

Aciclovir

Hapivir

Suspension 400mg/5mL

DESCRIPTION: Hapivir is the brand name for aciclovir, a synthetic nucleoside analogue, active against herpes and varicella viruses.

FORMULATION: Each 5mL of Hapivir (Acyclovir 400mg/5mL) contains 400mg of aciclovir.

MECHANISM OF ANTIVIRAL ACTION: Aciclovir is a synthetic purine nucleoside analogue with in vitro and in vivo inhibitory activity against Herpes Simplex Virus types 1 (HSV-1), 2 (HSV-2), and Varicella-Zoster Virus (VZV).

Aciclovir inhibit viral replication by inhibiting DNA synthesis. Aciclovir, before it can exert its action, must be phosphorylated first by viral thymidine kinase to become aciclovir monophosphate. Then it will be acted upon by guanylate kinase to be converted to aciclovir diphosphate; then to triphosphate by a number of cellular enzymes to become the active form (Aciclovir triphosphate). Thus the active form (acyclovir triphosphate) will inhibit viral DNA polymerase therefore terminating viral DNA replication. The affinity of aciclovir for Herpes-virus coded thymidine kinase is 200 times greater than for mammalian enzyme.

INDICATIONS AND USAGE: Hapivir is the 1st and Only 400mg/5mL Aciclovir pediatric suspension especially formulated for the prophylaxis and treatment of Varicella-Zoster (Chickenpox) among infants and children 2-12 years of age.

CONTRAINDICATIONS: Hapivir Suspension is contraindicated in patients who develop hypersensitivity to the components of the formulation.

WARNINGS: Hapivir Suspension is intended for oral administration.

PRECAUTIONS

General: The dosage, frequency of applications, and length of treatment should not exceed recommendation. (see DOSAGE AND ADMINISTRATION). There are no data to support the use of Hapivir (Aciclovir 400mg/5mL) Suspension to prevent transmission of infection to other persons or prevent recurrent infections when applied in the absence of signs and symptoms

Drug Interactions: Clinical experience has identified no interactions resulting concomitant use of topical or systemic drugs with Hapivir (Aciclovir 400mg/5mL) Suspension.

ADVERSE REACTIONS: Common adverse drug reaction associated with oral acyclovir therapy include: nausea, vomiting, diarrhea and/or headache. In high doses, hallucinations have been reported.

Infrequent adverse effects include: agitation, vertigo, confusion, dizziness, edema, arthralgia, sore throat, constipation, abdominal; pain, rash and/ or weakness.

Rare adverse effects include: coma, seizures, neutropenia, leucopenia, crystalluria, anorexia, fatigue, Steven-johnson syndrome, toxic epidermal necrolysis and anaphylaxis.

For Patients:

Please refer to your Physician for the recommended Dosage and Administration

DOSAGE AND ADMINISTRATION:

Therapy should be initiated as early as possible following onset of signs and symptoms. Please ask your Professional Marketing Representative for the Product Literature discussing the recommended Dosaging Table for Hapivir.

AVAILABILITY

Box of 60 mL amber bottle.

Box of 120 mL amber bottle.

STORAGE CONDITION: Store at temperatures not exceeding 30°C.

CAUTION: Foods, Drugs, Devices and Cosmetics Act prohibit dispensing without prescription.