Virux®

Acyclovir

Antiviral

COMPOSITION

Virux® tablet : Each tablet contains Acyclovir BP 200 mg.

Virux® cream : A smooth white cream containing 5% w/w Acyclovir BP (50 mg/gm).

PHARMACOLOGY

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 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 dosages 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® tablet and cream are indicated for the treatment of herpes simplex virus infections of the skin including initial and recurrent genital herpes and herpes labialis. Virux® tablet is indicated for the suppression of recurrent herpes simplex infections in both immune-competent and immune-compromised patients. Virux® tablet is also indicated for the treatment of varicella zoster virus infections (chicken pox and herpes zoster).

DOSAGE AND ADMINISTRATION

Tablet

For the treatment of initial and recurrent episodes of herpes simplex infections in adults, 200 mg Virux® tablet should be taken 5 times daily (at

4 hours intervals omitting the night-time dose). Treatment should continue for 5 days and may be extended for up to 10 days in severe initial infections. For suppression of herpes simplex infections in adults, treatment with Virux® tablet should be continued at a dose of 200 mg 4 times daily or 400 mg twice daily for up to 1 year. If the patient remains recurrence free for up to 2-3 months, this dose can be reduced to 200 mg 3 times daily. After 1 year, treatment should be stopped to reassess patient's clinical status. For prophylaxis of herpes simplex infections in immune-compromised patients, 200 mg Virux® tablet should be taken four times daily at 6 hourly intervals for 7 days. In severely immune-compromised patients (e.g. after bone marrow transplantation) or in patients with impaired absorption from the gut, the dose can be doubled. For treatment of herpes zoster infections in adults, 800 mg Virux® tablet should be taken 5 times daily (at 4 hourly intervals) for 7 days.

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.

Children

HSV infections in children over 2 years should be given adult doses and children below 2 years should be given half of the adult dose.

Renal Impairment

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

CONTRAINDICATION AND PRECAUTION

Virux® tablet and cream is contraindicated in patients known to be hypersensitive to acyclovir. Virux® cream 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 CONDITION

Virux® tablet and cream should be stored below 25˚C in a cool and dry place.

HOW SUPPLIED

Virux® tablet : Box containing 3 x 10 tablets in blister pack.
Virux® cream : Tube containing 5 g of Virux® cream.