ZOVIRAX® CREAM

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

ZOVIRAX CREAM

COMPOSITION:

1 gram of cream contains 0,05 grams of acyclovir

PHARMACOLOGICAL CLASSIFICATION:

A 20.2.8 Antiviral agent

PHARMACOLOGICAL ACTION:

Acyclovir is an antiviral agent which is active *in vitro* against herpes simplex (HSV) type I and II. Toxicity to mammalian host cells is low. Acyclovir is phosphorylated after entry into herpes infected cells to the active compound acyclovir triphosphate. The first step in this process is dependant on the presence of the HSV coded thymidine kinase. Acyclovir triphosphate acts as an inhibitor of and substrate for the herpes specific DNA polymerase preventing further viral DNA synthesis without affecting normal cellular processes.

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

INDICATIONS:

ZOVIRAX CREAM is indicated for the treatment of herpes simplex virus infections of the skin, lips or genitalia in the initial and recurrent situation.

CONTRA-INDICATIONS:

ZOVIRAX CREAM is contra-indicated in patients known to be hypersensitive to acyclovir, valacyclovir or propylene glycol, or any of the excipients of ZOVIRAX CREAM.

WARNINGS AND SPECIAL PRECAUTIONS:

In severely immune compromised patients (e.g. AIDS patients or bone marrow transplant recipients) topical ZOVIRAX may be inappropriate. Such patients should be encouraged to consult a physician concerning treatment of any infection. ZOVIRAX 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.

INTERACTIONS:

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

No clinically significant interactions have been identified.

Dilution: ZOVIRAX CREAM contains a specially formulated base and should not be diluted or used as a base for incorporation of other medicaments.

PREGNANCY AND LACTATION:

The safety of ZOVIRAX CREAM in pregnancy and lactation has not been established.

Limited human data show that acyclovir does pass into breast milk.

There is no information on the effect of ZOVIRAX CREAM on human female fertility. 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.

DOSAGE AND DIRECTIONS FOR USE:

Adults and Children

ZOVIRAX CREAM should be applied five times daily at approximately four hourly intervals.

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

Treatment should be continued for at least four days for *herpes labialis* and for 5 days for genital herpes. If healing has not occurred, treatment may be continued for up to 10 days.

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.

Skin and subcutaneous tissue disorders:

Uncommon

- Transient burning or stinging following application of ZOVIRAX 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 acyclovir.

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 contents of a ZOVIRAX CREAM 10 g tube containing 500 mg of acyclovir were ingested orally.

Acyclovir is dialysable.

IDENTIFICATION:

ZOVIRAX CREAM is white to off white.

PRESENTATION:

ZOVIRAX CREAM may be packaged in the following:

Collapsible aluminium tube of nominal fill 2 g, with membrane seal, internally lacquered with a plastic screw cap.

Collapsible aluminium tube of nominal fill 10 g, with membrane seal, internally lacquered with a plastic screw cap.

2 g Pump Dispenser: Polypropylene container (bottle) of nominal fill 2 g with a pump assembly and polypropylene cap.

STORAGE INSTRUCTIONS:

Keep out of reach of children.

Store below 25 °C.

Do not refrigerate.

REGISTRATION NUMBER:

R/20.2.8/271

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

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

Date of last approval: 23 July 2010

Date compliant with Regulation 11: 25 August 2016

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