Aclovir™ 250mg 500mg اِکلوور

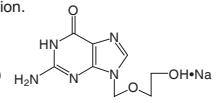
(A c y c l o v i r) For IV Infusion Only

For Injection U.S.P.

DESCRIPTION

Acyclovir is a synthetic analogue of guanidine used in the treatment and prophylaxis of infections due to herpes simplex or varicella zoster viruses. Acyclovir sodium is sterile powder for intravenous administration. Acyclovir should not be administered by rapid or bolus injection.

Stucture:
The chemical name of acyclovir sodium is 2 -amino-1, 9-dihydro-9-[(2-hydroxyethoxy) methyl]-6H-purine-6-one monosodium salt.



QUALITATIVE AND QUANTITATIVE COMPOSITION:

Aclovir (Acyclovir) For Injection U.S.P. 250mg:
Each vial contains:
Acyclovir Sodium eq. to Acyclovir.....250mg

Aclovir (Acyclovir) For Injection U.S.P. 500mg:
Each vial contains:
Acyclovir Sodium eq. to Acyclovir.....500mg

CLINICAL PHARMACOLOGY:

Mechanism of Action: In Adult, mean steady state peak plasma concentration following one hour infusion of 2.5 mg/kg, 5 mg/kg, 10 mg/kg and 15 mg/kg were 5.1 µg/ml, 9.8 µg/ml, 20.7 µg/ml and 23.6 µg/ml respectively. In Children, over 1 year of age similar mean peak were observed. In neonate (0-3 month) treated with 10mg/kg and 15mg/kg steady state peak plasma concentration following by one hour of infusion is 13.8 µg/ml and 18.8 µg/ml respectively.

Pharmacodynamics: Cerebrospinal fluid levels are approximately 50% of corresponding plasma level. Plasma protein binding relatively low i.e. 9-33%.

pharmacokinetics: In Adult the terminal plasma half-life after IV is about 2.9 hours. The most of the drug excreted unchanged by kidney.

INDICATIONS:

1. Encephalitis due to herpes simplex virus.
2.The prevention and treatment of Herpes simplex virus infections or prophylaxis of Immuno compromised patients.
3. Initial and recurrent Varicella-zoster virus infections.
4. The prevention and treatment of Herpes simplex virus infections in the neonates.
5. Prophylaxis of CMV infection in bone marrow transplant recipient.

DOSAGE & ADMINISTRATION

Adults & Adolescents: (12 Years of age and older):

• Herpes simplex infections in immunocompromised and immunocompetent patients and recurrent varicella zoster virus infections in immunocompetent patients: 5mg/kg at 8 hours intervals.

• Initial and recurrent Varicella-zoster virus infections in immunocompromised patients and herpes simplex encephalitis in immunocompromised and immunocompetent patients: 10mg/kg at 8 hours intervals.

Children: Paediatrics (Under 12 years of age) HSV-1 & HSV-2 Infections in immunocompromised patients. 10mg/kg infused at a constant rate over at least 1 hour, every 8 hours for 7 days.

Herpes Simplex Encephalitis: Paediatrics (3 months to 12 years of age): 20mg/kg infused at a constant rate over at least 1 hour, every 8 hours for 10 days.

Varicella-zoster virus infections: In immunocompromised patients Paediatrics (Under 12 years of age) 20mg/kg infused at a constant rate over at least 1 hour, every 8 hours for 7 days.

Neonatal: HSV Infections (Birth to 3 months): 10mg/kg infused at a constant rate over at least 1 hour, every 8 hours for 10 days. In Neonatal HSV infections doses of 15mg/kg or 20mg/kg (infused at a constant rate over at least 1 hour, every 8 hours) have been used; the safety and efficacy of these doses are not known.

Dosage adjustment for IV Acyclovir in Neonate, Infant, Children and Adult with Renal Impairment

Creatinine Clearance (ml/min/ 1.73m²)	Percent of Recommended Dose	Dosing Interval (hours)
>50	100%	8
25 - 50	100%	12
10 - 25	100%	24
0 - 10	50%	24

Hemodialysis: For Patients who require dialysis, The recommended dose (10mg/kg or 20 mg/kg body weight) should be halved and administrated every 24 hours and after dialysis.

Method of Preparation:

Acyclovir Sodium Equivalent Weight	Amount of Sterile water for Injection or 0.9% Sodium Chloride	Resulting Solution
250mg	10mL	25mg/mL
500mg	10mL 20mL	50mg/mL 25mg/mL
1000mg	10mL 20mL	100mg/mL 50mg/mL

The vial should be dissolved in sterile water for injection or 0.9% sodium chloride.

OBESE PATIENTS:

Obese patients should be closed at the recommended adult dose using ideal body weight.

