Zovirax™

Ophthalmic Ointment
Aciclovir

To the Medical and Pharmaceutical Professions.

Qualitative and Quantitative Composition
Aciclovir 3.0% W/W

Therapeutic indications
Treatment of herpes simplex keratitis.

Dosage and Administration
Topical administration to the eye.

Adults: 1cm ribbon of ointment should be placed inside the lower conjunctival sac five times a day at approximately four hourly intervals, omitting the night time application.
Treatment should continue for at least 3 days after healing is complete.

Children: As for adults

Use in the elderly: As for adults.

Contraindications
Aciclovir ophthalmic ointment is contraindicated in patients known to be hypersensitive to aciclovir or valaciclovir.

Warnings and Precautions
Patients should be informed that transient mild stinging immediately following application may occur.
Patients should avoid wearing contact lenses when using aciclovir ophthalmic ointment.

Interactions
No clinically significant interactions have been identified.

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

Ability to perform tasks that require judgement, motor or cognitive skills
No data.

Adverse Reactions
The following convention has been used for the classification of undesirable effects in terms of frequency: - Very common ≥1/10, common ≥1/100 and <1/10, uncommon ≥1/1000 and <1/100, rare ≥1/10,000 and <1/1000, very rare <1/10,000.
Clinical trial data have been used to assign frequency categories to adverse reactions observed during clinical trials with aciclovir 3% ophthalmic ointment. Due to the nature of the adverse events observed, it is not possible to determine unequivocally which events were related to the administration of the drug and which were related to the disease. Spontaneous reporting data has been used as a basis for allocating frequency for those events observed post-marketing.

Immune system disorders

Very rare:	Immediate hypersensitivity reactions including angioedema.

Eye disorders

Very common:	Superficial punctate keratopathy

This did not necessitate an early termination of therapy and healed without apparent sequelae.

Common:	Transient mild stinging of the eye occurring immediately following application, conjunctivitis
Rare:	Blepharitis

Local irritation and inflammation such as blepharitis and conjunctivitis have been reported in patients receiving aciclovir ophthalmic ointment.

Overdosage
No untoward effects would be expected if the entire contents of the tube containing 135 mg aciclovir (ophthalmic ointment) were ingested orally.

Clinical Pharmacology
Mechanism of Action
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 viral-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
Aciclovir 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 aciclovir in the blood by existing methods after topical application of aciclovir ophthalmic ointment, but trace quantities are detectable in the urine. These levels, however, are not therapeutically significant.

List of Excipients
White petrolatum USP

Incompatibilities
None known

Shelf Life
As indicated on the outer packaging.

Special Precautions for Storage
Store below 25°C
The contents are sterile until the tube is opened.
Use within one month of first opening.

Nature and Contents of Container
Laminate ophthalmic ointment tubes closed with high-density polyethylene screw caps or tamper evident screw caps.
Pack size: 4.5g

Instructions for Use/Handling
No special instructions

Manufactured by Jubilant Hollisterstier General Partnership, Quebec, Canada
For The Wellcome Foundation Limited*, UK.
* Member of the GlaxoSmithKline group of companies

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THIS IS A MEDICAMENT
Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.

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