

LEPITAM®
Tablet & 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 oral solution contains 100 mg of Levetiracetam with the following excipients: citric acid monohydrate, glycerin, maltitol solution, methylparaben, propylparaben, potassium acesulfame, sodium citrate dihydrate, banana flavor and purified water.

Each tablet of LEPITAM 250mg and 500mg contains respectively 250 mg and 500mg Levetiracetam with the following excipients: pregelatinized starch, povidone, croscarmellose sodium and magnesium stearate.

Levetiracetam is an antiepileptic drug used to treat seizures in epilepsy.

LEPITAM is indicated in the following cases:

- for the treatment of partial-onset seizures in patients 1 month of age and older.
- as adjunctive therapy for the treatment of myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy.
- as adjunctive therapy for the treatment of primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy.

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, age, dosage form and renal function.

- The oral solution is prescribed for pediatric patients with body weight less than or equal to 20kg.
- The oral solution or tablet is prescribed for pediatric patients with body weight more than 20kg.
- The dosage can be taken with or without food.
- Dosage adjustment is recommended in patients with kidney problems.
- The recommended dosing is as follow:

Indication	Dose
Partial onset seizure	Adults and adolescents 16 years and older: Treatment should be initiated with a daily dose of 1000mg/day, given twice daily in two equally divided doses (500mg twice daily). Increase the dose every 2 weeks by increments of 1000 mg/day to a maximum recommended daily dose of 3000mg. Pediatric patients: 1 month to less than 6 months: Treatment should be initiated with a daily dose of 14 mg/kg in two equally divided doses (7mg/kg twice daily). Increase the dose every 2 weeks by increments of 14 mg/kg to the recommended daily dose of 42 mg/kg (21mg/kg twice daily). 6 months to less than 4 years: Treatment should be initiated with a daily dose of 20mg/kg in two equally divided doses (10mg/kg twice daily). Increase the dose every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 50 mg/kg (25mg/kg twice daily). Dose can be reduced if the patient cannot tolerate a daily dose of 50mg/kg. 4 years to less than 16 years: Treatment should be initiated with a daily dose of 20mg/kg in two equally divided doses (10mg/kg twice daily). Increase the dose every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60 mg/kg (30mg/kg twice daily). Dose can be reduced if the patient cannot tolerate a daily dose of 60mg/kg. LEPITAM oral solution weight based dosing calculation for pediatric patients: Total daily dose (mL/day) = $\frac{\text{Daily dose (mg/kg/day)} \times \text{patient weight (kg)}}{100 \text{ mg/mL}}$
Myoclonic seizures in patients 12 years of age and older with juvenile myoclonic epilepsy	Treatment should be initiated with a daily dose of 1000mg/day, given twice daily in two equally divided doses (500mg twice daily). Increase the dose every 2 weeks by increments of 1000 mg/day to a maximum recommended daily dose of 3000mg.
Primary generalized tonic-clonic seizures in patients 6 years of age and older with idiopathic generalized epilepsy.	Adults 16 years of age and older: Treatment should be initiated with a daily dose of 1000mg/day, given twice daily in two equally divided doses (500mg twice daily). Increase the dose every 2 weeks by increments of 1000 mg/day to a maximum recommended daily dose of 3000mg. Pediatric patients 6 to less than 16 years of age: Treatment should be initiated with a daily dose of 20mg/kg in two equally divided doses (10mg/kg twice daily). Increase the dose every 2 weeks by increments of 20 mg/kg to the recommended daily dose of 60 mg/kg (30mg/kg twice daily).

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 Levetiracetam or to any of the components.

Precautions

- Do not stop taking this medicine without first checking with your doctor. The treatment should be discontinued gradually.
- This drug should be used with caution in case you have renal or hepatic problems.
- Possibility of a suicide attempt is inherent in patients taking antiepileptic drugs, and close supervision of high risk patients should accompany drug therapy.
- Levetiracetam may cause changes in behavior and psychotic symptoms. Tell your doctor if you have any of these symptoms: mood and behavior changes such as: aggression, agitation, anger, depression.
- Discontinue your treatment and contact your doctor in case you develop signs and symptoms of anaphylaxis or angioedema.
- 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.

Association with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Adverse reactions

The most commonly reported adverse reactions include: sleepiness, weakness, infection and dizziness.

The most commonly reported adverse reactions in children include: tiredness, aggressiveness, decreased appetite, nasal congestion, irritability.

Other reported adverse reactions include: loss of appetite, abdominal pain, vertigo, cough, nervousness, anxiety and rash.

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

LEPITAM, Levetiracetam 100 mg/mL, bottle of 120 mL.

LEPITAM, Levetiracetam 250mg, pack of 60 tablets.

LEPITAM, Levetiracetam 500mg, pack of 60 tablets.

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Marketing Authorization Holder and Manufacturer
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