Labatine®

Memantine hydrochloride

Composition

- The active substance is memantine hydrochloride. Each tablet contains 10 mg or 20 mg of memantine hydrochloride equivalent to 8.31 mg or 16.62 mg memantine, respectively.
- The other ingredients are:
  Core of the tablet: lactose monohydrate, cellulose microcrystalline, crospovidone type B, silica colloidal anhydrous, magnesium stearate.
  Coating of the tablet: hypromellose, titanium dioxide (E171), iron oxide red (E172) (only 20 mg film-coated tablets), macrogol 400.

Pharmaceutical Form

Film coated tablets.

Mechanism of action

Labatine belongs to a group of medicines known as anti-dementia medicines.
Memory loss in Alzheimer's disease is due to a disturbance of message signals in the brain. The brain contains so-called N-methyl-D-aspartate (NMDA)-receptors that are involved in transmitting nerve signals important in learning and memory. Labatine belongs to a group of medicines called NMDA-receptor antagonists. Labatine acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

Therapeutic indication

Labatine is used for the treatment of patients with moderate to severe Alzheimer's disease.

Posology and method of administration

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Dosage
The recommended dose of Labatine for adults and elderly patients is 20 mg once a day.
In order to reduce the risk of side effects this dose is achieved gradually by the following daily treatment scheme. For up-titration other tablet strengths are available.

Week 1	half a 10 mg tablet (5 mg)
Week 2	one 10 mg tablet
Week 3	one and a half 10 mg tablet (15 mg)
Week 4 and beyond	two 10 mg tablets OR one 20 mg tablet once a day

At the beginning of treatment you will start by using a half film-coated tablet once a day (1x5 mg) for the first week. This dose will be increased weekly by 5 mg until the recommended (maintenance) dose is reached. The recommended maintenance dose is 20 mg once a day, which is reached at the beginning of the 4th week.
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.
Administration
Labatine should be administered orally once a day. To benefit from your medicine you should take it regularly every day at the same time of the day. The tablets should be swallowed with some water. The tablets can be taken with or without food.
Duration of treatment
Continue to take Labatine as long as it is of benefit to you. Your doctor should assess your treatment on a regular basis.

Contraindications

If you are allergic to memantine or any of the other ingredients of this medicine.

Special warnings and precautions for use

Talk to your doctor before taking Labatine:

- If you have a history of epileptic seizures
- If you have recently experienced a myocardial infarction (heart attack), or if you are suffering from congestive heart failure or from an uncontrolled hypertension (high blood pressure).

In these situations the treatment should be carefully supervised, and the clinical benefit of Labatine reassessed by your doctor on a regular basis.
If you suffer from renal impairment (kidney problems), your doctor should closely monitor your kidney function and if necessary adapt the Memantine doses accordingly.
The use of medicinal products called amantadine (for the treatment of Parkinson's disease), ketamine (a substance generally used as an anaesthetic), dextromethorphan (generally used to treat cough) and other NMDA-antagonists at the same time should be avoided.
Children and adolescents
Labatine is not recommended for children and adolescents under the age of 18 years.

Interactions with other medicines and other forms of interaction

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
In particular, Labatine may change the effects of the following medicines and their dose may need to be adjusted by your doctor:

- amantadine, ketamine, dextromethorphan
- dantrolene, baclofen
- cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine
- hydrochlorothiazide (or any combination with hydrochlorothiazide)
- anticholinergics (substances generally used to treat movement disorders or intestinal cramps)
- anticonvulsants (substances used to prevent and relieve seizures)
- barbiturates (substances generally used to induce sleep)
- dopaminergic agonists (substances such as L-dopa, bromocriptine)
- neuroleptics (substances used in the treatment of mental disorders)
- oral anticoagulants.

If you go into hospital, let your doctor know that you are taking Labatine.
Labatine with food and drink
You should inform your doctor if you have recently changed or intend to change your diet substantially (e.g. from normal diet to strict vegetarian diet) or if you are suffering from states of renal tubulary acidosis (RTA, an excess of acid-forming substances in the blood due to renal dysfunction (poor kidney function)) or severe infections of the urinary tract (structure that carries urine), as your doctor may need to adjust the dose of your medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
The use of Memantine in pregnant women is not recommended.
Women taking Labatine should not breast-feed.

Effect on ability to drive and use machines

Your doctor will tell you whether your illness allows you to drive and to use machines safely. Also, Labatine may change your reactivity, making driving or operating machinery inappropriate.
Labatine contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Undesirable effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
In general, the observed side effects are mild to moderate.
Common (affects 1 to 10 users in 100):

- Headache, sleepiness, constipation, elevated liver function tests, dizziness, balance disorders, shortness of breath, high blood pressure and drug hypersensitivity

Uncommon (affects 1 to 10 users in 1,000):

- Tiredness, fungal infections, confusion, hallucinations, vomiting, abnormal gait, heart failure and venous blood clotting (thrombosis/ thromboembolism)

Very rare (affects less than 1 user in 10,000):

- Seizures

Not known (frequency cannot be estimated from the available data):

- Inflammation of the pancreas and psychotic reactions

Alzheimer's disease has been associated with depression, suicidal ideation and suicide. These events have been reported in patients treated with Labatine.
If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Overdose

- In general, taking too much Labatine should not result in any harm to you. You may experience increased symptoms as described in section 5. "Undesirable effects".
- If you take a large overdose of Labatine, contact your doctor or get medical advice, as you May need medical attention.

If you forget to take Labatine

- If you find you have forgotten to take your dose of Labatine, wait and take your next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Special precautions for storage

Store below 30 °C.
Keep this medicine out of the sight and reach of children.
Keep blisters in the outer carton in order to protect from light.
Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Nature and contents of the pack

Labatine 10 mg film-coated tablets are oblong, biconvex, 9.5 x 4.5 mm tablets, white or almost white, with score line; after breaking colour of tablet core is white or almost white. The tablets can be divided into equal doses.
Labatine 20 mg film-coated tablets are oblong, biconvex, 12.5 x 5.5 mm tablets, pink with narrowing and with bilateral score line; after breaking colour of tablet core is white or almost white. The tablets can be divided into equal doses.

Presentations

Labatine® 10 mg: 14, 28, 30, 42, 49, 50, 56, 70, 84, 98, 100, 100, 112 film-coated tablets.
Labatine® 20 mg: 14, 28, 42, 49, 56, 70, 84, 98, 100, 112 film-coated tablets.
Not all pack sizes may be marketed.

Manufactured by: Pharmaceutical Works Polpharma SA 19, Pelplińska Street 83-200 Starogard Gdański Poland
Applicant: Farmaprojects SAU C/ Santa Eulalia,240,242, Hospitalet de Llobregat 08902, Barcelona, Spain.
Marketing Authorisation Holder: Labatec Pharma S.A., CH-1217 Meyrin (Geneva), Switzerland.

Council of Arab Health Ministers, Union of Arab Pharmacists

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Rev. 09/2014