Aciclovir

Virest

Tablet - Antiviral

DESCRIPTION

Virest 200 Tablet : Hexagon-shaped, blue uncoated tablet, bevel-edged with flat faces.
Virest 400 Tablet : Hexagon-shaped, pink uncoated tablet, bevel-edged with flat faces.

FORMULATION

Virest 200 Tablet : Each tablet contains Aciclovir 200 mg.
Virest 400 Tablet : Each tablet contains Aciclovir 400 mg.

ACTIONS AND PHARMACOLOGY

Aciclovir is converted to aciclovir monophosphate, a nucleotide, by the viral thymidine kinases of herpes simplex virus (HSV) and varicella-zoster virus (VZV). Aciclovir monophosphate is converted to the diphosphate by cellular guanylate kinase and to the triphosphate by a number of cellular enzymes. Aciclovir triphosphate interferes with HSV and VZV DNA polymerase and inhibits viral DNA replication. The triphosphate can be incorporated into growing chains of DNA by viral DNA polymerase, resulting in termination of the DNA chain. Aciclovir is therefore selectively converted to the active triphosphate form by HSV and VZV-infected cells.

Aciclovir crosses the placenta and are excreted through the kidney and in breast milk. The terminal half-life is reported to be 2-3 hours for adults without renal impairment. The half-life increases in patients with renal impairment.

Aciclovir is poorly absorbed from the gastrointestinal tract. Not significantly affected by food.

INDICATIONS

Used for the systemic treatment of varicella-zoster (Chicken pox shingles) and the systemic and topical treatment of herpes simplex infections of the skin and mucous membranes.

CONTRAINDICATIONS

This medication should not be used when the following medical problems exist:
Hypersensitivity to aciclovir or ganciclovir.

PRECAUTIONS

- Dehydration or renal function impairment - intravenous aciclovir may increase the potential for nephrotoxicity; it is recommended that aciclovir be administered in a reduced dosage to patients with impaired renal function.
- Neurological abnormalities or prior neurologic reactions to cytotoxic medications - intravenous aciclovir may increase the potential for neurologic side effects.
- Aciclovir should be used with caution to patients with renal impairment and doses should be adjusted according to creatinine clearance.
- Women with herpes genitalis may have an increased risk of developing cervical cancer; annual Pap tests may be required. Check with physician if no improvement within a few days.
- Use of aciclovir has not been shown to prevent the transmission of herpes simplex virus to sexual partners.
- Aciclovir crosses placenta. No adverse fetal effects have been reported. FDA Pregnancy category C.
- Aciclovir passes into breast milk. No toxicity was observed in infants.

MAIN SIDE/ADVERSE EFFECTS

- Acute renal failure.
- Gastrointestinal disturbances (nausea or vomiting, diarrhoea, abdominal pain).
- Lightheadedness.
- Skin rashes.
- Increase values for liver enzymes.
- Increase in blood concentrations of urea and creatinine.
- Haematological changes.
- Encephalopathic changes (lethargy, confusion, tremors, seizures).

DRUG INTERACTION

Probenecid reduces excretion of aciclovir when used concurrently, resulting in increased aciclovir plasma concentration and risk of toxicity.

TREATMENT OF OVERDOSAGE

Since there is no specific antidote, treatment of adverse effects and/or overdose should be symptomatic and supportive with possible utilization of the following:

- Adequate hydration to prevent precipitation of aciclovir in the renal tubules.
- Hemodialysis to aid in the removal of aciclovir from the blood, especially in patients with acute renal failure and anuria.

DOSAGE AND ADMINISTRATION

Adults

Genital herpes infections

Initial therapy : Oral, 200 mg 5 times a day for 10 days.
- Creatinine clearance >10 ml/min : Oral, 200 mg 5 times a day for 10 days.
- Creatinine clearance 0-10 ml/min : Oral, 200 mg twice a day for 10 days.

Intermittent therapy : Oral, 200 mg 5 times a day for 5 days.
- Creatinine clearance >10 ml/min : Oral, 200 mg 5 times a day for 5 days.
- Creatinine clearance 0-10 ml/min : Oral, 200 mg twice a day for 5 days.

Chronic suppressive therapy : Oral, 400 mg twice a day; or 200 mg 2 to 5 times a day.
- Creatinine clearance >10 ml/min : Oral, 400 mg twice a day.
- Creatinine clearance 0-10 ml/min : Oral, 200 mg twice a day.

Herpes zoster

Oral, 800 mg 5 times a day for 7 to 10 days.

Creatinine clearance >25 ml/min:
800 mg 5 times a day for 7 to 10 days.

Creatinine clearance 10-25 ml/min:
800 mg 3 times a day for 7 to 10 days.

Creatinine clearance 0-10 ml/min:
800 mg twice a day for 7 to 10 days.

Varicella

Oral, 20 mg per kg of body weight, up to 800 mg per dose, 4 times a day for 5 days. Treatment should be initiated at the earliest sign or symptom of chickenpox

Herpes simplex

Oral, 200 to 400 mg 5 times a day for 10 days in immunocompromised patients.

Paediatrics

***Children < 2 years*:**

Dosage has not been established in children up to 2 years of age. However, no unusual toxicity or paediatric-specific problems have been observed in studies done in children using doses of up to 3000 mg/m2/day and 80 mg/kg/day.

***Children 2 to 12 years*:**

Varicella: Oral 20 mg per kg of body weight, up to 800 mg per dose, 4 times a day for 5 days. Treatment should be initiated at the earliest sign or symptom of chickenpox

Caution: Food, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.

Storage : Store at temperatures not exceeding 30˚C.
Availability : Tablet 200 mg x 25's, blisters of 5 x 5's;
Tablet 400 mg x 25's, blisters of 5 x 5's

The information given here is limited. For further information consult your doctor or pharmacist.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

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