



DESCRIPTION: Hapivir ZO is the brand name for aciclovir, combined with zinc oxide, a formulation for topical administration.

FORMULATION: Each gram of Hapivir ZO Ointment contains 50 mg of aciclovir and 100mg Zinc Oxide.

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 inhibits 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 (aciclovir 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 ZO ointment is indicated in the treatment of Varicella Zoster (Chickenpox) and Herpes Simplex Viruses I and II (Cold Sores and Genital Herpes). Zinc Oxide, when used in combination with aciclovir, will have an anti-inflammatory, mild bactericidal, deodorizing and protectant effect on mucocutaneous lesions of Varicella Zoster and Herpes Simplex Viruses.

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

WARNINGS: Hapivir ZO Ointment is intended for cutaneous use only and should not be used in the eye.

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 ZO Ointment to prevent transmission of infection to other persons or prevent recurrent infections when applied in the absence of signs and symptoms. Hapivir ZO Ointment should not be used for the prevention of recurrent HSV infections. Although clinically significant viral resistance associated with the use of Hapivir ZO Ointment has not been observed, this possibility exists.

Drug Interactions: Clinical experience has identified no interactions resulting from concomitant use of this topical ointment with other systemic drugs.

ADVERSE REACTIONS: In the controlled clinical trials, mild pain (including transient burning and stinging) was reported by about 30% of patients in both the active and placebo arms; treatment was discontinued in 2 of these patients. Local pruritus occurred in 4% of these patients. In all studies, there was no significant difference between the drug and placebo group in the rate or type of reported adverse reactions nor were there any differences in abnormal clinical laboratory findings.

General: Edema and/or pain at the application site.

Skin: Pruritus, rash.

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 for Hapivir ZO.

AVAILABILITY

Aluminum tube of 5 grams, Box of 1.

Aluminum tube of 20 grams, Box of 1.

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

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