CLOVIR IV Infusion

ACYCLOVIR USP

Compositions:
Clovir 250 Injection : Each vial contains Acyclovir Sodium equivalent to Acyclovir USP 250 mg as Lyophilized Powder.Clovir 500 Injection : Each vial contains Acyclovir Sodium equivalent to Acyclovir USP 500 mg as Lyophilized Powder.

Pharmacology:
Acyclovir is a synthetic purine nucleoside analogue with in vitro and in vivo inhibitory activity against human herpes viruses, including Herpes simplex virus types 1 and 2, Varicella zoster virus (VZV), Epstein Barr virus (EBV) and Cytomegalovirus (CMV). In cell culture, acyclovir has the greatest antiviral activity against HSV-1, followed (in decreasing order of potency) by HSV-2, VZV, EBV and CMV.

Dosage And Administration:
ADULT: Herpes simplex infection: 5 mg/kg every 8 hours; Herpes simplex encephalitis: 10 mg/kg every 8 hours; Very severe Herpes zoster infection (shingles): 5 mg/kg every 8 hours; Varicella zoster infection: 10 mg/kg every 8 hours. Each dose should be administered by slow intravenous infusion over a one-hour period. Children: The dose of Clovir 250 Injection in children aged 1-12 years should be calculated on the basis of body weight: Immunocompromised children in this age group with Herpes simplex infections (except Herpes simplex encephalitis) or Varicella zoster infections: 10 mg/Kg body weight; Immunocompromised children in this age group with Varicella zoster virus infection or with Herpes simplex encephalitis: every 8 hours for 7 days. Reconstitution & Administration:1. Draw 10 ml (for 250 mg) or 20 ml (for 500 mg) Normal Saline (0.9% w/v Sodium Chloride solution) with the disposable syringe to reconstitute the Clovir 250 and Clovir 500. 2. Insert 10 ml (for 250 mg) or 20 ml (for 500 mg) Normal Saline (0.9% w/v Sodium Chloride solution) into the Clovir 250 and Clovir 500 to make a solution. 3. Then insert the prepared solution into the 50 ml (for 250 mg) and 100 ml (for 500 mg) Normal Saline (0.9% w/v Sodium Chloride solution) bottle.4. Administere the solution at a constant rate over 1 hour.*The reconstituted solution should be used within 12 hours

Contraindications:
Acyclovir injection is contraindicated for patients who develop hypersensitivity to acyclovir.

Warning And Precaution:
Precipitation of acyclovir crystals in renal tubules can occur if the maximum solubility of free acyclovir (2.5 mg/ml at 37° C in water) is exceeded or if the drug is administered by bolus injection. Ensuing renal tubular damage can produce acute renal failure. Abnormal renal function (decreased creatinine clearance) can occur as a result of acyclovir administration and depends on the state of the patient's hydration, other treatments, and the rate of drug administration. Concomitant use of other nephro-toxic drugs, pre-existing renal disease, and dehydration make further renal impairment with acyclovir more likely. Administration of acyclovir by intravenous infusion must be accompanied by adequate hydration. When dosage adjustments are required they should be based on estimated creatinine clearance.

Side Effects:
The most frequent adverse reactions reported during administration of acyclovir were inflammation or phlebitis at the injection site, Nausea or vomiting occurred, Itching, Rash or hives occurred. Hematologic abnormalities occurred like anemia, neutropenia, thrombocytopenia, thrombocytosis, leukocytosis and neutrophilia. In addition, anorexia and

hematuria were observed.

Use in Pregnancy and Lactation:
Pregnancy: Teratogenic Effects. Pregnancy Category B. Acyclovir administered during organogenesis was not teratogenic in the mouse (450 mg/kg/day, PO), rabbit (50 mg/kg/day, SC and IV), or rat (50 mg/kg/day, SC). These exposures resulted in plasma levels the same as, 4 and 9, and 1 and 2 times, respectively, human levels. There are no adequate and well-controlled studies in pregnant women. Acyclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing Mothers: Acyclovir concentrations have been documented in breast milk in 2 women following oral administration of acyclovir and ranged from 0.6 to 4.1 times corresponding plasma levels. These concentrations would potentially expose the nursing infant to a dose of acyclovir up to 0.3 mg/kg/day. Acyclovir should be administered to a nursing mother with caution and only when indicated.

Drug Interaction:
Co-administration of probenecid with acyclovir has been shown to increase the mean acyclovir half-life and the area under the concentration-time curve. Urinary excretion and renal clearance were correspondingly reduced.

Overdosage:
Over dosage of intravenous acyclovir has resulted in elevations of serum creatinine, blood urea nitrogen and subsequent renal failure. Neurological effects including confusion, hallucinations, agitation, seizures and coma have been described in association with over dosage. Hemodialysis significantly enhances the removal of acyclovir from the blood and may, therefore, be considered an option in the management of overdose of this medicine.

Storage:
Store at 15-25°C. temperature. Protect from light. Keep out of the reach of children.

Packing:
Clovir 250 Injection: Each box contains One vial of 250 mg Acyclovir Lyophilized Powder for Infusion, One bottle of 50 ml of 0.9% Sodium Chloride solution, One 10 ml disposable syringe, One infusion set and One hanger, First aid bandage & alcohol pad. Clovir 500 Injection: Each box contains One vial of 500 mg Acyclovir Lyophilized Powder for Infusion, One bottle of 100 ml of 0.9% Sodium Chloride solution, One 20 ml disposable syringe, One infusion set and One hanger, First aid bandage & alcohol pad.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
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