



D3. Proposed Package Insert



AXCEL[®]
ACYCLOVIR CREAM

COMPOSITION:

Acyclovir / Aciclovir (micronised) 5% w/w
Chlorocresol 0.1% w/w as preservative.

PRESENTATION:

White, water-miscible cream.

INDICATION:

Treatment of herpes simplex virus infection of the skin including genital herpes and herpes labialis.

PHARMACOLOGY:

Acyclovir is a synthetic purine nucleoside analogue structurally related to guanine. It is used mainly for the treatment of viral infections due to herpes simplex virus (type 1 and 2) and varicella-zoster virus (herpes zoster and chickenpox). Absorption of acyclovir is usually slight following topical application to intact skin. It is only partially absorbed from the gastrointestinal tract (about 15% to 30% of a dose given by mouth). The absorbed acyclovir is excreted through the kidney by both glomerular filtration and tubular secretion. Acyclovir crosses the placenta and is excreted in breast milk in concentration approximately 3 times higher than those in maternal serum.

DIRECTION FOR USE:

For adults, children and geriatric: apply cream to the affected area 5 or 6 times daily every 3 or 4 hours for periods of 5 to 10 days. Acyclovir cream should be applied to the lesions area as early as possible after the start of an infection. It is particularly important to start treatment of recurrent episodes during the prodromal period or when the lesions first appear.

CONTRAINDICATION:

Patients known to be hypersensitive to acyclovir.

PRECAUTIONS:

Acyclovir cream should not be applied to mucous membranes, eg. in the mouth, eyes or vagina. In severely immune-compromised patients (eg. AIDS patients or bone marrow transplant recipients), oral acyclovir dosing should be considered.

Use in Pregnancy and Lactation:

No information is available on the effects of topical administration of acyclovir during human pregnancy. The use of acyclovir cream should be considered when the potential benefits outweigh the possibility of known risk.

SIDE EFFECTS:

Acyclovir is generally well tolerated. Topical application of acyclovir, especially to genital lesions, may sometimes produce transient stinging and burning.

Erythema or mild drying and flaking of the skin have been reported in small proportion of patients.

DRUG INTERACTION:

Probenecid has been reported to block the renal clearance of acyclovir.

OVERDOSAGE AND TREATMENT:

There is little absorption of acyclovir when applied topically. No untowards effect due to overdosage would be expected. Overdosage has not been reported to be a problem when acyclovir is given by mouth. Hence accidental ingestion of the cream would not cause any toxic effect. However, should acyclovir need to be removed then haemodialysis would be effective.

STORAGE:

Keep container well closed. Store below 30°C. Protect from light.

**KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK**

PACK QUANTITIES:

Available in aluminium tube of 5 gm.

Further information can be obtained from pharmacist, physician or the manufacturer.

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