PART III: CONSUMER INFORMATION

Ebixa®
Memantine hydrochloride tablets

Information in this leaflet is intended for patients and/or caregivers. "You" refers to the patient or someone in your care.

This leaflet is part III of a three-part "Product Monograph" published when Ebixa® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Ebixa®. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this information before you start to take your medication, even if you have taken this drug before. Keep this leaflet with your medication in case you need to refer to it again.

ABOUT THIS MEDICATION

What the medication is used for:
Ebixa® has been prescribed to you, by a doctor to relieve symptoms of Alzheimer's disease.

What it does:
The brain contains N-methyl-D-aspartate (NMDA) receptors that are involved in transmitting nerve signals and may be important for learning and memory. Abnormal transmission of nerve signals through NMDA-receptors in the brain may affect memory and other mental functions and contribute to symptoms of Alzheimer's disease. Ebixa® belongs to a group of medicines called NMDA-receptor antagonists. The action of Ebixa® on NMDA-receptors may help normalize the transmission of nerve signals, which may help slow the decline in some of the symptoms of Alzheimer disease.

When it should not be used:
- You should not be taking Ebixa® if you are pregnant, unless in the opinion of the doctor, the expected benefit to the patient markedly outweighs the possible hazards to the foetus.
- You should not be taking Ebixa® if you are breast-feeding.
- Do not take Ebixa® if you are allergic to it, or to any of the other ingredients listed in this leaflet (see **'What the non-medicinal ingredients are'**).
- Stop taking Ebixa® if you experience an allergic reaction or any severe side effect.

What the medicinal ingredient is:
Memantine hydrochloride

What the nonmedicinal ingredients are:
Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, methacrylic acid - ethyl acrylate copolymer (1:1), microcrystalline cellulose, polysorbate 80, sodium lauryl sulphate, simethicone emulsion, talc and triacetin.

What dosage forms it comes in:
White to off-white 10 mg tablets in blister packs.

WARNINGS AND PRECAUTIONS

BEFORE you use Ebixa® talk to your doctor or pharmacist if:

- You have/had a medical condition, including heart problems, uncontrolled hypertension (high blood pressure), history of seizures or kidney disease
- You are taking any medications (prescription or non-prescription) or have taken any within the last 14 days.
- You ever had an allergic reaction to any medication
- You are pregnant or thinking of becoming pregnant, or if you are breast-feeding.
- There are conditions which can change the speed at which the body would normally eliminate the drug over time and you should tell your doctor, as Ebixa® dosage may have to be adjusted if:
    - You have recently changed or intend to change your diet substantially (e.g. from normal diet to strict vegetarian diet)
    - You are suffering from renal tubulary acidosis (RTA, an excess of acid-forming substances in the blood due to renal dysfunction [kidney problems])
    - You have a urinary tract infection

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Ebixa ® include:
- NMDA-receptor antagonists (e.g. amantadine)
- Cimetidine
- Ranitidine
- Procainamide
- Quinidine
- Quinine
- Hydrochlorothiazide (or any combination with hydrochlorothiazide)
- Anticholinergics (generally used to treat movement disorders or intestinal cramps)
- L-dopa and dopaminergic agonists (drugs such as bromocriptine, ropinirole, pramipexole)
- Ketamine
- Dextromethorphan (found in cough syrup labelled DM)
- Anticoagulant (blood thinner) medications taken by mouth

PROPER USE OF THIS MEDICATION

Usual dose:

- It is important that you take Ebixa® exactly as your doctor has instructed.

- Usually your doctor will prescribe 20 mg per day, which you will take as two separate doses of 10 mg. In order to reduce the risk of side effects this dose will be achieved gradually by the following daily treatment scheme, starting at a dose of 5 mg per day:

10 mg Tablets		
	AM	PM
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

- Never change the dose of Ebixa® unless your doctor tells you to.

- Swallow the tablets whole with some water. Do not chew tablets. Ebixa® can be taken with or without food.

- Continue to take Ebixa® as long as directed by your doctor and you do not experience any unacceptable side effects. Your doctor should assess your treatment on a regular basis.

Overdose:

If you have accidentally taken too much Ebixa® contact your regional Poison Control Centre, hospital emergency department or your doctor immediately, even if you do not feel sick. You may require medical attention. If you go to the doctor or the hospital, take the Ebixa® container with you.

Missed Dose:

- If you miss a dose, do not worry. Do not take the missed tablet(s) – just take the next dose when it is due.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Ebixa® can cause side effects, although not everybody gets them. In general, these are mild to moderate. If any of the side effects become severe or if they are troublesome or persistent, talk to your doctor.

Common side effects (affects 1 to 10 users in 100) may include:

- headache
- sleepiness
- constipation
- tiredness
- confusion
- hallucinations (strange visions or sounds)
- vomiting
- loss of appetite
- dizziness
- sleep disturbance
- anxiety
- high blood pressure
- change in frequency of urination

Uncommon side effects (affects 1 to 10 users in 1000) may include:

- fungal infections
- changes in vision
- skin allergies

Your doctor will tell you whether your illness allows you to drive or operate machinery. Also, as this product may cause sleepiness or dizziness, do not drive or operate machinery under these conditions.

Alzheimer's disease has been associated with depression, thoughts of suicide and suicide. These events have been reported in patients treated with Ebixa®.

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency treatment
		Only if severe	In all cases	
Uncommon	Fungal infection	√		
	Abnormal gait [Abnormal way of walking]		√	
	Heart failure [persistent chest pain, rapid heart rate, severe shortness of breath, swelling of legs or ankles, increased tiredness, lack of appetite, confusion]			√
	Venous blood clotting [pain, swelling, changes in skin color, increased warmth in one leg]			√
Very rare	Seizures [loss of consciousness with uncontrollable shaking]			√
	Hepatitis/hepatic failure [yellow skin and eyes, nausea, loss of appetite, dark-coloured urine]			√
	Inflammation of the pancreas [severe upper stomach pain, often with nausea and vomiting]			√
	psychotic reactions			√
	Serious skin reactions [rash, red skin, blistering of the lips, eyes or mouth, skin peeling]			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency treatment
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Very rare (continued)	For example: Stevens-Johnson Syndrome: Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals Acute Generalized Exanthematous Pustulosis: Red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever Erythema Multiforme: Rash that may blister, with spots that look like small targets			√

This is not a complete list of side effects. For any unexpected effects while taking Ebixa®, contact your doctor or pharmacist.

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

HOW TO STORE IT

- As with all medicines, keep Ebixa® out of the reach of children.
- Store your tablets at room temperature (15°C-30°C) and in a dry place.
- If your doctor tells you to stop taking your medicine you should return any leftover tablets to the pharmacist, unless the doctor tells you to keep them at home.

REMEMBER: This medicine is for YOU or for someone in your care. Only a doctor can prescribe it, so never offer it to any other person, even if their symptoms seem to be the same as yours or as for the person in your care.

REPORTING SUSPECTED SIDE EFFECTS

NOTE: THIS IS NOT AN EMERGENCY NUMBER
To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
By toll-free fax: 866-678-6789
On-line: www.healthcanada.gc.ca/medeffect
By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa ON K1A 0K9

NOTE: **Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.**

MORE INFORMATION

For questions or concerns and to find the full product monograph prepared for healthcare professionals, go to http://www.lundbeck.ca or contact the sponsor, Lundbeck Canada Inc. at 1-800-586-2325.

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