Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Acic Cold Sore 5% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1g contains 50mg aciclovir

Excipients with known effect:
Contains Propylene Glycol 15% and Cetyl Alcohol 1.5%
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream
A white to off-white creamy mass

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

ACIC Cold Sore 5% w/w Cream is indicated for the treatment of Herpes simplex virus infections of the skin, lips and face (recurrent herpes labialis).

4.2 Posology and method of administration

Route of Administration: Cutaneous

Recommended Dosage Schedule:
Adults:
ACIC Cream should be applied five times daily at approximately four-hourly intervals omitting the night time application. 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.

ACIC Cream should be applied as soon as possible, preferably during the earliest stages (prodrome or erythema). Treatment can also be started during the later (papule or blister) stages.

Children:
Children should use the adult dose.

4.3 Contraindications

Hypersensitivity to the active substance, valaciclovir, propylene glycol or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Acic Cream should only be used on cold sores on the lips and face. It 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 immune-compromised 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.

People with particular severe recurrent herpes labialis should be encouraged to seek medical advice.

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).
Propylene glycol may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions have been identified.

4.6 Fertility, pregnancy and lactation

Fertility
See clinical studies in section 5.3.

Pregnancy
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.

A post-marketing aciclovir pregnancy registry has documented pregnancy outcomes in women exposed to any formulation of aciclovir. 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 exposure to aciclovir from topical application of aciclovir 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.

Lactation:
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.

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

Skin and subcutaneous tissue disorders

Uncommon
- Transient burning or stinging following application of Acic 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 and urticaria.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No untoward effects would be expected if the entire contents of a 2g tube of aciclovir cream containing 100 mg of aciclovir were ingested orally.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D06BB03: Antibiotics and chemotherapeutics for dermatological use.
Antivirals

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.

Aciclovir cream significantly reduced episodes healing time ($p<0.02$) and time to pain resolution ($p<0.03$) compared with placebo cream in two large, double-blind, randomize clinical studies involving 1.385 subjects with recurrent herpes labialis. Overall approximately 60% of patients started treatment at an earlier lesion stage (prodrome or erythema) and 40% at a late lesion stage (papule or blister).

5.2 Pharmacokinetic properties

Limited pharmacology studies have shown only minimal systemic absorption of aciclovir following repeated topical administration of aciclovir cream.

5.3 Preclinical safety data

There is no experience of the effect of aciclovir cream on human female fertility. In patients with normal sperm count, chronically administered oral aciclovir 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 does not 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 systemic doses of acyclovir greatly in excess of those employed therapeutically. Two generation studies in mice did not reveal any effect of orally administered acyclovir on fertility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearoyl macrogolglycerides
Dimeticone 350
Cetyl alcohol
White soft paraffin
Liquid paraffin
Propylene glycol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

48 months.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate. Store in the original package.

6.5 Nature and contents of container

Acic Cold Sore 5% w/w Cream is packed in tubes of 2 g internally lacquered aluminium tubes with polyethylene caps.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Dilution: Acic Cold Sore 5%w/w Cream should not be diluted or used as a base for incorporation of other medicaments.

7 MARKETING AUTHORISATION HOLDER

Rowex Ltd.
Bantry
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0711/017/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd November 2012

Date of last renewal: 22nd November 2017

10 DATE OF REVISION OF THE TEXT

March 2018