SUMMARY OF PRODUCTS CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vectatone 1% cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram of Vectatone cream contains 10 mg penciclovir.

Excipients with known effect:
Cetostearyl alcohol 77mg/g
Propylene glycol 416mg/g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

The cream is beige to light brown.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Vectatone cream is indicated for the treatment of cold sores (herpes labialis) caused by herpes simplex virus in immune competent patients.

4.2 Posology and method of administration

Posology

Adults (including older people) and children over 12 years of age:

Vectatone cream should be applied at approximately two hourly intervals during waking hours. Vectatone cream shall be applied with a clean finger in the amount required for the size of the affected area of skin. Treatment should be continued for 4 days.

Treatment should be started as early as possible after the first sign of an infection; but effect is also shown when the treatment is started later in the process (when the papule or vesicle has developed).

Paediatric population

Children (below 12 years of age):

No data are available for children below 12 years of age.

Method of administration

Cutaneous use. The cream should be applied with a clean finger onto the affected area of skin.

4.3 Contraindications

Hypersensitivity to the active substance, famciclovir or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

The cream should only be used on cold sores on the lips and around the mouth. It is not recommended for application to mucous membranes (e.g. in the eyes, mouth, nose or genitals). Particular care should be taken to avoid application in or near the eyes.

Treatment of HSV-infection with patients having concomitant dermatitis of other origin per oral has not been studied.

The cream should not be given to strongly immunosuppressed individuals such as AIDS-patients and transplanted patients since an increased risk of development of resistance cannot be excluded for these patients. Such patients must be advised to consult a physician before the treatment of any infection.

Excipient warnings

The cream contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

This medicine contains 416mg of propylene glycol per gram of cream which may cause skin irritation

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. Clinical trial experience has not identified any interactions resulting from concomitant administration of topical or systemic drugs with Vectatone cream.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is unlikely to be any cause for concern regarding adverse effects when the cream is used in pregnant women as systemic absorption of penciclovir following topical administration of Vectatone cream has been shown to be minimal (see Section 5.2).

Breast-feeding

There is no information on the excretion of penciclovir in human milk. There is unlikely to be any cause for concern regarding adverse effects when the cream is used in lactating women as systemic absorption of penciclovir following topical administration of Vectatone cream has been shown to be minimal (see Section 5.2).

Like all drugs, pregnant and breastfeeding women should avoid taking this product unless benefits outweigh the risks in view of the treating physician.

Fertility

There is no clinical information available about the effects of this product on fertility.

4.7 Effects on ability to drive and use machines

Vectatone has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Clinical trial experience has shown that there was no difference between Vectatone cream and placebo in the frequency or type of adverse reactions reported. The most common adverse reactions are application site reactions.

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: *very common* (>1/10); *common* (>1/100 to < 1/10); *uncommon* (>1/1,000 to < 1/100); *rare* (> 1/10,000 to < 1/1,000); *very rare* (<1/10,000), not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Event
General disorders and administration site conditions	Common	Application site reactions (including skin burning sensation, pain of skin, hypoaesthesia)
Immune system disorders	Not Known	Hypersensitivity, urticaria
Skin and subcutaneous tissue disorders	Not Known	Dermatitis allergic (including rash, pruritus, blisters and oedema)

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 national reporting system listed in

[To be completed nationally]

4.9 Overdose

No untoward effects would be expected even if the entire contents of a container of Vectatone cream were ingested orally; penciclovir is poorly absorbed following oral administration. However, some irritation in the mouth could occur. No specific treatment is necessary if accidental oral ingestion occurs.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Aantivirals, ATC code: D06BB06

Mechanism of action

Penciclovir has demonstrated *in vivo* and *in vitro* activity against herpes simplex viruses (types 1 and 2) and varicella zoster virus. Penciclovir affetcs virus-infected cells and is rapidly converted to triphosphate (mediated via virus-induced thymidine kinase).

Pharmacodynamic effects

Penciclovir triphosphate is present in infected cells for more than 12 hours and inhibits replication of viral DNA. The half-live of penciclovir triphosphate is 9, 10 and 20 hours, respectively, in cells infected with varicella zoster virus, herpes simplex virus type 1 and herpes simplex virus type 2, respectively. In uninfected cells exposed to penciclovir, concentrations of penciclovir triphosphate are barely detectable. Accordingly, uninfected cells are unlikely to be affected by therapeutic concentrations of penciclovir.

Clinical efficacy and safety

Treatment with Vectatone cream reduces the time for excretion of virus, for pain and for healing with up to 24 hours.

5.2 Pharmacokinetic properties

Absorption
Following application of Vectatone cream in a healthy human volunteer study at a daily dose of 180 mg penciclovir (approximately 67 times the proposed therapeutic daily dose), to occluded and abraded skin for 4 days, penciclovir was not quantifiable in plasma and urine.

5.3 Preclinical safety data

Local administration of penciclovir 5% cream for 4 weeks to rats and rabbits was well tolerated. There was no evidence of local reactions when administered to guinea pigs.

A full preclinical programme has been conducted for penciclovir administrated intravenously. The results of these studies did not raise any safety concerns regarding local use of penciclovir cream. There is a minimal systemic absorption of penciclovir following local administration.

The results of extensive mutagenicity studies *in vitro* and *in vivo* do not indicate that locally administered penciclovir poses a genotoxic systemic risk to human.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, soft white Paraffin, liquid Cetostearyl alcohol Propylene glycol
Macrogol cetostearyl ether 1000

Iron oxide, red and yellow (E172)

Water, purified

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 Years

6.4 Special precautions for storage

Store below 25 °C. Do not freeze.

6.5 Nature and contents of container

2 g and 5 g aluminium tube closed with a plastic screw cap (polyethene). The tube is lined on the inside with an epoxy-phenol resin lacquer.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special
requirements.

7 MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8 MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10 DATE OF REVISION OF THE TEXT

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