Lapcetam RTU 1000 Infusion

Levetiracetam 1000 mg Infusion

Dosage Form: Intravenous (IV) Infusion
Strength: 1000 mg per 100 mL

Indications

Levetiracetam infusion is used 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 feasible.**

Mechanism of Action

Levetiracetam is an antiepileptic medication that works by binding to the synaptic vesicle protein 2A (SV2A), a protein involved in the release of neurotransmitters. This binding affects synaptic transmission, helping to stabilize neuronal activity, and prevent excessive neuronal firing that leads to seizures. Although its exact mechanism of action is not fully understood, it is believed to reduce the likelihood of abnormal electrical activity in the brain, contributing to seizure control.

Dosage and Administration

Adults and Adolescents (≥16 years):

- **Initial Dose: A typical initial dose is 1000 mg administered as a single IV infusion.**
- **Maintenance Dose:**
    - **After the initial dose, the usual dose is 1000 mg every 12 hours, adjusted based on clinical response.**
    - **The maximum recommended dose is 3000 mg daily, typically given in divided doses.**
- **Administration:**
    - **Levetiracetam should be administered via intravenous infusion over 15 minutes.**
    - **Do not mix with other medications or solutions unless compatibility has been confirmed.**
    - **The infusion should be administered through a central or peripheral vein.**

Pediatric Dosing (1 month to 15 years):

- **Initial Dose: The recommended starting dose is 20 mg/kg administered as an IV infusion.**
- **Maintenance Dose: The dose is usually 20–40 mg/kg daily, administered in divided doses.**
- **The maximum recommended dose for children should not exceed 3000 mg/day.**

Contraindications

- **Hypersensitivity to levetiracetam or any excipient in the formulation.**
- **Caution in patients with a history of psychiatric disorders or renal impairment.**

Warnings and Precautions

1. **Psychiatric and Behavioral Effects:**
   - **Levetiracetam may cause mood changes, irritability, aggression, depression, and suicidal ideation. Close monitoring for psychiatric symptoms is recommended, particularly during treatment initiation or dose adjustments.**
2. **Renal Impairment:**
   - **As levetiracetam is primarily excreted by the kidneys, dose adjustments are necessary for patients with renal dysfunction. Renal function should be monitored regularly.**
3. **Seizure Control:**
   - **Discontinuation of levetiracetam should be done gradually to prevent an increase in seizure frequency. Any changes in dosage should be under the supervision of a healthcare provider.**
4. **Extravasation:**
   - **Care should be taken to prevent extravasation of the IV infusion, as this may cause local tissue damage.**

Side Effects

Common Side Effects:

- **Drowsiness, fatigue, dizziness**
- **Headache**
- **Nausea, anorexia**
- **Irritability, mood changes**
- **Pain or swelling at the IV infusion site (IV site reactions)**

Serious Side Effects:

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

Drug Interactions

- **CNS Depressants (e.g., alcohol, benzodiazepines): Increased risk of sedation and drowsiness.**

- **Other Antiepileptic Drugs (AEDs): Levetiracetam typically has minimal interactions with other AEDs, but it should still be monitored when used in combination with other medications.**
- **Methadone and Opioids: Enhanced CNS depressant effects; caution is advised when used together.**

Use in Special Populations

- **Pregnancy: Category C. Levetiracetam should only be used during pregnancy if the potential benefit justifies the risk to the fetus. Seizure control must be maintained during pregnancy to reduce the risk of complications for both mother and baby.**
- **Lactation: Levetiracetam is excreted in breast milk, and its use in breastfeeding mothers should be done with caution.**
- **Elderly: No specific dose adjustment is needed for elderly patients, but renal function should be carefully monitored in this population due to potential age-related declines in kidney function.**

Storage

- **Store at room temperature (15–25°C or 59–77°F).**
- **Protect from light and keep the infusion solution tightly closed.**
- **Do not freeze the infusion solution.**
- **Keep out of reach of children.**

Missed Dose

- **If a dose 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.**

Overdose Management

- **Symptoms of overdose may include extreme drowsiness, agitation, aggression, or respiratory depression.**
- **Seek immediate medical attention if an overdose is suspected.**
- **Treatment: Overdose is typically managed with supportive care. Levetiracetam can be removed from the bloodstream by hemodialysis in case of overdose.**

Note: Levetiracetam infusion should be administered under the supervision of a healthcare provider in a hospital or clinical setting. Regular monitoring of clinical response and potential side effects is important to ensure safe and effective use.

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