SCHEDULING STATUS:

S1

1. NAME OF THE MEDICINE

BETA-VIRA TOPICAL CREAM (0,05 g, Cream)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g contains:

Acyclovir 0,05 g

Preservative:

Benzyl alcohol 0,75 % *m/m*

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream.

Smooth, white, soft cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BETA-VIRA TOPICAL CREAM is applied to the lips in the early treatment of recurrent *Herpes simplex* virus infections.

4.2 Posology and method of administration

Posology

Adults and Children:

BETA-VIRA TOPICAL CREAM may be applied five to six times daily or every three to four hours, for periods of five to ten days.

Topical treatment of lesions caused by *Herpes simplex* should be initiated as early as possible.

It is particularly important to start treatment of recurrent episodes during the prodromal period or when the lesions first appear.

Method of administration

Topical application on lesions.

4.3 Contraindications

BETA-VIRA TOPICAL CREAM is contraindicated in:

Patients with known hypersensitivity to acyclovir, valacyclovir and propylene glycol or to any of the excipients in the formulation (see **section 6.1**).

4.4 Special warnings and precautions for use

Topical applications of **BETA-VIRA TOPICAL CREAM** may produce burning or erythema.

In severely immune compromised patients (e.g., AIDS patients or bone marrow transplant recipients), topical application of **BETA-VIRA TOPICAL CREAM** may be inappropriate.

BETA-VIRA TOPICAL CREAM is intended for cutaneous use only and is not recommended for application to mucous membranes, such as in the mouth, eye, or vagina.

Care should be taken to avoid accidental introduction into the eye.

Resistance has been reported with varicella zoster virus.

BETA-VIRA TOPICAL CREAM contains cetostearyl alcohol and may cause local skin reactions such as contact dermatitis.

BETA-VIRA TOPICAL CREAM contains 500 mg of propylene glycol per 5 g and may cause skin irritation.

BETA-VIRA TOPICAL CREAM contains benzyl alcohol and may cause allergic reactions and mild local irritation.

Severe cutaneous adverse reactions (SCARs):

Drug reaction with eosinophilia and systemic symptoms (DRESS)

DRESS, which can be life-threatening or fatal, has been reported in association with **BETA-VIRA TOPICAL CREAM** treatment. At the time of prescription, patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of DRESS appear, **BETA-VIRA TOPICAL CREAM** should be withdrawn immediately, and an alternative treatment considered (as appropriate). If the patient has developed DRESS with the use of **BETA-VIRA TOPICAL CREAM**, treatment with **BETA-VIRA TOPICAL CREAM** must not be restarted in this patient at any time.

4.5 Interaction with other medicines and other forms of interaction

Probenecid increases the acyclovir mean half-life and area under the plasma concentration curve.

Other medicines affecting renal physiology could potentially influence the pharmacokinetics of acyclovir.

No clinically significant interactions have been identified.

4.6 Fertility, pregnancy, and lactation

Pregnancy:

The safety of **BETA-VIRA TOPICAL CREAM** in pregnancy has not been established.

Breastfeeding:

The safety of **BETA-VIRA TOPICAL CREAM** in lactation has not been established.

Limited human data show that acyclovir does pass into breast milk.

Fertility:

Information on the effect of **BETA-VIRA TOPICAL CREAM** on human female fertility is not available. It has been established that **BETA-VIRA TOPICAL CREAM** does not have any clinically significant effect on male fertility.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use of machines has not been established with the use of **BETA-VIRA TOPICAL CREAM**.

4.8 Undesirable effects

The following undesirable effects are classified according to MedDRA system organ class using the following convention: frequent, less frequent and frequency unknown.

Frequency	**System organ class**	**Undesirable effects**
Less frequent	Skin and subcutaneous tissue disorders	• transient burning or stinging; • Erythema or mild drying and flaking of the skin; • Itching; • Contact dermatitis following application.

Less frequent	Immune system disorders	• Immediate hypersensitivity reactions including angioedema.
Post-marketing experience: The following adverse reaction has been identified during post approval use of **BETA-VIRA TOPICAL CREAM.** Immune system: Drug reaction with eosinophilia and systemic symptoms (DRESS) **(**see **Section 4.4).**		

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Adverse Drug Reactions may also be reported to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

4.9 Overdose

Treatment of overdosage of **BETA-VIRA TOPICAL CREAM** is symptomatic and supportive. In overdose, side effects can be precipitated and /or be of increased severity (see **section 4.8**).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 20.2.8 Antiviral agents

Mechanism of action:

Acyclovir has antiviral activity that is essentially confined to the herpes viruses. It is particularly active *in vitro* against *Herpes simplex type 1* and *Herpes simplex type 2*.

Acyclovir inhibits viral replication by inhibiting DNA synthesis.

5.2 Pharmacokinetic properties

Acyclovir is phosphorylated intracellularly by viral thymidine kinase to the monophosphate with subsequent conversion to the diphosphate and the active triphosphate. This active form inhibits the herpes virus DNA polymerase enzyme as well as being incorporated into viral DNA. Normal cellular processes are not affected.

Pharmacology studies have shown only minimal systemic absorption of acyclovir following repeated topical administration of acyclovir cream.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin

White Soft Paraffin

Self-Emulsifying Glyceryl Monostearate

Cetostearyl Alcohol

Cetomacrogol 1000 (Volpo CS 20)

Propylene Glycol

Benzyl Alcohol

Hydrochloric Acid

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light.

6.5 Nature and contents of container

BETA- VIRA TOPICAL CREAM is packed in collapsible aluminium tubes, containing 2 g of cream.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer care: 0860 ADCOCK / 232625

Marketed by: United Pharma Marketing (Pty) Ltd.

8. REGISTRATION NUMBER

31/20.2.8/0549

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

25 October 2000

10. DATE OF REVISION OF THE TEXT

02 December 2024

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