

LEVETRIMED®
100 mg/mL 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 LEVETRIMED

Each 1 mL of LEVETRIMED oral solution contains 100 mg of Levetiracetam. The excipients are: citric acid monohydrate, glycerin, maltitol solution, methylparaben, propylparaben, potassium acesulfame, sodium citrate dihydrate, banana flavor and purified water. Levetiracetam is an antiepileptic drug used to treat seizures in epilepsy.

LEVETRIMED is indicated in the following cases:

- Monotherapy in the treatment of partial onset seizures with or without secondary generalization in adults and adolescents 16 years and older with newly diagnosed epilepsy.
- Adjunctive therapy in the treatment of partial onset seizures with or without secondary generalization in adults, adolescents and children 1 month of age and older.
- 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 adolescents 12 years of age and older with Idiopathic Generalized Epilepsy (IGE).

The way to take LEVETRIMED

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 dose is:

Indication	Dose
Monotherapy	Adults and adolescents 16 years and older: Treatment should be initiated with a daily dose between 5mL (500mg) and 15mL (1500mg) twice daily in two equally divided doses. The doctor will prescribe a lower dose for two weeks before starting on the lowest recommended dose.
Adjunctive therapy	Adults and adolescents 12 years and older: Treatment should be initiated with a daily dose between 5mL (500mg) and 15mL (1500mg) twice daily in two equally divided doses. Children 6 months and older: Treatment should be initiated with a daily dose between 0.1mL/kg (10mg/kg) and 0.3mL/kg (30mg/kg) twice daily in two equally divided doses. Infants 1 month to less than 6 months: Treatment should be initiated with a daily dose between 0.07mL/kg (7mg/kg) and 0.21mL/kg (21mg/kg) twice daily in two equally divided doses.

- Dosage adjustment may be recommended in patients with kidney problems.

Mode of administration

The oral solution may be diluted in a glass of water and may be taken with or without food. The daily dose is administered in two equally divided doses.

Duration of treatment

The duration of treatment is determined according to the condition 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 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 of renal, hepatic or cardiac impairment.
- 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.
- Contact your doctor if you notice any slowdown in the growth of your child.
- Consult your doctor before using this medication in case of pregnancy or lactation. 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.

Do not take Macrogol for one hour before and one hour after taking Levetiracetam.

Adverse reactions

The most commonly reported adverse reactions include: somnolence, dizziness, fatigue, headache and nasopharyngitis.

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. Do not use after 7 months of first opening the bottle. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

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

Issue date: 03/2024

LEES5/002

Manufactured by Mediphar Laboratories -Lebanon