Information For the Use
Levetiracetam (500mg) Infusion

Lapcetam RTU 500 Infusion

Levetiracetam 500 mg Infusion

Dosage Form: Intravenous (IV) Infusion
Strength: 500 mg per 100 mL

Indications

Levetiracetam infusion is indicated for the treatment of:

1. **Epilepsy (Seizure Disorders):**
   - **Monotherapy: For partial-onset seizures in adults and children aged 16 years and older.**
   - **Adjunctive Therapy:**
     - **For partial-onset seizures in children aged 1 month and older.**
     - **For generalized tonic-clonic 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.**
2. **Status Epilepticus: Levetiracetam infusion may be used in the management of status epilepticus when oral administration is not possible or practical.**

Mechanism of Action

Levetiracetam is an antiepileptic drug that functions by binding to the synaptic vesicle protein 2A (SV2A). This interaction helps regulate the release of neurotransmitters, which stabilizes neuronal activity and prevents the abnormal firing of neurons. This mechanism of action aids in controlling seizures, although the precise method by which levetiracetam works is not fully understood.

Dosage and Administration

Adults and Adolescents (≥16 years):

- **Initial Dose: The usual starting dose is 500 mg administered as a single IV infusion.**
- **Maintenance Dose:**
  - **After the initial dose, the dose is typically increased to 500 mg every 12 hours.**
  - **Depending on the clinical response and tolerance, the dose may be increased in increments, up to a maximum of 3000 mg per day, divided into two doses (1500 mg every 12 hours).**
- **Administration:**
  - **The infusion should be administered over a period of 15 minutes.**
  - **Levetiracetam should not be mixed with other medications or solutions unless compatibility has been confirmed.**
  - **It can be administered through either a central or peripheral vein.**

Pediatric Dosing (1 month to 15 years):

- **Initial Dose: The recommended starting dose is 20 mg/kg as an IV infusion.**
- **Maintenance Dose: The maintenance dose can range from 20–60 mg/kg/day, divided into two doses.**

- **The maximum recommended daily dose for children is 3000 mg/day.**

Contraindications

- **Hypersensitivity to levetiracetam or any excipient in the formulation.**
- **Caution is advised in patients with a history of psychiatric disorders, such as depression or suicidal ideation.**
- **Renal impairment: Dose adjustments are required in patients with renal dysfunction.**

Warnings and Precautions

1. **Psychiatric and Behavioral Effects:**
   - **Levetiracetam may cause mood disturbances, including irritability, aggression, agitation, depression, or suicidal thoughts. These symptoms should be monitored, especially when starting or adjusting the dose.**
2. **Renal Impairment:**
   - **Since levetiracetam is primarily eliminated via the kidneys, dose adjustments are necessary in patients with renal impairment. Kidney function should be assessed and monitored regularly.**
3. **Seizure Control:**
   - **Abrupt discontinuation of levetiracetam should be avoided to prevent an increase in seizure frequency. Dosage adjustments should be made under medical supervision.**
4. **Extravasation:**
   - **Care should be taken during IV administration to avoid extravasation, which could cause local tissue damage.**

Side Effects

Common Side Effects:

- **Drowsiness, fatigue, or dizziness**
- **Headache**
- **Irritability, mood swings**
- **Nausea or loss of appetite**
- **Pain, swelling, or redness at the injection site**

Serious Side Effects:

- **Psychiatric Effects: Severe mood changes, including aggression, suicidal thoughts, agitation, or depression.**
- **Severe Allergic Reactions: Rash, swelling, difficulty breathing (signs of anaphylaxis or angioedema).**
- **Fatigue or Muscle Weakness: Unusual tiredness or muscle weakness.**
- **Severe CNS Effects: Impaired coordination, confusion, or severe sedation.**

Drug Interactions

- **CNS Depressants (e.g., alcohol, benzodiazepines): Increased sedation or drowsiness.**
- **Other Antiepileptic Drugs (AEDs): Levetiracetam typically has minimal interactions with other AEDs, but monitoring is recommended when used in combination with other antiepileptic treatments.**
- **Methadone and Opioids: Increased CNS depressant effects; caution is advised when used together.**

Use in Special Populations

- **Pregnancy: Category C. Levetiracetam should be used during pregnancy only if the potential benefit justifies the risk to the fetus. Seizure control is essential during pregnancy, but it should be managed carefully with consideration for the fetus.**
- **Lactation: Levetiracetam is excreted in breast milk. Its use during breastfeeding should be carefully considered, balancing the potential benefits for the mother with the risks for the infant.**
- **Elderly: No specific dose adjustment is required, but renal function should be monitored in elderly patients, as renal impairment may affect the drug's clearance.**

Storage

- **Levetiracetam infusion should be stored at room temperature (15–25°C or 59–77°F).**
- **Do not freeze the infusion.**
- **Protect the infusion from light and store it in a tightly closed container.**
- **Keep out of reach of children.**

Missed Dose

- **If the infusion is missed, it should be administered as soon as possible. If the next scheduled dose is near, skip the missed dose and continue with the usual dosing schedule. Do not administer double doses to make up for a missed dose.**

Overdose Management

- **Symptoms of overdose may include excessive sedation, agitation, confusion, or respiratory depression.**
- **Seek immediate medical attention in case of overdose.**
- **Treatment: Overdose is generally managed with supportive care. Hemodialysis may be effective in removing levetiracetam from the bloodstream in cases of severe overdose.**

Note: Levetiracetam infusion should be administered under the supervision of a healthcare provider in a hospital or clinic setting. Regular monitoring for effectiveness, side effects, and renal function is necessary to ensure optimal therapeutic outcomes.

Manufactured in India for:

Cafoli™ LIFECARE

Cafoli Lifecare Pvt. Ltd.
(An ISO 9001: 2015 Certified Co.)
Plot no.: 367-FF, Industrial Area Phase-I,
Panchkula-134113