

Virux[®]

Acyclovir

COMPOSITION

Virux[®] 200 Tablet: Each tablet contains Acyclovir USP 200 mg.

Virux[®] 400 Tablet: Each tablet contains Acyclovir USP 400 mg.

Virux[®] Oral Suspension: Each 5 ml suspension contains Acyclovir USP 200 mg.

Virux[®] Cream: Each gm cream contains Acyclovir USP 50 mg.

PHARMACOLOGY

Virux[®] contains Acyclovir which is a synthetic purine derivative. Acyclovir exerts its antiviral effect on herpes simplex viruses (HSV) and varicella-zoster virus by interfering with DNA synthesis and inhibiting viral replication. The exact mechanisms of action against other susceptible viruses have not been fully elucidated. In vitro studies with herpes simplex viruses indicate that Acyclovir triphosphate is the pharmacologically active form of the drug; the triphosphate functions as both a substrate for and preferential inhibitor of viral DNA polymerase.

Absorption of Acyclovir from the GI tract is variable and incomplete. It is estimated that 15-30% of an oral dose of the drug is absorbed. Acyclovir is widely distributed into body tissues and fluids including the brain, kidney, saliva, lung, liver, muscle, spleen, uterus, vaginal mucosa and secretions, CSF, and herpetic vesicular fluid. The drug is also distributed into semen, achieving concentrations about 1.4 and 4 times those in plasma during chronic oral therapy at doses of 400 mg and 1 g daily, respectively.

Plasma concentrations of Acyclovir appear to decline in a biphasic manner. In adults with normal renal function, the half-life of Acyclovir in the initial phase averages 0.34 hours and the half-life in the terminal phase averages 2.1-3.5 hours.

INDICATION

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

Virux[®] is indicated for the treatment of herpes simplex virus infections of the skin & mucous membrane 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

Tablet & 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 immunocompromised) or as directed by the physician.

Children under 2 years: Half of the adult dose.

Children over 2 years: Adult dose.

Prevention of recurrence of herpes simplex: 200 mg 4 times daily or 400 mg 2 times 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 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 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 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: An oral dosage of 400 mg 5 times daily for 10 days or until clinical resolution occurs has been recommended.

Cream

Virux[®] cream should be applied to lesions or impending lesions 5 times daily (at 4 hourly intervals omitting the night-time dose). Treatment should continue for 5 days. If healing does not occur, treatment may be extended for up to 10 days.

Renal Impairment

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

CONTRAINDICATION AND PRECAUTION

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

It is not recommended for application to mucous membrane such as eye, mouth, vagina etc.

SIDE EFFECT

Acyclovir is well tolerated when given orally. Skin rashes which, resolve after withdrawal of the drug have been reported with Acyclovir. GI effects including nausea, vomiting, diarrhea, headache and abdominal pain have been reported in patients receiving oral Acyclovir. The most common adverse effect is mild pain including transient burning and stinging at the site of application following Acyclovir cream.

DRUG INTERACTION

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

Amphotericin B has been shown to potentiate the antiviral effect of Acyclovir against pseudorabies virus in vitro when both drugs are added to the culture medium. Ketoconazole and Acyclovir 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.

USE IN PREGNANCY AND LACTATION

Acyclovir 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 Acyclovir 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 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.

STORAGE

Virux[®] Tablet: Store below 30°C. Protect from light & moisture.

Virux[®] Oral Suspension: Store below 25°C. Protect from light.

Virux[®] Cream: Store below 30°C. Protect from light.

Keep out of children's reach.

HOW SUPPLIED

Virux[®] 200 Tablet: Box containing 1 x 10 / 2 x 10 / 3 x 10 / 5 x 10 / 6 x 10 tablets in blister pack.

Virux[®] 400 Tablet: Box containing 1 x 10 / 2 x 10 / 3 x 10 / 5 x 10 / 6 x 10 / 10 x 10 tablets in blister pack.

Virux[®] Oral Suspension: Box containing 50 ml / 70 ml / 100 ml suspension in PET bottle and a measuring cup.

Virux[®] Cream: Tube containing 5 gm / 10 gm cream.

SQUARE