

ACICLOVIR TABLETS BP

Herperax-800

Composition:

Each uncoated tablet contains:
Aciclovir BP 800 mg.

Pharmacological Category:

Antiviral drug.

Chemistry:

9-(2-hydroxyethoxymethyl) guanine

Mechanism of Action:

Aciclovir is a synthetic purine nucleoside analogue with in vitro and in vivo inhibitory activity against human herpes viruses including Herpes simplex virus (HSV) types 1 & 2, Varicella Zoster virus (VZV), Epstein Barr virus (EBV) and Cytomegalovirus (CMV).

The inhibitory activity of Aciclovir is highly selective. The enzyme thymidine kinase of normally non infected cell does not use Aciclovir effectively as a substrate hence toxicity to mammalian cells is low. However Thymidine Kinase encoded by HSV, VZV, and EBV converts Aciclovir to Aciclovir monophosphate, which is further converted to diphosphate and finally to triphosphate by cellular enzymes. Aciclovir triphosphate interferes with viral DNA polymerase and inhibits viral DNA replication with resultant chain termination following its incorporation into viral DNA.

Pharmacokinetics:

Gastrointestinal absorption is rather poor with a total bioavailability of 15%-30%. A oral dose of 200 mg results in a peak serum level of 0.35 to 1.0 m g/ml after 1.5 to 1.75 hours. The half life of oral Aciclovir is 3.3 hours. After administration of 200 mg orally, levels 0.19mg/ml & 0.8 mg/ml, respectively were attained in saliva & vagina. Plasma protein binding is 30%. About 10%-15% of the drug is excreted unchanged in the urine and 15%-25% is excreted unchanged in the faeces.

Indications:

Aciclovir is indicated in the treatment of:

1. Herpes Simplex virus infections of the skin & mucous membranes, including initial and recurrent genital herpes.
2. Suppression of recurrent Herpes simplex infections in immuno competent patients;
3. Prophylaxis of Herpes simplex infections in immuno compromised patients;
4. Varicella & Herpes Zoster infections.

Contraindications:

Aciclovir is contraindicated in patients known to be hypersensitive to Aciclovir.

Adverse Effects:

The most frequently reported reactions during short term administration are nausea or vomiting & headache. Less frequent side effects included diarrhoea, dizziness, anorexia, fatigue, edema, skin rash, leg pain, medication taste & sore throat. The most common reactions during long term administration are headache, diarrhoea, nausea/vomiting, vertigo and arthralgia.

Precautions & Warnings:

Keep out of reach of children. Aciclovir is to be administered with precaution in patients with renal impairment.

Drug Interactions:

Probenecid increases the Aciclovir mean half life & area under plasma concentration-time curve. Other drugs affecting renal physiology could potentially influence the pharmacokinetics of Aciclovir. However clinical experience has not identified other drug interactions with Aciclovir.

Usage in Pregnancy & Lactation:

Limited data are available on the use of Aciclovir in pregnancy. Aciclovir should not be used in pregnancy unless the potential benefit justifies the potential risk to the foetus. Aciclovir is excreted in human milk. Caution is therefore advised if Aciclovir is to be administered to a nursing woman.

Dosage & Administration:

Initial attacks or infrequent recurrences of Genital Herpes: 1 tablet of 200 mg 5 times/day; for 5-10 days.

Recurrent herpetic infections:

Treatment: 1 tablet of 200 mg 5 times/day; for 5-10 days.

Suppression: 1 tablet of 200 mg 4 times/day, reduced to 3 times/day, even 2 times/day.

Herpes Labialis: Adults : 1 tablet of 200 mg 5 times/day for 5-10 days.

Chicken Pox: Less than 2 yrs : 1 tablet of 200 mg 4 times/day for 5 days.

2-6 yrs : ½ tablet of 800 mg 4 times/day for 5 days.

More than 6 yrs : 1 tablet of 800 mg 4 times/day for 5 days.

Adults : 1 tablets of 800 mg 5 times/day for 7 days.

Shingles: Adults : 1 tablets of 800 mg 5 times/day for 7days.

Zoster ophthalmicus: Adults : 1 tablets of 800 mg 5 times/day for 7 days

Known Symptoms of over Dosage and treatment:

No massive over dosage has been reported. Precipitation of free Aciclovir in renal tubule may occur when solubility in the intratubular fluid is exceeded.

Treatment: Aciclovir is dialysable. In the event of acute renal failure and anuria, the patient may benefit from hemodialysis until renal function is restored.

Presentation:

10 x 10's Blister pack.

Storage:

Store at 25°C. Keep out of reach of children.

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Manufactured by:



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