Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vectavir Cold Sore Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of the cream contains 10 mg penciclovir.

Excipients with known effect:
cetostearyl alcohol, propyleneglycol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
Smooth white cream of homogeneous appearance.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Vectavir Cold Sore Cream is indicated for the treatment of cold sores (herpes labialis) in adults (including older people) and children over 12 years of age.

4.2 Posology and method of administration

Posology

Adults (including older people)and children over12 years ofage:

Vectavir Cold Sore Cream should be applied at approximately two hourly intervals during waking hours.

Paediatric population

Children (under 12 years):
The safety and efficacy of Vectavir Cold Sore Cream in children below 12 years of age have not been established.
No data are available.

Method of administration

Vectavir Cold Sore Cream may be applied with a clean finger, or with a single-use applicator (for packages which contain applicators), in the amount required for the size of the affected area of skin. Treatment should becontinued for 4 days.

Treatment should be started as early as possible after the first sign of an infection.

4.3 Contraindications

Hypersensitivity to penciclovir, famciclovir or to any of theexcipients 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, or nose or on the genitals). Particular care should be taken to avoid application in or near the eyes.
Severely immunocompromised patients (eg AIDs patients or bone marrow transplant recipients) should be encouraged to consult a physician in case oral therapy is indicated.
The cream contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis). It also contains 416 mg of propylene glycol per gram of cream, which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interactions

Clinical trial experience has not identified any interactions resulting from concomitant administration of topical or systemic drugs with Vectavir Cold Sore 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 Vectavir Cold Sore Cream has been shown to be minimal (see Section 5.2).

Since the safety of penciclovir in human pregnancy has not been established, Vectavir Cold Sore Cream should only be used during pregnancy or in nursing mothers on the advice of a doctor, if the potential benefits are considered to outweigh the potential risks associated with treatment.

Breast feeding

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 Vectavir Cold Sore Cream has been shown to be minimal (see Section 5.2).

There is no information on excretion of penciclovir in human milk.

4.7 Effects on ability to drive and use machines

Vectavir Cold Sore Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

Vectavir Cold Sore Cream has been well-tolerated in human studies. Clinical trial experience has shown that there was no difference between Vectavir Cold Sore Cream and placebo in the rate or type of adverse reactions reported. The most common events are application site adverse events.

Tabulated list of adverse 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 (SOC) **Frequency**	**Adverse Reaction**
General disorders and administration site condition	
Common	Application site reactions (including skin burning sensation, pain of skin, hypoaesthesia).

Post-marketing surveillance has revealed the following adverse events (all reactions were either localised or generalised). Adverse events from post-marketing experience are difficult to calculate a frequency for and therefore the events are listed as unknown frequency.

System Organ Class (SOC) Frequency	Adverse Reaction
Immune system disorders	
Not known Not known	Hypersensitivity Urticaria
Skin and subcutaneous disorders	
Not known	Dermatitis allergic (including rash, pruritus, blisters and oedema)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 even if the entire contents of a container of Vectavir Cold Sore 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: Topical antiviral agent, 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. In virus-infected cells penciclovir is rapidly and efficiently converted into a triphosphate (mediated via virus-induced thymidine kinase). Penciclovir triphosphate persists in infected cells for more than 12 hours where it inhibits replication of viral DNA and has a half-life of 9, 10 and 20 hours in cells infected with varicella zoster virus, herpes simplex virus type 1 and herpes simplex virus type 2 respectively. In uninfected cells treated with penciclovir, concentrations of penciclovir triphosphate are only barely detectable. Accordingly, uninfected cells are unlikely to be affected by therapeutic concentrations of penciclovir.

Clinical efficacy and safety

In clinical studies, Vectavir Cold Sore Cream treated patients healed 30% faster than placebo (up to one day earlier), pain resolution was 25-30% faster (median improvement of up to one day) and infectivity resolved up to 40% faster (one day earlier) than placebo.

5.2 Pharmacokinetic properties

Following application of Vectavir Cold Sore Cream in a human volunteer study at a daily dose of 180mg penciclovir (approximately 67 times the proposed daily clinical dose), to occluded and abraded skin for 4 days, penciclovir was not quantifiable in plasma and urine.

5.3 Preclinical safety data

General toxicology

Topical application of 5% Vectavir Cold Sore Cream for 4 weeks to rats and rabbits was well tolerated. There was no evidence of contact sensitisation in guinea pigs.

A full programme of studies has been completed using intravenous penciclovir. These studies did not raise any safety concerns regarding topical use of Vectavir Cold Sore Cream. There is a minimal systemic absorption of penciclovir following topical administration.

Genotoxicity and Reproductive toxicity

Animal studies have not shown any embryotoxic or teratogenic effects with penciclovir given intravenously (at doses greater than 1200 times those recommended for clinical use via topical application), nor were there any effects on male and female fertility and general reproductive performance (at doses greater than 1600 times those recommended for clinical use via topical application). Studies in rats show that penciclovir is excreted in the breastmilk of lactating females given oral famciclovir (famciclovir; the oral form of penciclovir, is converted in vivo to penciclovir).

The results of a wide range of mutagenicity studies invitro and invivo indicates that penciclovir does not pose a genotoxic risk to man.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Liquid paraffin
Cetostearyl alcohol (see section 4.4 'Special warnings and precautions for use')
Propylene glycol (see section 4.4 'Special warnings and precautions for use')
Cetomacrogol 1000
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2g and 5g aluminium tubes - 3 years.
2g plastic airless pump dispenser - 2 years.

6.4 Special precautions for storage

Store at temperatures not exceeding 30°C.
Do not freeze.

6.5 Nature and contents of container

2g and 5g aluminium tube. May be supplied with 20 single-use Low Density Polyethylene(LDPE) applicators.

2g plastic airless pump dispenser.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Chefaro Ireland DAC
The Sharp Building
Hogan Place
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1186/020/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 February 2001

Date of last renewal: 27 February 2006

10 DATE OF REVISION OF THE TEXT

June 2021