To the Medical and Pharmaceutical Professions

Cream containing aciclovir 5% w/w BP. (See list of excipients)

Indications

MUNICAUDIS
70V/RAX Cream is indicated for the treatment of Hernes simplex virus infections of the skin including initial and recurrent genital

herpes and herpes labialis.
Route of administration: topical. Do not use in eyes

Dosage and Administration

Adults and Children:

ZOVIRAX Cream should be applied five times daily at approximately four hourly intervals omitting the night time application. 20/IIIA/C Orean should be splied the finite laws at specificanteer your noting miservals furning the right under specifications of impending lesions as soon as possible, preferably during the earliest stages (proforme or erythema). Treatment can also be started during the later (papule or blister) stages.

Treatment should be continued for 4 days. If healing has not occurred treatment may be continued for up to an additional 5 days.

Use in the elderly: No special comment

Contra-indications

ZOVIRAX Cream is contra-indi excipients of ZOVIRAX Cream. -indicated in natients known to be hypersensitive to aciclovir valaciclovir propylene glycol or any of the

Precautions and Warnings

ZOVIRAX Cream is not rec commended 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 eve In severely immune-compromised patients (eg AIDS patients or bone marrow transplant recipients) oral ZOVIRAX dosing should be considered. Such patients should be encouraged to consult a physician concerning the treatment of any infection.

Drug Interactions

No clinically significant interactions have been identified.

Pregnancy and Lactation

registery and calculation.

A post-marketing action/in 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.

The use of ZOVIRAX Cream 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 teratopenic effects in rabbite rate or mico

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.

toxicity was produced. The climate heaving of these minings is interesting.

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 ZOVIRAX Cream would be insignificant.

Adverse Reactions

are neactions following convention has been used for the classification of undesirable effects in terms of frequency: Ver mon ≥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 Skin and subcutaneous tissue disorders

Uncommon

Transient burning or stinging following application of Zovirax Cream Mild drying or flaking of the skin Itching

Rare

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 aciclovir.

Immune system disorders

Immediate hypersensitivity reactions including angioedema

Overdosage

No untoward effects would be expected if the entire contents of a 10 gram tube of ZOVIRAX cream containing 500 mg of aciclovir were ingested orally.

Pharmacodynamic Properties

Mode 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

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(papule or blister) Pharmacokinetic Properties

Pharmacology studies have shown only minimal systemic absorption of aciclovir following repeated topical administration of ZOVIRAX Cream.

Further Information

Preclinical Safety Data

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

Aciclovir was not found to be carcinogenic in long-term studies in the rat and the mouse. Largely reversible adverse effects on spermatogenesis in association with overall toxicity in rats and dogs have been reported only at systemic doses of aciclovir greatly in excess

of those employed therapeutically. Two-generation studies in mice did n effect of orally administered aciclovir on fertility.

Pharmaceutical Precautions and Reco Do not store above 25°C.

Do not refrigerate

Shelf Life

The expiry date is indicated on the packaging.

List of Excipients

Poloxamer 407 Cetostearyl alcohol

Sodium lauryl sulphate

White soft paraffin

Liquid paraffin Propylene alycol

Purified w Arlacel 165 (containing glycerol monostearate and polyoxyethylene stearate)

Instructions for Use/Handling

Tillution:
ZOVIRAX Cream contains a specially formulated base and should not be diluted or used as a base for incorporation of other

medicaments.

Dimeticone 20

Manufactured by: Glaxo Operations UK Limited*, Barnard Castle, UK *Member of the GlaxoSmithKline group of companies

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THIS IS A MEDICAMENT

Medicament is a product which affects your hea and its consumption contrary to instructions dangerous for you. Follow strictly the doctor's prescription, the meth of use and the instructions of the pharmacist w sold the medicament.

The doctor and the pharmacist are the experts st 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

