doctor.
- Usually the doctor will prescribe 20 mg per day, which can be taken as two separate doses of 10 mg.
- To reduce the risk of undesirable reactions, the 20 mg dose will be achieved gradually, depending on the person's response and tolerability.
- The minimum recommended interval between increasing the dose is one week, as shown in the following table:

10 mg tablet	Morning	Afternoon
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

- Do not change the dose of the medication, unless the doctor instructs you to do so.
- The medication can be taken with or without food.
- Swallow the tablets whole, with some water. Do not chew tablets.
- Stop taking the medication and contact the doctor immediately if you experience an allergic reaction or any severe reaction.
- Continue to take the medication as long as directed by the doctor and you do not experience any unacceptable reactions. The doctor should monitor and assess the treatment regularly.
- If you miss a dose, do not take the missed tablet, but take the next dose when it is due.

What are the possible side effects?

Along with its beneficial effect, Ebixa may cause some undesirable reactions. These may include fatigue, dizziness, sleepiness, headache, hypertension (high blood pressure), constipation, vomiting, anxiety, confusion,

hallucinations and sleep disturbance. If you develop any other side effects while taking this medication, consult the doctor. If you suffer from epileptic seizures, there is a slight possibility that the medication may increase the chances of one occurring. Also, as this product may cause sleepiness or dizziness, do not drive or operate machinery under these conditions.

What to do if an overdose is taken:

If more medication has been taken than what is prescribed, contact either your doctor, hospital emergency department, or the nearest poison control centre immediately, even if you do not feel sick.

How do you store this medication?

Ebixa tablets contain memantine hydrochloride. The 10 mg tablets are white to off-white.

- Keep this medication in a safe place, out of the reach of children,
- Store the tablets at room temperature (between 15°C to 30°C) and in a dry place.
- If the doctor tells you to stop taking the medication, return any leftover tablets to the pharmacist, unless the doctor tells you to keep them.

How much does it cost and who pays for this medication?

The medication costs approximately \$5.00 per day. Currently, it is only covered under the provincial drug plan in the Province of Quebec. Some private insurance plans may cover the medication.

Who produces this medication?

Lundbeck Canada Inc. is the distributor of this medication. You can contact the company's medical information line at 1-866-880-4636 for more information.

For further information:

This information sheet is a brief description about this medication. For further information or advice, please contact your doctor or pharmacist.

- * For conditions that are life-threatening or cause severe impairment (such as Alzheimer's disease), the Health Products and Food Branch (HPFB), Health Canada, can authorize a drug manufacturer to market a drug with the condition that the drug manufacturer undertake additional studies to verify the drug's benefit. The authorization is a Notice of Compliance with condition (NOC/c). A NOC/c is given to an eligible drug which has demonstrated promising clinical effectiveness in clinical trials. The product must be of high quality and possess an acceptable benefit. The conditions include a requirement to closely monitor the drug for adverse reactions and to provide HPFB with regular updates. Once the conditions are met, the designation is removed.

For more information on how drugs are approved in Canada, see the Alzheimer Society of Canada's information sheet on the Drug Approval Process for the Treatment of Alzheimer's Disease available from your local Alzheimer Society or visit the website at www.alzheimer.ca.

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Alzheimer Society

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