PACKAGE INSERT TEMPLATE FOR ACYCLOVIR OPHTALMIC OINTMENT

Brand or Product Name

[Product name] Ophtamic Ointment 3%w/w

Name and Strength of Active Substance(s)

Acyclovir 3%w/w

Product Description

[Visual description of the appearance of the product (eg colour, odour etc)
eg :A white ointment]

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.

Pharmacokinetics

Acyclovir is rapidly absorbed from the ophthalmic ointment through the corneal epithelium and superficial ocular tissues with the result that viral toxic concentrations are achieved in the aqueous humor. It has not been possible to detect acyclovir in the blood by existing methods after topical application of Acyclovir Ophthalmic Ointment but trace quantities are detectable in the urine. These levels, however, are not therapeutically significant.

Indication

Acyclovir Ophthalmic Ointment is indicated for the treatment of herpes simplex keratitis.

Recommended Dosage

The dosage for all age groups is the same. A 10mm ribbon of the ointment should be placed inside the lower conjunctival sac 5 times a day at approximately 4 hourly intervals. Treatment should continue for at least 3 days after healing.

Mode of Administration

Intraocular

Contraindications

Contraindicated in patients known to be hypersensitive to acyclovir.

Warnings and Precautions

Patients should be informed that transient mild stinging immediately following application may occur.

Mutagenicity

The results of a wide range of mutagenicity tests in vitro and in vivo indicate that acyclovir does not pose a genetic risk to man.

Fertility

Largely reversible adverse effects on spermatogenesis in association with overall toxicity in rats and dogs have been reported only at doses of acyclovir greatly in excess of those employed therapeutically. Two-generation studies in mice did not reveal any effect of orally administered acyclovir on fertility. There is no information on the effect of Acyclovir Ophthalmic Ointment on human female fertility. Acyclovir Tablets have been shown to have no definitive effect on sperm count, morphology or motility in man.

Carcinogenicity

Acyclovir was not found to be carcinogenic in long-term studies in the rat and the mouse.

Interactions with Other Medicaments

Probenecid increases the mean half-life and area under the plasma concentration curve of systemically administered acyclovir. Clinical experience has not identified other drug interactions with acyclovir. Other drugs affecting renal physiology could potentially influence the pharmacokinetics of acyclovir.

Statement on Usage During Pregnancy and Lactation

Pregnancy

Systemic administration of acyclovir did not produce embryotoxic or teratogenic effects in rabbits, rats or mice. Experience in humans is limited, so the use of Acyclovir Ophthalmic Ointment should be considered only when the potential benefits outweigh the possibility of unknown risks.

Lactation
Limited human data show that the drug does pass into breast milk.

Adverse Effects / Undesirable Effects

Transient mild stinging immediately following application of Acyclovir Ophthalmic Ointment may occur in a small proportion of patients. Superficial punctate keratopathy has been recorded. This did not necessitate an early termination of therapy and healed without apparent sequelae.
Local irritation and inflammation such as blepharitis and conjunctivitis have been reported in patients on Acyclovir Ophthalmic Ointment.

Overdose and Treatment

No untoward effects would be expected if the entire contents of the tube containing 135mg acyclovir were ingested orally. Doses of 800mg 5 times a day (4g per day) have been administered for 5 days without adverse effects. Single intravenous doses of up to 80mg/kg have been inadvertently administered without adverse effects. Acyclovir is dialysable.

Instruction for Use
[To add appropriate information & graphic]

Storage Conditions
Store below ….°C

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]

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