LEPITAM®
ORAL SOLUTION

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 LEPITAM
Each 1 mL of LEPITAM contains 100 mg of levetiracetam.
Other ingredients are citric acid monohydrate, glycerin, maltitol solution, methylparaben, propylparaben, potassium acesulfame, sodium citrate dihydrate, banana flavor, purified water.
Levetiracetam is an antiepileptic drug that has been found to target high-voltage, N-type calcium channels as well as the synaptic vesicle protein 2A (SV2A).
LEPITAM is indicated in the following cases:
-Monotherapy in the treatment of partial onset seizures with or without secondary generalization in patients from 16 years of age with newly diagnosed epilepsy.
-Adjunctive therapy in the treatment of partial onset seizures in adults and children one month of age and older with epilepsy.
-Adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents 12 years of age and older with Juvenile Myoclonic Epilepsy (JME).
-Adjunctive therapy in the treatment of Primary Generalized Tonic-Clonic (PGTC) seizures in adults and children aged 6 years and over with Idiopathic Generalized Epilepsy (IGE).
The way to use LEPITAM
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 usual recommended doses are:

Indication	**Dose**
Monotherapy in the treatment of partial onset seizures with or without secondary generalization	Treatment should be initiated with 250 mg twice daily. The dose should be increased after 2 weeks to 500 mg twice daily. The daily dosage may be adjusted subsequently in increments of 250 mg twice daily every 2 weeks to a maximum of 1500 mg twice daily
Adjunctive therapy in the treatment of partial onset seizures	**Adults (16 years and older):** Treatment should be initiated with a daily dose of 1000 mg/day, given as twice-daily dosing (500 mg BID). Additional dosing increments may be given (1000 mg/day additional every 2 weeks) to a maximum recommended daily dose of 3000 mg. **Pediatric patients (4 to 16 years) :** Treatment should be initiated with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg BID). The daily dose should be increased every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60 mg/kg (30 mg/kg BID). **Pediatric patients (6 months to 4 years) :** Treatment should be initiated with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg BID). The daily dose should be increased every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 50 mg/kg (25 mg/kg BID). **Pediatric patients (1 month to 6 months) :** Treatment should be initiated with a daily dose of 14 mg/kg in 2

	divided doses (7 mg/kg BID). The daily dose should be increased every 2 weeks by increments of 14 mg/kg to the recommended daily dose of 42 mg/kg (21 mg/kg BID).
Adjunctive therapy in the treatment of myoclonic seizures	Treatment should be initiated with a dose of 1000 mg/day, given as twice-daily dosing (500 mg BID). Dosage should be increased by 1000 mg/day every 2 weeks to the recommended daily dose of 3000 mg.
Adjunctive therapy in the treatment of Primary Generalized Tonic-Clonic (PGTC) seizures	**Adults (16 years and older):** Treatment should be initiated with a dose of 1000 mg/day, given as twice-daily dosing (500 mg BID). Dosage should be increased by 1000 mg/day every 2 weeks to the recommended daily dose of 3000 mg. **Pediatric patients (6 to 16 years):** Treatment should be initiated with a daily dose of 20 mg/kg in 2 divided doses (10 mg/kg BID). The daily dose should be increased every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60 mg/kg (30 mg/kg BID).

Adjustment of the dose is recommended in elderly patients with compromised renal function**.**
No dose adjustment is needed in patients with mild to moderate hepatic impairment**.**

Mode of administration
The oral solution may be diluted in a glass of water and may be taken with or without food. A graduated oral syringe and an adaptor for the syringe are provided with the product. The daily dose is administered in two equally divided doses.

Instructions for use:

- Open the bottle
- Separate the adaptor from the syringe. Insert the adaptor into the bottle neck . Ensure it is well fixed**.**
- Take the syringe and put it in the adaptor opening. Turn the bottle upside down**.**
- Fill the syringe with the amount of solution prescribed by your doctor by pulling the piston down to the corresponding graduation mark in milliliters.
- Turn the bottle the right way up. Remove the syringe from the adaptor
- Empty the contents of the syringe in a glass of water or baby's bottle by pushing the piston to the bottom of the syringe
- Drink the whole contents of the glass/baby's bottle.
- Close the bottle with its cap.
- Wash the syringe with water only

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 history of hypersensitivity to any of the components.
Precautions
-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.
-This drug should be used with caution in case of renal, hepatic or cardiac impairment and in geriatric patients.
-Possibility of a suicide attempt is inherent in patients taking antiepileptic drugs, and close supervision of high risk patients should accompany drug therapy.
-Caution should be taken when operating machinery or driving a motor vehicle until you know how you respond to the drug.
-Consult your doctor before using this medication in case of pregnancy or lactation. The safety of administration during pregnancy has not been established. Breast-feeding is not recommended while taking this drug.

Association with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.
Pre-marketing data from clinical studies indicate that this drug did not influence the serum concentrations of existing antiepileptic products (phenytoin, carbamazepine, valproic acid, phenobarbital, lamotrigine, gabapentin and primidone) and that these antiepileptics did not influence the pharmacokinetics of levetiracetam.

Adverse reactions

This drug is usually well tolerated in most people. The most commonly reported adverse reactions in adults were somnolence, fatigue, asthenia, dizziness, headache, infection, behavioral disturbances such as agitation and anxiety; The most commonly reported adverse reactions in the pediatric population were somnolence, hostility, nervousness, emotional lability, agitation, anorexia, asthenia and headache
Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°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

LEPITAM, 100 mg/ml, bottle of 120 mL with a graduated syringe and an adaptor.

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