SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lipsore 5% w/w cream
Cymex Ultra
Tesco Cold Sore 5% w/w cream
Essential Waitrose Cold Sore 5% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1g of Cream contains 50mg aciclovir

For excipients see 6.1.

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The treatment of herpes simplex virus infections of the of the lips and face (recurrent herpes labialis).

Immunocompromised Patients
Aciclovir Cream is not recommended for use in immunocompromised patients. Such patients must be advised to consult a physician concerning the treatment of any infection.

4.2 Posology and method of administration

Route of administration – topical
Adults and children: A thin film of cream should be applied to the infected and immediately adjacent skin areas 5 times daily at 4 hour intervals during the day, 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. 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.
Use in the elderly: No special comment

4.3 Contraindications

Hypersensitivity to aciclovir, valaciclovir, propylene glycol or any other ingredients of the preparation.

4.4 Special warnings and precautions for use

Aciclovir cream should only be used on cold sores on the mouth and face. It is not recommended for application to mucous membranes, such as in the mouth or eye and must not be used to treat genital herpes.

Particular care should be taken to avoid contact with eye. People with particularly severe recurrent *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.

Aciclovir cream is not recommended or use by people who know that they are immunocompromised. Such individuals should be encouraged to consult a physician concerning the treatment of any infection.

The excipient propylene glycol can cause skin irritations and the excipient cetyl alcohol can cause local skin reactions (e.g. contact dermatitis).

Ocular herpes
Aciclovir Cream must not be used for treatment of ocular herpes infections.

Genital herpes
Aciclovir Cream must not be used for treatment of genital herpes.

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

Systemic administration of aciclovir in internationally accepted standard tests did not produce embryotoxic or teratogenic effects in rats, rabbits 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.

A post-marketing aciclovir pregnancy registry has documented pregnancy outcomes in women exposed to any formulation of Lipsore Cream. The birth defects described amongst Lipsore Cream exposed subjects have not shown any uniqueness or consistent pattern to suggest a common cause.

The use of Lip Sore 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.

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 Lip Sore Cream would be expected to be insignificant.

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 expected to be insignificant.

Fertility

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

See Clinical Studies in section 5.2

4.7 Effects on ability to drive and use machines

None known.

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

- Mild drying or flaking of the skin
- Transient burning or stinging following application of Lipsore Cream
- 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 base rather than aciclovir.

Immune system disorders

Very rare

- Immediate hypersensitivity reactions including angioedema

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 Overdose

No untoward effects would be expected if the entire 2g contents of Lip Sore Cream containing 100mg of aciclovir were ingested orally or applied topically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Aciclovir is an antiviral agent which is highly active *in vitro* against herpes simplex virus (HSV) types 1 and 2. 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.

In two large, double blind, randomised clinical studies involving 1,385 subjects treated over 4 days for recurrent herpes labialis, aciclovir cream was compared to vehicle cream. In these studies, time from start of treatment to healing was 4.6 days using aciclovir Cream and 5.0 days using vehicle cream ($p<0.001$). Duration of pain was 3.0 days after start of treatment in the aciclovir Cream group and 3.4 days in the vehicle group ($p=0.002$). Overall, approximately 60% of patients started treatment at an early lesion stage (prodrome or erythema) and 40% at a late stage (papule or blister). The results were similar in both groups of patients.

5.2 Pharmacokinetic properties

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

Clinical Studies

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.

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.

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

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25ºC. Do not refrigerate or freeze.

6.5 Nature and contents of container

The cream is filled into tubes. The tubes consisting of aluminium are closed with a polypropylene cap. The tubes are packed into cardboard boxes together with package leaflets.

Pack size: Tubes of 2g.

6.6 Special precautions for disposal

Patients 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.

7 MARKETING AUTHORISATION HOLDER

Relonchem Limited
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WA8 0RP
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 20395/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/10/2005

10 DATE OF REVISION OF THE TEXT

03/04/2017