

# Virux<sup>®</sup>

## Aciclovir BP

**Virux<sup>®</sup>** contains Aciclovir which is a synthetic purine derivative. Aciclovir 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 Aciclovir appears to depend principally on the intracellular conversion of the drug to Aciclovir Triphosphate. Aciclovir is converted to Aciclovir 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, lung, liver, muscle, spleen, uterus, vaginal mucosa and secretions, CSF, and herpetic vesicular fluid. Aciclovir is excreted through the kidney by the glomerular filtration & tubular secretion.

### COMPOSITION:

**Virux<sup>®</sup> 200:** Each tablet contains Aciclovir BP 200 mg.

**Virux<sup>®</sup> 400:** Each tablet contains Aciclovir BP 400 mg.

**Virux<sup>®</sup> Cream:** Each gram cream contains Aciclovir BP 50 mg.

**Virux<sup>®</sup> Oral suspension:** Each 5 ml suspension contains Aciclovir BP 200 mg.

### INDICATION:

- **Virux<sup>®</sup>** 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<sup>®</sup>** is indicated for the treatment of herpes simplex virus infections of the skin and mucous membranes including initial and recurrent genital herpes.
- **Virux<sup>®</sup>** is also indicated for the prophylaxis of herpes simplex infections in immunocompromised patients.

### DOSAGE AND ADMINISTRATION:

#### **Virux<sup>®</sup> Tablet and Oral Suspension:**

**Treatment of initial herpes simplex:** 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 incomplete; increase dose to 800 mg 5 times daily for genital herpes in immuno-compromised) or as directed by the registered physician.

*Children under 2 years: half of the adults dose.*

*Children over 2 years: Adult dose.*

**Prevention of recurrence of herpes simplex:** 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.

**Prophylactic treatment of herpes simplex in the immunocompromised:** 200 to 400 mg 4 times daily.

Children under 2 years: Half of the adult dose.

Children over 2 years: Adult dose.

**Treatment of vericella (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 under 2 years : 200 mg 4 times daily

Children 2-5 years : 400 mg 4 times daily

Children Over 6 years : 800 mg 4 times daily

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

**Treatment of initial rectal (Proctitis) herpes infections:** 400 mg 5 times daily for 10 days or until clinical resolution occurs has been recommended.

#### **Virux<sup>®</sup> Cream:**

Virux<sup>®</sup> cream should be applied to lesions or impending lesions 5 times daily. If healing does not occur treatment should be extended for up to 10 days.

#### **Renal Impairment:**

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

#### **SIDE EFFECT:**

Rashes, gastro-intestinal disturbances, rises in bilirubin and liver-related enzymes, increases in blood urea and creatinine, decreases in hematological indices, headache, neurological reactions, fatigue.

#### **CONTRAINDICATION:**

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

#### **PRECAUTION AND WARNING:**

Aciclovir should be administered with caution to patient with renal impairment and doses should be adjusted according to creatinine clearance.

#### **USE IN PREGNANCY AND LACTATION:**

Pregnancy category B.

Aciclovir has not been shown to be teratogenic in standard tests following subcutaneous administration in rats and rabbits. The drug does cross the placenta in humans. There are no adequate and controlled studies to date using Aciclovir in pregnant women, and the drug should be used during pregnancy only when the potential benefits justify the possible risks to the fetus; the drug's potential for causing chromosomal damage at high concentrations should be considered.

Limited data indicate that Aciclovir 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 Aciclovir 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.

**DRUG INTERACTION:**

Concomitant administration of probenecid and Aciclovir has reportedly increased the mean plasma half-life and decreased urinary excretion and renal clearance of Aciclovir.

Amphotericin B has been shown to potentiate the antiviral effect of Aciclovir against pseudorabies virus in vitro when both drugs are added to the culture medium. Ketoconazole and Aciclovir have shown dose-dependent, synergistic, antiviral activity against herpes simplex virus types 1 and 2 (HSV-1 and HSV -2) in in-vitro replication studies.

**PHARMACEUTICAL PRECAUTION:**

**Virux**<sup>®</sup> Tablet, Cream and Oral Suspension should be stored below 25 degree C. It should be protected from light and moisture. Keep drugs out of the reach of children.

**HOW SUPPLIED:**

**Virux**<sup>®</sup> 200: Each box containing 3x10 tablets in blister pack

**Virux**<sup>®</sup> 400: Each box containing 2x10 tablets in blister pack.

**Virux**<sup>®</sup> Cream: Each tube containing 5 gm cream.

**Virux**<sup>®</sup> Oral suspension: Each box contains 70 ml suspension in PET bottle and a measuring cup.

**Manufactured by:**



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**PHARMACEUTICALS LTD.**  
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