

# ACYCLOVIR OINTMENT USP 5% w/w

## Herperax Ointment

### COMPOSITION:

Acyclovir USP 5% w/w  
in an ointment base.

### CHEMISTRY:

Aciclovir chemically described as 2-Amino-1, 9-dihydro-9-((2-hydroxyethoxy) methyl)-3H-purin-6-one

### PHARMACOLOGICAL CATEGORY: Antiviral agent

### PHARMACOLOGY:

Aciclovir is an antiviral agent which is highly active *in vitro* against herpes simplex virus (HSV) types I and II and varicella zoster virus. Toxicity to mammalian host cells is low.

Aciclovir is phosphorylated after entry into herpes infected cells to the active compound Aciclovir triphosphate. The first step in this process is dependent on the presence of the HSV-coded thymidine kinase. Aciclovir triphosphate acts as an inhibitor of, and substrate for, the herpes-specified DNA polymerase, preventing further viral DNA synthesis without affecting normal cellular processes.

### PHARMACOKINETICS:

Pharmacology studies have shown only minimal systemic absorption of Aciclovir following repeated topical administration of Aciclovir ointment.

### INDICATIONS:

Aciclovir is used for the treatment of Herpes simplex infection (local treatment) of the skin including initial and recurrent genital herpes and herpes labialis.

### CONTRAINDICATIONS:

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

### SIDE EFFECTS/ADVERSE EFFECTS:

Drying of the skin; erythema; itching of the skin; transient burning; transient stinging

### PRECAUTIONS AND WARNINGS:

Avoid contact with eyes and mucous membranes

Aciclovir ointment is not recommended for application to mucous membranes such as in the mouth, eye or vagina, as it may be irritant.

Particular care should be taken to avoid accidental introduction into the eye.

In severely immunocompromised patients (e.g. AIDS patients or bone marrow transplant recipients) oral Aciclovir dosing should be considered. Such patients should be encouraged to consult a physician concerning the treatment of any infection.

#### **DRUG INTERACTIONS:**

No clinically significant interactions have been identified.

#### **PREGNANCY AND LACTATION:**

**Pregnancy:** Limited absorption from topical Aciclovir preparations.

**Breast feeding:** Limited human data show that the drug does pass into breast milk following systemic administration. However, the dosage received by a nursing infant following maternal use of Aciclovir ointment would be insignificant.

#### **DOSAGE AND ADMINISTRATION:**

Herpes simplex infection (local treatment)

To the skin

**Child:** Apply 5 times a day for 5-10 days, to be applied to lesions approximately every 4 hours, starting at first sign of attack.

**Adult:** Apply 5 times a day for 5-10 days, to be applied to lesions approximately every 4 hours, starting at first sign of attack.

With topical use in children: Cream licensed for use in children (age range not specified by manufacturer).

#### **OVERDOSAGE AND TREATMENT:**

Overdose is unlikely to occur, if the ointment is applied locally as indicated. There are no reports concerning an overdose of Aciclovir ointment.

#### **STORAGE CONDITIONS:**

Store below 30°C. Keep out from the reach of children.

#### **PRESENTATION:**

Aluminium collapsible Tube of 5 gm.

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Manufactured by :

EXG-ML011-1941



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