ADMINISTRATION:

After reconstitution Aclovir (Acyclovir) IV may be administered by a controlled-rate infusion pump. Alternatively, the reconstituted solution may be further diluted to give an acyclovir concentration of not greater than 5 mg/ml (0.5% w/v) for administration by infusion:

• Add the required volume of reconstituted solution to the chosen infusion solution, as recommended below, and shake well to ensure adequate mixing occurs.

• For children and neonates, where it is advisable to keep the volume of infusion fluid to a minimum, it is recommended that dilution is on the basis of 4 ml reconstituted solution (100 mg acyclovir) added to 20 ml of infusion fluid.

• For adults, it is recommended that infusion bags containing 100 ml of infusion fluid are used, even when this would give an acyclovir concentration substantially below 0.5% w/v. Thus one 100 ml infusion bag may be used for any dose between 250 mg and 500 mg acyclovir (10 and 20 ml of reconstituted solution) but a second bag must be used for doses between 500 mg and 1000 mg. When diluted in accordance with the recommended schedules, Acyclovir IV is known to be compatible with the following infusion fluids and stable for up to 12 hours at room temperature (15 °C to 25 °C):

• Sodium Chloride Intravenous Infusion B.P. (0.45% & 0.9% w/v)
• Sodium Chloride (0.18% w/v) & Glucose (4% w/v) Intravenous Infusion B.P.
• Sodium Chloride (0.45% w/v) and Glucose (2.5% w/v) Intravenous Infusion B.P.
• Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution).

Important: Since no antimicrobial preservative is included, reconstitution and dilution must be carried out under full aseptic conditions, immediately before use, and any unused solution discarded. Should any visible turbidity or crystallization appear in the solution before or during infusion, the preparation should be discarded. From a microbiological point of view the diluted solution should be used immediately. If not used immediately in use storage times and conditions are the responsibility of the user.

OVER DOSAGE

Symptoms & Signs: 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.

Treatment: Patients should be observed closely for signs of toxicity. Haemodialysis significantly enhances the removal of acyclovir from the blood and may, therefore, be considered a management option in the event of symptomatic overdose.

Contraindication: Patients known to be hypersensitive to acyclovir.

Precautions: 1) Rapid or bolus intravenous and intramuscular or subcutaneous injection must be avoided.
2) Therapy should be initiated as early as possible following onset of signs and symptoms.
3) Administration to the infant or children must be carefully; especially the safety in immature infant and new born is not established.
The drug should be used only when the potential benefits justify the possible risks.

USE IN PREGNANCY AND LACTATION:

Pregnancy: The drug does cross the placenta in humans. There are no adequate and controlled studies to date using acyclovir in pregnant women, and the drug should be used during pregnancy only when the potential benefits justify the possible risks to the fetus.

Lactation: Limited data indicate that acyclovir is distributed into milk, generally in concentrations greater than concurrent maternal plasma concentrations, and can be absorbed by nursing infants. Because of the potential for serious adverse reactions to acyclovir in nursing infants, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the woman.

Adverse Reactions: 1) Acyclovir may cause gastrointestinal effects such as nausea, vomiting and diarrhea, headache. skin rashes have also been reported.
2) Pruritus, rash, or vulvitis occur rarely.
3) Occasional adverse effects following IV administration include increase of liver enzyme and hematological changes.
4) Encephalopathic changes including lethargy, confusion, tremors and seizures have been reported in a small number of patients, particularly in those who immunocompromised.
5) Shock rarely occurs.
6) BUN increase in serum creatinine, albuminurea, leukocyte in precipitate of urine occasionally occurs.

Interaction: The risk of renal impairment is increases by the concomitant use of other nephrotoxic drugs. Probenecid and cimetidine is reported to block the renal clearance of acyclovir so AUC of acyclovir enhances.

Incompatibility: This medicinal product must not be mixed with other medicinal products except those mentioned under the heading Instruction for use.

INSTRUCTIONS FOR RECONSTITUTION:

Reconstitute with 10ml of sterile water for injection. Do not use Bacteriostatic water for Injection containing preservatives.
Shake well until solution is clear.
Do not use if solution is cloudy or it contains undissolved particles. Use only freshly prepared solution.
Discard unused solution.

INSTRUCTIONS:

Dosage as directed by the physician.
Store at 25°C, excursions permitted to 15°C -30°C.
Protect from sunlight and moisture.
Keep all medicines out of the reach of children.

PRESENTATION:

Aclovir (Acyclovir) For Injection U.S.P. 250mg is available in pack of 1 Vial + 10ml Sterile Water For Injection with Leaflet.
Aclovir (Acyclovir) For Injection U.S.P. 500mg is available in pack of 1 Vial + 10ml Sterile Water For Injection with Leaflet.

ہدایات:

خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
۲۵ ڈگری سینٹی گریڈ پیکنگ رکھیں، محفوظ رکھنے کی حد ۱۵ سے ۳۰ ڈگری سینٹی گریڈ ہے۔
سورج کی روشنی اور نمی سے محفوظ رکھیں۔ تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخہ پر فروخت کریں۔

For detailed information please contact:

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