LEPIGINE®
100 mg Tablets

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about LEPIGINE
Each LEPIGINE tablet for oral administration contains lamotrigine 100 mg with the following excipients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium and magnesium stearate.
Lamotrigine is an antiepileptic drug of the phenyltriazine class. Lamotrigine stabilizes neuronal membranes by blocking voltage-sensitive sodium channels, which inhibits the release of excitatory neurotransmitters that play a role in the generation and spread of epileptic seizures.
LEPIGINE is indicated in the following conditions:
-Adjunctive or monotherapy treatment of partial seizures and generalized seizures, including tonic-clonic seizures in adults and adolescents over 13 years of age.
-Adjunctive therapy or as initial antiepileptic drug to start with in case of seizures associated with Lennox-Gastaut syndrome in adults and adolescents over 13 years of age.
-Adjunctive treatment of partial seizures and generalized seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome and as monotherapy of typical absence seizures in children aged 2 to 12 years.
-Prevention of depressive disorders in patients over 18 years of age with bipolar I disorder.
Your doctor may use this medicine to treat other conditions as well.
The way to take LEPIGINE
Follow closely the dosing recommendations provided by your doctor. Do not modify the dose and do not discontinue the treatment without consulting your doctor.
Dosage and duration of treatment are individualized and adjusted according to the condition under treatment. The dosage regimen of LEPIGINE also depends on the concomitant treatment (other antiepileptic drugs or medicinal products).
Recommended initial dose and subsequent dose escalations of lamotrigine should not be exceeded in order to avoid an increased risk of rash. Concomitant use of valproate increases the risk of rash.
LEPIGINE is administered orally without regard to meals.
Consult a doctor for dosing recommendations in patients less than 12 years of age.
The usual recommended doses for treating epilepsy in adults and children over 13 years of age and for the management of bipolar disorder are:

Indication	**Dose**
Monotherapy in epilepsy or adjunctive therapy without valproate and without inducers of lamotrigine glucuronidation	The initial dose is 25 mg once daily for 2 weeks followed by 50 mg once daily for 2 weeks; thereafter the dose is increased by a maximum of 50 mg to 100 mg every 1 to 2 weeks to usual maintenance dose of 100 mg to 200 mg daily (1 to 2 tablets of 100 mg daily) given in one or two divided doses. In monotherapy, some patients have required up to 500 mg daily.
Adjunctive therapy with valproate (inhibitor of lamotrigine glucuronidation)	The initial dose is 25 mg every other day for 2 weeks followed by 25 mg once daily for 2 weeks; thereafter the dose is increased by a maximum of 25 mg to 50 mg every 1 to 2 weeks to usual maintenance dose of 100 mg to 200 mg daily (1 to 2 tablets of 100 mg daily) given in one or two divided doses.
Adjunctive therapy without valproate and with inducers of lamotrigine glucuronidation (phenytoin, carbamazepine, phenobarbitone, primidone, rifampicin, lopinavir/ritonavir)	The initial dose is 50 mg once daily for 2 weeks followed by 50 mg twice daily for 2 weeks; thereafter the dose is increased by a maximum of 100 mg every 1 to 2 weeks to usual maintenance dose of 200 mg to 400 mg daily (2 to 4 tablets of 100 mg) given in 2 divided doses. Some patients have required up to 700 mg daily.
Management of bipolar disorder	Lamotrigine should be started at a reduced dose and increased

	gradually to the maintenance stabilization dose over 6 weeks. - The target dose of lamotrigine is 200 mg (2 tablets of 100 mg) daily given in one or two divided doses as monotherapy with lamotrigine or as adjunctive therapy without valproate and without inducers of lamotrigine glucuronidation. - For patients taking valproate the target dose is 100 mg (1 tablet of 100 mg) daily given in one or two divided doses. A maximum dose of 200 mg per day may be given. - In patients taking inducers of lamotrigine glucuronidation without valproate, the target dose, given as two divided doses, is 300 mg daily (3 tablets of 100 mg) in week 6, and may be increased to 400 mg daily (4 tablets of 100 mg) in week 7 to achieve optimal response. The target stabilization dose depends on clinical response. Dosage adjustment of lamotrigine is required in cases of withdrawal or addition of other psychotropic drugs and/or antiepileptic drugs.

Specific dosing requirements are needed in case of concomitant administration or withdrawal of oral contraceptives or other female hormonal products.
If the potential for interaction with the adjunctive drugs is unknown, treatment with lamotrigine should follow the same dosing regimen as that used with valproate.
Doses should be reduced in patients with hepatic impairment.

Duration of treatment

Duration of treatment is determined according to the disease under treatment.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in case of hypersensitivity to lamotrigine or any of the components.

Precautions

- Inform your doctor immediately if rashes or redness, ulcers in the mouth, throat, nose or genitals, fever, flu-like symptoms, swollen lymph glands, painful sore in the mouth or around the eyes, unexpected bleeding or bruising, swelling around your face, or if worsening of seizure control occur.
-Caution is required when treating patients with a history of allergy or rash to lamotrigine, other antiepileptic drugs and other medicines for bipolar disorder.
- It is not recommended to restart therapy with lamotrigine in patients who have discontinued it due to rash. Treatment with lamotrigine should not be restarted in patients who have developed Lyell syndrome and Stevens-Johnson syndrome or meningitis after taking lamotrigine.
-Do not stop taking this medicine without first checking with your doctor. He may want you to reduce gradually the amount you are taking before stopping completely. As with other antiepileptics, withdrawal of therapy or transition to or from another type of antiepileptic therapy should be made gradually to avoid precipitating an increase in the frequency of seizures.
-Possibility of a suicide attempt is inherent in patients taking antiepileptic drugs, and close supervision of high risk patients should accompany drug therapy.
- This drug should be used with caution in patients with renal or hepatic impairment and in elderly.
-Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.
-Consult your doctor before using this medication in case of pregnancy or lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.
The metabolism of lamotrigine is enhanced by the enzyme inducers carbamazepine, phenytoin, phenobarbitone, primidone, rifampicin, ethinyloestradiol/ levonorgestrel combination (oral contraceptives or other female hormonal products), medicines used to treat Human Immunodeficiency Virus (HIV)

infection (atazanavir/ritonavir, lopinavir/ritonavir) and inhibited by valproate. Concomitant administration of these drugs and lamotrigine requires dosage adjustments to maintain efficacy and/or avoid toxicity.
Use with caution with medications that inhibit folate metabolism, other antiepileptic drugs (e.g. oxcarbazepine, felbamate, gabapentin, levetiracetam, pregabalin, topiramate, zonisamide), and psychoactive agents (e.g. lithium, olanzapine, aripiprazole, risperidone, bupropion).

Adverse reactions

The most common reported adverse reactions include: somnolence, dizziness, tremor, insomnia, agitation, headache, aggression, irritability, nausea, vomiting, diarrhea, dry mouth, skin rash, arthralgia, tiredness, and back pain.
Other reported adverse reactions include lack of coordination, ataxia, double or blurred vision, nystagmus, blood disorders, confusion, tics and hallucinations.
Rarely, severe skin reactions, including Lyell syndrome and Stevens-Johnson syndrome have been reported.
Please inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.
The expiry date is printed on the pack; don’t use this medicine after this date.

Pack Presentation

LEPIGINE, Lamotrigine 100 mg, pack of 30 tablets

Revision date: 07/2013
LEPT1/002