Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zovirax 5 % w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 50mg of aciclovir (equivalent to 5% w/w).

Excipients with known effect:
Propylene glycol 400mg/g
Cetostearyl alcohol 67.5mg/g
Sodium laurilsulfate 7.5mg/g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A smooth white to off-white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Zovirax Cream is indicated for the treatment of Herpes simplex virus infections of the skin including initial and recurrent genital herpes and herpes labialis.

4.2 Posology and method of administration

Method of administration
Zovirax Cream should be applied five times daily at approximately four hourly intervals omitting the night time application.

Zovirax Cream should be applied to the lesions or impending lesions as soon as possible preferably during the earliest stages (prodrome 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 five days for genital herpes. If healing has not occurred, treatment may be continued for up to ten days.

4.3 Contraindications

Zovirax Cream is contra-indicated in patients known to be hypersensitive to aciclovir, valaciclovir,propylene glycol or any of the excipients of Zovirax Cream as listed in section 6.1.

4.4 Special warnings and precautions for use

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 contact with the eye.

In severely immunocompromised patients (e.g. AIDS patients or bone marrow transplant recipients) oral dosing should be considered. Such patients should be encouraged to consult a physician concerning the treatment of any infection.

Excipients
This medicine contains 67.5mg of cetostearyl alcohol per gram of product. Cetostearyl alcohol can cause local skin reactions (e.g. contact dermatitis).

This medicine contains 400 mg of propylene glycol per gram of product. Propylene glycol may cause skin irritation. Particular care should be taken in paediatrics less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns).

This medicine contains 7.5 mg of sodium laurilsulfate per gram of product. Sodium laurilsulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

4.5 Interaction with other medicinal products and other forms of interactions

No clinically significant interactions have been identified.

4.6 Fertility, pregnancy and lactation

Pregnancy
The use of Zovirax Cream should be considered only when the potential benefits outweigh the possibility of unknown risks however the systemic exposure to aciclovir from topical application of aciclovir cream is very low.

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 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.

Breast-feeding
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.

Fertility
See clinical studies in section 5.3

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable 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 ≥1/1000 and <1/100, rare ≥1/10,000 and <1/1000, very rare <1/10,000.

Immune system disorders

Very rare

- Immediate hypersensitivity reactions including angioedema and urticaria

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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: group Anti infective, ATC code D06BB03

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 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.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

Fertility
There is no information on the effect of aciclovir oral formulations or IV for infusion on human female fertility. In a study of 20 male patients with normal sperm count, oral aciclovir administered at doses of up to 1g per day for up to six months has been shown to have no clinically significant effect on sperm count, motility or morphology.

NON-CLINICAL INFORMATION
Mutagenicity
The results of a wide range of mutagenicity tests *in vitro* and *in vivo* indicate that aciclovir is unlikely to pose a genetic risk to man.

Carcinogenicity
Aciclovir was not found to be carcinogenic in long-term studies in the rat and the mouse.

Fertility

Largely reversible adverse effects on spermatogenesis in association with overall toxicity in rats and dogs have been reported only at 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Liquid paraffin
Poloxamer 407
Propylene glycol (E1520)
Purified water
Sodium laurilsulfate
White soft paraffin
Dimeticone 20
Glycerol Monostearate / Macrogol Stearate (Arlacel 165)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate.

6.5 Nature and contents of container

Zovirax Cream is stored in two sizes of the following container:

Aluminium tube – Collapsible lacquered aluminium tubes with plastic screw caps. The tubes contain a latex end-seal at the crimped end and a membrane seal at the nozzle end. A spike is incorporated into the structure of the cap.

Pack size: 2 g and 10 g.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline (Ireland) Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1077/084/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 2 May 2009

10 DATE OF REVISION OF THE TEXT

June 2021