SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GENERIC: Aciclovir Cream BP 5% w/w

BRAND NAME: AVIRAX

DESCRIPTION:

A smooth white to off white soft homogenous cream, free from any gritty particles.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Aciclovir BP……5% w/w

In a cream base ..... q.s.

Excipients with known effects:

1 gm of cream contains 0.4 gm of Propylene glycol

1 gm of cream contains 0.675 gm of Cetostearyl alcohol

1 gm of cream contains 0.1 gm of Sodium lauryl sulfate

For complete list of excipients refer section 6.1.

3. PHARMACEUTICAL FORM:

Semisolid topical dosage form -Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication:

It is indicated for the treatment of Herpes Simplex virus infections of the skin including initial and recurrent genital herpes and herpes labialis.

Route of administration: topical.

Do not use in eyes.

4.2 Posology and method of administration:

Adults and Children: Aciclovir Cream should be applied five times daily at approximately four hourly intervals, omitting the night time application.

Aciclovir Cream should be applied to the lesions or impending lesions as soon as possible, preferably during the early stages (prodrome or erythema). Treatment can also be started during the later (papule or blister) stages.

Treatment should be continued for at least 4 days for herpes labialis and for 5 days for genital herpes. If healing has not occurred then treatment may be continued for up to an additional 5 days.
Use in the elderly: No special comment

4.3 Contraindications:

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

4.4 Warning and precautions for use

Aciclovir 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.

Aciclovir Cream contains a specially formulated base and should not be diluted or used as a base for the incorporation of other medicaments.

Excipients

This medicine contains 67.5 mg of Cetostearyl alcohol per gram of product.

The excipient 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. Do not use it on open wounds or large areas of broken or damaged skin (such as burns) without checking with your doctor or pharmacist.

This medicine contains 10 mg of Sodium lauryl sulfate per gram of product. Sodium lauryl sulfate 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 Drug Interactions

No clinically significant interactions have been identified.

4.6 Pregnancy & Lactation

Pregnancy:

A post-marketing aciclovir pregnancy registry has documented pregnancy outcomes in women exposed to any formulation of Aciclovir Cream. The registry findings have not shown an increase in the number of birth defects amongst aciclovir 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.

The use of Aciclovir 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.

Teratogenicity:

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure to indicate little relevance to clinical use

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 Aciclovir Cream would be insignificant.

Fertility:

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

4.7 Effects on ability to drive and use machines:

Not applicable

4.8 Adverse 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 Aciclovir Cream

• Mild drying or flaking of the skin

• Itching

Rare

• Erythema

• Contact dermatitis.

4.9 Overdose

No untoward effects would be expected if the entire contents of a 10 gram tube of Aciclovir Cream containing 500 mg of aciclovir were ingested orally. However the accidental, repeated overdose of oral aciclovir, over several days has resulted in gastrointestinal effects (nausea and vomiting) and neurological effects (headache and confusion). Aciclovir is dialysable by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

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 Aciclovir Cream.

5.3 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Poloxamer 407,Cetostearyl alcohol,Sodium lauryl sulfate,White soft paraffin

Light Liquid paraffin, Propylene glycol, Emulwax 165, Dimethicon 20 cSt

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

24 Months.

Discard the tube 30 days post opening.

6.4 Special precautions for storage:

Do not store above 30°C.
Protect from light.
Do not freeze. Do not accept if the seal is broken.
Keep the tube tightly closed after use.
Keep out of the reach and sight of children.

6.5 Nature and contents of container

15 g Lami tube

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements

7. APPLICANT

Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.

8. MARKET AUTHORISATION REFERENCE NUMBER

CTD11318

9. DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION

Not applicable

10. DATE OF REVISION OF THE TEXT

Not applicable