Information For the User

Acyclovir (250mg)

Aclonist 250 Injection

Acyclovir (250 mg) Injection

Composition:
Each vial contains:

- **Acyclovir**: 250 mg (as acyclovir sodium)

Therapeutic Class:

- **Antiviral**

Indications:

Acyclovir injection is indicated for the treatment of severe or life-threatening infections caused by the herpes simplex virus (HSV) and varicella-zoster virus (VZV), including:

- **Herpes Simplex Virus (HSV) infections**: Treatment of severe infections like **herpes simplex encephalitis**, **neonatal HSV infections**, and **immunocompromised patients** with HSV infections.
- **Varicella-Zoster Virus (VZV) infections**: Treatment of **severe shingles (herpes zoster)**, and **complicated chickenpox (varicella)** in immunocompromised patients.
- **Prevention of HSV infection**: In immunocompromised patients, particularly those undergoing organ transplantation or chemotherapy.

Note: Acyclovir injection is typically used for **severe or systemic infections** where oral administration is not feasible or the infection is life-threatening.

Pharmacology:

Acyclovir is a synthetic nucleoside analogue of guanine. After entering the virus-infected cell, acyclovir is converted into its active triphosphate form by the viral enzyme thymidine kinase. This active form inhibits the viral DNA polymerase, preventing viral DNA replication, and thereby stops the virus from multiplying and spreading.

Dosage and Administration:

Adults:

- **For Herpes Simplex Encephalitis**: The recommended dosage is **5 mg/kg** of body weight, **every 8 hours** intravenously, for **14-21 days**.
- **For Severe Herpes Simplex Virus Infections** (e.g., neonatal HSV, immunocompromised patients): The usual dose is **5-10 mg/kg** every 8 hours for 7-10 days, or as directed by the healthcare provider based on the severity of the infection.
- **For Herpes Zoster (Shingles)**: The typical dose is **10 mg/kg** every 8 hours for **7-10 days**, depending on the severity of the condition.
- **For Varicella (Chickenpox) in Immunocompromised Patients**: The dosage may be similar to that for herpes zoster, usually **10 mg/kg** every 8 hours for **5-7 days**.

Administration:

- **Route of Administration**: Acyclovir injection is administered **intravenously (IV)**.
- **Infusion Rate**: Administer the injection as a slow intravenous infusion over **1 hour** to avoid potential renal toxicity or phlebitis.

Preparation:

- Reconstitute the injection with sterile water or appropriate diluent as per the manufacturer's instructions. Follow the specific guidance on dilution and infusion times.

Contraindications:

- **Hypersensitivity**: Acyclovir is contraindicated in patients with a known hypersensitivity to acyclovir or any of the excipients.

- **Severe Renal Impairment**: Caution is required in patients with renal impairment. Dosage adjustment may be necessary to prevent accumulation of the drug and minimize the risk of toxicity.

Warnings and Precautions:

- **Renal Impairment**: Acyclovir may cause **renal toxicity**, especially in patients with pre-existing kidney conditions. Hydration should be maintained during treatment to reduce the risk of nephrotoxicity. Dosage adjustments are required in patients with renal impairment.
- **Neurological Effects**: High doses or rapid infusion of Acyclovir may lead to **neurotoxicity**, including symptoms such as confusion, agitation, tremors, and seizures. These effects are more common in patients with renal dysfunction or those receiving high doses.
- **Hydration**: Ensure adequate fluid intake during treatment to prevent crystallization of Acyclovir in the kidneys.

Side Effects:

Common Side Effects:

- **Local injection site reactions**: Pain, redness, or swelling at the infusion site.
- **Renal dysfunction**: May include increased serum creatinine or reduced urine output.
- **Gastrointestinal disturbances**: Nausea, vomiting, diarrhea.

- **Neurological symptoms**: Confusion, seizures, hallucinations, and tremors, especially in patients with renal impairment or high-dose therapy.
- **Renal toxicity**: Acute kidney injury, elevated creatinine, or oliguria (reduced urine output).

Drug Interactions:

- **Nephrotoxic Drugs**: Concurrent use with nephrotoxic agents (e.g., aminoglycosides, cyclosporine) may increase the risk of renal toxicity.
- **Probenecid**: Can reduce the renal clearance of Acyclovir, increasing its plasma concentration and potential for toxicity.
- **Other Antiviral Agents**: Caution should be exercised when Acyclovir is used with other antiviral agents like zidovudine, as it may increase their effects.

Overdose:

Symptoms of overdose may include confusion, seizures, and kidney damage. In case of overdose, immediate medical attention is required. Treatment includes supportive care, hydration, and dialysis if necessary for renal failure.

Storage:

- **Store at Room Temperature**: 15-30°C (59-86°F).
- **Do Not Freeze**: Avoid freezing the reconstituted solution.
- **Shelf Life**: Check expiration date on the label and discard unused medication after this date.

Packaging:

- Available in vials of **250 mg** of Acyclovir sodium per vial, in sterile powder form for intravenous use.

Acyclovir injection is a potent antiviral treatment used for managing severe viral infections, particularly in immunocompromised patients. It is critical to administer the drug under medical supervision, especially for patients with renal issues, and to monitor for potential side effects, including renal toxicity and neurological symptoms. Always follow healthcare provider instructions and ensure proper hydration during treatment to avoid complications.

Manufactured in India for:

Cafoli™ LIFECARE

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