ZOVIRAX OPHTHALMIC OINTMENT

APPROVED PACKAGE INSERT

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

ZOVIRAX Ophthalmic Ointment

COMPOSITION:

Each gram contains 30 mg acyclovir in white, soft paraffin.

PHARMACOLOGICAL CLASSIFICATION:

A 15.4 Ophthalmic preparations. Other

PHARMACOLOGICAL ACTION:

Acyclovir is an antiviral agent which is highly active *in vitro* against herpes simplex (HSV) type I and II viruses, but its toxicity to the infected mammalian cells is low. Acyclovir is phosphorylated to the active compound acyclovir triphosphate after entry into a herpes-infected cell. The first step in this process requires the presence of the HSV 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.

INDICATIONS:

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

CONTRA-INDICATIONS:

ZOVIRAX Ophthalmic Ointment is contra-indicated in patients known to be previously hypersensitive to acyclovir or valaciclovir.

WARNINGS AND SPECIAL PRECAUTIONS:

Patients should be informed that transient mild stinging immediately following application of ZOVIRAX Ophthalmic Ointment may occur.

Patients should avoid wearing contact lenses when using ZOVIRAX Ophthalmic Ointment.

INTERACTIONS:

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

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

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

Fertility: There has been no experience of the effect of ZOVIRAX Ophthalmic Ointment on human fertility. However, in two generation mouse studies no effects on fertility have been demonstrated.

In a study of 20 male patients with normal sperm count, oral acyclovir administered at doses of up to 1 g per day for up to six months has been shown to have no clinically significant effect on sperm count, motility or morphology.

Lactation: Human data show that the acyclovir does pass into breast milk.

DOSAGE AND DIRECTIONS FOR USE:

Dosage for all age groups is the same. A 10 mm ribbon of the ointment should be placed inside the lower conjunctival sac five times a day at approximately four hourly intervals. Treatment should continue for at least three days after healing.

SIDE EFFECTS:

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 ≥1/1 000 and <1/100, rare ≥1/10 000 and <1/1 000, very rare <1/10 000.

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.

Local irritation and inflammation, such as blepharitis and conjunctivitis, have been reported in patients receiving ZOVIRAX Ophthalmic Ointment.

Immune System disorders:

Very rare: immediate hypersensitivity reactions including angioedema**.**

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

No untoward effects would be expected if the entire content of the tube containing 135 mg of acyclovir were ingested orally. Acyclovir is dialysable by haemodialysis.

IDENTIFICATION:

The sterile ointment is white to pale yellow in colour and is supplied in tubes containing 4,5 g.

PRESENTATION:

Tubes containing 4,5 g.

STORAGE INSTRUCTIONS:

Keep out of reach of children. Store below 25 °C. An opened tube of ZOVIRAX Ophthalmic Ointment should be discarded after one month.

REGISTRATION NUMBER:

P/15.4/238

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

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