Information For the Use Levetiracetam (500mg)

Lapcetam 500 Tablet

Levetiracetam 500 mg Tablet

Dosage Form: Oral Tablet Strength: 500 mg

Indications

Levetiracetam is used to treat the following conditions:

- 1. Epilepsy (Seizure Disorders):
 - Monotherapy: For partialonset seizures in adults and children aged 16 years and older.
 - Adjunctive Therapy:
 - For partial-onset seizures in children aged 4 years and older.
 - For generalized tonicclonic seizures in adults and children aged 6 years and older with idiopathic generalized epilepsy.
 - For myoclonic seizures in adults and adolescents aged 12 years and older with juvenile myoclonic epilepsy.

Mechanism of Action

Levetiracetam works by binding to a specific protein in the brain called synaptic vesicle protein 2A (SV2A), which plays a key role in neurotransmitter release. This binding stabilizes the activity of nerve cells, helping to prevent abnormal electrical activity in the brain that leads to seizures.

Dosage and Administration

Adults and Adolescents (≥16 years):

- Initial Dose: 500 mg twice daily.
- Maintenance Dose: The dose can be increased in 500 mg increments (up to a maximum of 1500 mg twice daily) depending on clinical response and tolerance.
- Renal Impairment: Dose adjustment may be required based on kidney function.

Children (4–15 years):

• Dose is weight-based. The pediatric dose is adjusted according to the child's weight and clinical condition.

Instructions for Use:

- Swallow the tablet whole with water.
- Can be taken with or without food.

Contraindications

- Hypersensitivity to levetiracetam or any of the excipients in the formulation.
- Use with caution in patients with a history of psychiatric conditions (e.g., depression, suicidal thoughts) or kidney issues.

Warnings and Precautions

- 1. Psychiatric Symptoms:
 - Levetiracetam may cause mood swings, depression, or suicidal thoughts. Patients should be monitored for these effects, especially when starting the medication.
- 2. Cognitive and Motor Impairment:
 - May cause drowsiness, dizziness, or impaired coordination. Patients should be cautious when engaging in activities requiring mental alertness (e.g., driving or operating machinery).
- 3. Seizure Control:
 - Abrupt withdrawal can increase the risk of seizures. It is important to gradually taper the dose under the supervision of a healthcare provider.
- 4. Renal Impairment:
 - Dose adjustment may be needed for patients with kidney problems, as levetiracetam is primarily excreted through the kidneys.

Side Effects

Common Side Effects:

- Drowsiness or fatigue
- Dizziness or lightheadedness
- Headache
- Irritability or mood changes
- Nausea or loss of appetite

Serious Side Effects:

- Psychiatric Symptoms: Severe mood swings, depression, or suicidal ideation.
- Allergic Reactions: Rash, swelling, difficulty breathing (anaphylaxis or angioedema).
- Severe Fatigue or Muscle Weakness
- Coordination Problems: Difficulty walking or maintaining balance.

Drug Interactions

- CNS Depressants (e.g., alcohol, benzodiazepines): Increased risk of sedation and drowsiness.
- Other Antiepileptic Drugs (AEDs): Levetiracetam generally has minimal interactions with other AEDs but should be monitored when used in combination.
- Methadone or Opioids: Potential for additive CNS depression.

Use in Special Populations

- Pregnancy: Category C. Use only if the benefits outweigh the risks. Seizure control should not be disrupted during pregnancy.
- Lactation: Levetiracetam is excreted in breast milk. Caution is advised when used by breastfeeding mothers.
- Elderly: No special dose adjustments are necessary, but renal function should be assessed regularly.

Storage

• Store at room temperature (15–30°C or 59–86°F).

- Keep away from direct sunlight, moisture, and heat.
- Keep out of reach of children.

Missed Dose

• If a dose is missed, take it as soon as you remember. If the next dose is near, skip the missed dose and take your next dose at the regular time. Do not take two doses at once.

Overdose Management

- Symptoms of overdose may include extreme drowsiness, agitation, aggression, or respiratory depression.
- Seek immediate medical attention.
- Treatment: Overdose is generally managed with supportive care. Hemodialysis may help remove the drug from the body.

Note: Levetiracetam should be used under the supervision of a healthcare provider. Regular follow-up is essential to monitor effectiveness, side effects, and to ensure proper seizure management.

Manufactured in India for:



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