

## Data Sheet

# ZOVIRAX<sup>®</sup> Cold Sore Cream

*Aciclovir 5% w/w*

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## Presentation

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Topical cream

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## Indications

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ZOVIRAX Cold Sore Cream is indicated for the treatment of Herpes simplex virus infections of the lips and face (recurrent herpes labialis).

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## Dosage and Administration

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### Adults and children:-

ZOVIRAX COLD SORE Cream should be applied five times daily at approximately four hourly intervals omitting the night time application. It is important to start treatment as early as possible after the start of an infection, ideally during the prodromal period. Treatment can also be started during the later (papule or blister) stages.

Treatment should be continued for at least 4 days. If healing has not occurred, treatment may be continued for up to 10 days. If lesions are still present after 10 days, users should be advised to consult a doctor.

Users should wash their hands before and after applying the cream, and avoid unnecessary rubbing of the lesions or touching them with a towel, to avoid aggravating or transferring the infection.

### Renal and Hepatic Impairment

Although the principal route of elimination of aciclovir is renal, the systemic absorption of aciclovir following topical administration is negligible. Accordingly, there is no requirement for any dose modification in patients with renal or hepatic impairment (see Pharmacokinetics).

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## Contraindications

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ZOVIRAX COLD SORE Cream is contraindicated in patients known to be hypersensitive to aciclovir, valaciclovir, propylene glycol or any of the excipients of aciclovir cream.

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## **Warnings and Precautions**

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ZOVIRAX COLD SORE Cream should only be used on cold sores on the mouth and face. It is not recommended for application to mucous membranes, such as inside the mouth or eye and must not be used to treat genital herpes. Particular care should be taken to avoid contact with the eye. People with particularly severe herpes labialis should be encouraged to seek medical advice.

Cold sore sufferers should be advised to avoid transmitting the virus, particularly when active lesions are present (eg wash hands before and after use – refer to Dosage and Administration section).

ZOVIRAX COLD SORE Cream is not recommended for use by people who know that they are immunocompromised. Such individuals should be encouraged to consult a physician concerning the treatment of any infection.

### ***Use in Pregnancy***

Category B3

Aciclovir has been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed.

Studies in animals have shown evidence of an increased occurrence of fetal damage, the significance of which is considered uncertain in humans.

The use of aciclovir cream should be considered only when the potential benefits outweigh the possibility of unknown risks.

A post-marketing aciclovir 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. Systemic exposure to aciclovir from topical application of ZOVIRAX COLD SORE Cream is very low.

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.

### ***Use in Lactation***

Limited human data show that aciclovir does pass into breast milk following systemic administration. However, the dosage received by a nursing infant following maternal use of ZOVIRAX COLD SORE Cream would be insignificant.

### ***Effects on Fertility***

There is no information on the effect of aciclovir oral or intravenous formulations of aciclovir on human female fertility.

In a study of 20 male patients with normal sperm count, oral aciclovir 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.

### ***Effects on Ability to Drive and Use Machines***

Aciclovir cream is unlikely to produce an effect.

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## **Adverse Effects**

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The following convention has been used for the classification of undesirable effects in terms of frequency: Very common  $\geq 1/10$ , common  $\geq 1/100$  and  $< 1/10$ , uncommon  $\geq 1/1,000$  and  $< 1/100$ , rare  $\geq 1/10,000$  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 aciclovir.

### **Immune system disorders**

#### Very rare

- Immediate hypersensitivity reactions including angioedema.

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## **Interactions**

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No clinically significant interactions have been identified.

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## Overdosage

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No untoward effects would be expected if the entire 2g contents of ZOVIRAX COLD SORE cream containing 100mg of aciclovir were ingested orally or applied topically due to minimal systemic exposure. In the event of a suspected overdose, patients should seek medical advice.

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## Further Information

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### ***Mechanism of Action***

Aciclovir is an antiviral agent which is highly active *in vitro* against herpes simplex virus (HSV) types I and II. 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 HSV-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***

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

### ***Preclinical Safety Data***

The results of a wide range of mutagenicity tests *in vitro* and *in vivo* indicate that aciclovir 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.

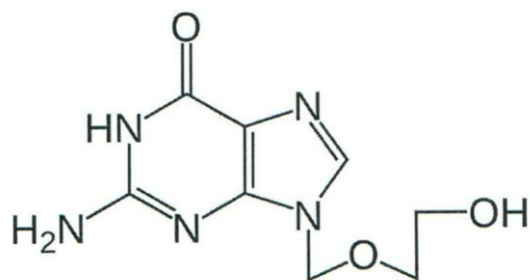
Largely reversible adverse effects on spermatogenesis in association with overall toxicity in rats and dogs have been reported only at systemic doses of aciclovir greatly in excess of those employed therapeutically. Two-generation studies in mice did not reveal any effect of orally administered aciclovir on fertility.

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## Other

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### *Chemical structure*



### *List of Excipients*

Poloxamer 407

White Soft Paraffin

Cetostearyl Alcohol\*

Liquid Paraffin

Dimeticone

Sodium Laurilsulfate

Propylene Glycol

Purified Water

Arlacel 165

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## Pharmaceutical Precautions

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### *Shelf Life*

Aluminium Tube: 36 months from date of manufacture

Pump Dispenser Pack: 24 months from date of manufacture

### ***Special Storage Precautions***

Store below 25 °C.

Do not refrigerate.

### ***Incompatibilities***

Not known.

### ***Instructions for Use/Handling***

For external use only.

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## **Package Quantities**

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Tubes and pump packs of 2 g cream. Each tube or pump pack contains aciclovir 5% w/w.

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## **Medicines classification**

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General Sale Medicine

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## **Name and address**

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GlaxoSmithKline (NZ) Ltd  
Trading as GlaxoSmithKline Consumer Healthcare  
Auckland, New Zealand  
Telephone: (09) 367 2970

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## **Date of preparation**

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