

Virux[®]

Acyclovir USP

COMPOSITION

Virux[®] 200 Tablet: Each tablet contains Acyclovir USP 200 mg.
Virux[®] 400 Tablet: Each tablet contains Acyclovir USP 400 mg.
Virux[®] Cream: Each gm cream contains Aciclovir BP 50 mg.
Virux[®] Suspension: Each 5 ml suspension contains Aciclovir BP 200 mg.

PHARMACOLOGY

Acyclovir is a synthetic purine derivative. It exerts its antiviral effect on *Herpes simplex virus* (HSV) and *Varicella zoster virus* by interfering with DNA synthesis and inhibiting viral replication. In cells infected with herpes virus, the antiviral activity of Acyclovir appears to depend principally on the intracellular conversion of the drug to Acyclovir Triphosphate. Acyclovir is converted to Acyclovir Monophosphate principally via virus coded thymidine kinase; the monophosphate is phosphorylated to the diphosphate via cellular guanylate kinase and then via other cellular enzyme to the triphosphate, which is the pharmacologically active form of the drug. 15-30% of an oral dose of the drug is absorbed from GI tract. Peak plasma concentrations usually occur within 1.5-2 hours after oral administration. It is widely distributed into body tissues and fluids including the brain, saliva, lungs, liver, muscle, spleen, uterus, vaginal mucosa and secretions, CSF, and herpetic vesicular fluid. Acyclovir is excreted through the kidney by the glomerular filtration & tubular secretion.

INDICATION

Virux[®] is indicated for the treatment of viral infections due to *Herpes simplex virus* (type I & II) and *Varicella zoster virus* (herpes zoster & chicken pox).

Virux[®] is indicated for the treatment of Herpes simplex virus infections of the skin and mucous membranes including initial and recurrent genital herpes and herpes labialis.

Virux[®] is also indicated for the prophylaxis of *Herpes simplex* infections in immunocompromised patients.

DOSAGE AND ADMINISTRATION

Virux[®] Tablet and Suspension:

Treatment of initial *Herpes simplex* infections: 200 mg 5 times daily usually for 5 days. For immunocompromised patients 400 mg 5 times daily for 5 days (longer if new lesions appear during treatment or if healing is incomplete; increase dose to 800 mg 5 times daily for genital herpes in immunocompromised) or as directed by the registered physician.

Children under 2 years: Half of the adult dose.

Children over 2 years: Adult dose.

Prevention of recurrence of *Herpes simplex* infections: 200 mg 4 times daily or 400 mg twice daily possibly reduced to 200 mg 2 or 3 times daily and interrupted every 6-12 months.

Children under 2 years: Half of the adult dose.

Children over 2 years: Adult dose.

Prophylactic treatment of *Herpes simplex* infections in the immunocompromised patients:

200 to 400 mg 4 times daily.

Children under 2 years: Half of the adult dose.

Children over 2 years: Adult dose.

Treatment of varicella (chicken pox):

Adult and children over 40 kg: 800 mg 4 times daily for 5 days.

Children below 40 kg: 20 mg/kg (maximum 800 mg) per dose orally 4 times daily (80 mg/kg/day) for 5 days.

Or

Children 1 month-2 years: 200 mg 4 times daily for 5 days.

Children 2-5 years :400 mg 4 times daily for 5 days.

Children 6-12 years :800 mg 4 times daily for 5 days.

Treatment of herpes zoster (Shingles): 800 mg 5 times daily for 7 days.

Treatment of initial rectal (Proctitis) herpes infections: An oral Acyclovir

dosage of 400 mg 5 times daily for 10 days or until clinical resolution occurs has been recommended.

Renal Impairment: For the patients with severe renal impairment, a reduction of the doses is recommended.

Virux[®] Cream: Should be applied to lesions 5 times daily for 5-10 days.

USE IN PREGNANCY AND LACTATION

Pregnancy category B. Acyclovir should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Caution should be exercised when it is administered to a nursing mother.

CONTRAINDICATION

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

PRECAUTION AND WARNING

Acyclovir should be administered with caution in patients with renal impairment and doses should be adjusted according to creatinine clearance. Monitor neutrophil count at least twice weekly in neonates.

DRUG INTERACTION

Probenecid reduces Acyclovir excretion and so increases plasma concentration and risk of toxicity.

SIDE EFFECT

Rash, gastro-intestinal disturbance, rise in bilirubin and liver-related enzymes, increase in blood urea and creatinine, decrease in hematological indices, headache, neurological reaction, fatigue.

STORAGE

Virux[®] Tablet, Cream and Suspension should be stored below 30° C. It should be protected from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Virux[®] 200: Each box contains 30 tablets in blister pack.

Virux[®] 400: Each box contains 20 tablets in blister pack.

Virux[®] Cream: Each tube contains 10gm cream.

Virux[®] Suspension: Each box contains 70 ml suspension in PET bottle and a measuring cup.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
Kaliakoir, Gazipur, Bangladesh

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