SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Virasorb Cold Sore Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5%w/w Aciclovir.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Cream
White to off-white, smooth cream without agglomerates, coarse lumps or contaminations and with characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Virasorb Cold Sore Cream is indicated for the treatment of recurrent herpes labialis.

4.2 Posology and method of administration

Dose:
Unless otherwise instructed, apply a thin layer of cream over the site of infection every four hours, five times a day.

Length of Treatment:
The cream should be applied to the lesion or developing lesion as soon as possible after the start of the infection. Treatment with Virasorb Cold Sore Cream is normally continued for five days. If there is no clinical benefit after 5 days, treatment should continue for up to another 5 days. If after ten days there is still no clinical (crusted vesicles, healing of lesions), treatment should be discontinued and patients should consult their physician.

Method of administration:
A cotton bud should be used to apply a sufficient quantity of Virasorb Cold Sore Cream to cover all lesions. The cream should be applied to visibly infected sites (vesicles, swelling, erythema) and the adjoining areas. If hands are used to apply the cream, they should be thoroughly washed before and after application to prevent further infection of the lesions by bacteria and to prevent autoinoculation of the virus to other mucous membrane and cutaneous sites not yet infected.

4.3 Contra-indications

Virasorb cream is contraindicated in patients known to be hypersensitive to aciclovir, valaciclovir, propylene glycol or any of the excipients of Virasorb cream

4.4 Special warnings and precautions for use

Cold Sore sufferers should be advised to avoid transmitting the virus by direct contact, particularly when active lesions are present.

Virasorb Cold Sore Cream should not be used on mucous membranes (e.g. oral cavity, eye, vagina) since local reactions may occur. Particular care should be taken to avoid accidental introduction into the eye.

Patients with severe Herpes Labialis should seek medical advice.

In severely immunocompromised patients (e.g. AIDS patients or bone marrow transplant recipients) oral aciclovir dosing should be considered. Such patients should be encouraged to consult their physician concerning the treatment of any infection and before starting treatment with Virasorb Cold Sore Cream.

Virasorb Cold Sore Cream must not be used for treatment of ocular herpes infections or for the treatment of genital herpes.

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

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions have been identified.

4.6 Pregnancy and lactation

Pregnancy:
Only about 0.1% of the aciclovir applied to the skin is detectable in the plasma. Concentrations are minimal so that no systemic effect should occur.

The use of aciclovir 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 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:
As there is only minimal systemic absorption of aciclovir, adverse effects on the infant during lactation are unlikely. Limited human data show that the drug does pass into breast milk following systemic administration. 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

Virasorb Cold Sore Cream is unlikely to impair a patient's ability to drive or to use machines.

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.

Clinical trial data have been used to assign frequency categories to adverse reactions observed during clinical trials with aciclovir 3% ophthalmic ointment. Due to the nature of the adverse events observed, it is not possible to determine unequivocally which events were related to the administration of the drug and which were related to the disease. Spontaneous reporting data has been used as a basis for allocating frequency for those events observed post-marketing.

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 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. The contact dermatitis is characterised by the occurrence of the cutaneous reactions as described above, with a widespread distribution.

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

4.9 Overdose

As only about 0.1% of the aciclovir applied to the skin is detectable in the plasma, overdose is unlikely. No untoward effects would be expected if the entire contents of the tube containing 100 mg of aciclovir cream were ingested orally.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

After penetrating into a cell infected by herpes simplex virus, aciclovir converts to aciclovir triphosphate. Viral replication is selectively inhibited by viral DNA polymerase.

Aciclovir does not eradicate latent virus.

5.2 Pharmacokinetic properties

Concentrations in the plasma are minimal so that there should be no systemic effect.

5.3 Preclinical safety data

Local effects:
Aciclovir cream was applied to guinea pig and rabbit skin (damaged and normal) once a day for 21 days. A mild irritation occurred after repeated application.

Since the amount of active ingredient absorbed from the cream does not lead to significant plasma levels (see paragraph 5.2 on pharmacokinetics) there were no further studies on this form of administration.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Self-emulsifying glyceryl monostearate (Arlatone 983S), Dimeticone, Cetyl Alcohol, Liquid Paraffin, White Soft Paraffin, Propylene Glycol, Purified Water.

6.2 Incompatibilities

None.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.
Do not refrigerate.

6.5 Nature and contents of container

Aluminium tube containing 2g of Virasorb Cold Sore Cream.
One tube is packed in a carton together with a patient information leaflet.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
Linthwaite Laboratories
Huddersfield
HD7 5QH
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0136

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21/11/2006

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26/11/2014