

PACKAGE INSERT TEMPLATE FOR ACYCLOVIR CREAM

Brand or Product Name

[Product name] Cream 5% w/w

Name and Strength of Active Substance(s)

Acyclovir 5% w/w

Product Description

*[Visual description of the appearance of the product (eg colour, odour, viscosity, texture etc)
eg :A smooth white cream]*

Pharmacodynamics

Acyclovir 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.

Acyclovir 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 viral-coded thymidine kinase.

Acyclovir triphosphate acts as an inhibitor of and substrate for the herpes specified DNA polymerase preventing further viral DNA synthesis without affecting normal cellular processes.

Acyclovir Cream significantly reduced episode healing time and time to pain resolution compared with placebo cream in subjects with recurrent herpes labialis.

Pharmacokinetics

Pharmacology studies have shown only minimal systemic absorption of acyclovir following repeated topical administration of Acyclovir Cream.

Indication

Acyclovir Cream is indicated for the treatment of herpes simplex virus infections of the skin including initial and recurrent genital herpes and herpes labialis.

Recommended Dosage

Updated August 2011

Adults and children

Acyclovir Cream should be applied five times daily at approximately four hourly intervals omitting the night time application.

Acyclovir Cream should be applied to the lesions or impending lesions as soon as possible, preferably during the earliest stages (prodrome or erythema). Treatment can also be started during the later (papule or blister) stages.

Treatment should be continued for 5 days. If healing has not occurred treatment may be continued for up to 10 days.

Mode of Administration

Topical

Contraindications

Contraindicated in patients known to be hypersensitive to acyclovir, valacyclovir or any of the excipients of Acyclovir Cream.

Warnings and Precautions

Acyclovir Cream 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 immune-compromised patients (eg AIDS patients or bone marrow transplant recipients) oral acyclovir dosing should be considered. Such patients should be encouraged to consult a physician concerning the treatment of any infection.

Interactions with Other Medicaments

No clinically significant interactions have been identified.

Statement on Usage During Pregnancy and Lactation

Pregnancy

A post-marketing acyclovir pregnancy registry has documented pregnancy outcomes in women exposed to any formulation of acyclovir. The registry findings have not shown an increase in the number of birth defects amongst acyclovir exposed subjects compared with the general population, and any birth defects showed no uniqueness or consistent pattern to suggest a common cause.

Updated August 2011

The use of Acyclovir Cream should be considered only when the potential benefits outweigh the possibility of unknown risks.

Systemic administration of aciclovir in internationally accepted standard tests did not produce embryotoxic or teratogenic effects in rabbits, rats or mice.

In a non-standard test in rats, foetal abnormalities were observed but only following such high subcutaneous doses that maternal toxicity was produced. The clinical relevance of these findings is uncertain.

Lactation

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 Acyclovir Cream would be insignificant.

Adverse Effects / Undesirable Effects

Skin and subcutaneous tissue disorders

Uncommon

- Transient burning or stinging following application of Acyclovir Cream
- Mild drying or flaking of the skin
- Itching

Rare

- Erythema
- Contact dermatitis following application. Where sensitivity tests have been conducted, the reactive substances have most often been shown to be components of the cream rather than aciclovir.

Immune system disorders

Very rare

- Immediate hypersensitivity reactions including angioedema.

Overdose and Treatment

No untoward effects would be expected if the entire contents of a tube of Acyclovir Cream containing 500 mg of aciclovir were ingested orally.

Instruction for Use

Acyclovir Cream should not be diluted or used as a base for incorporation of other medicaments.

Storage Conditions

Updated August 2011

Store below°C.
Do not refrigerate.

Dosage Forms and Packaging Available

*[Packaging type & pack size eg
Aluminium tubes of 2g/box]*

Name and Address of Manufacturer

[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder

[Name & full address of marketing authorization holder]

Date of Revision of Package Insert

[day/month/year]