PROPOSED PROFESSIONAL INFORMATION FOR

ACITOP

SCHEDULING STATUS **S1**

1. NAME OF THE MEDICINE

ACITOP (5,0 % *w/w* Acyclovir, cream)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 50 mg of Acyclovir (5,0 % *w/w* Acyclovir).

Preservative: Chlorocresol 0,12 % *w/w*

For the full list of excipients, see **section 6.1**.

3. PHARMACEUTICAL FORM

Cream.

A white to off-white smooth cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ACITOP is indicated for the symptomatic treatment of herpes simplex infections of the lips.

Both the initial and recurrent infections can be successfully treated.

4.2 Posology and method of administration

Posology

Adults and children:

Apply 5 to 6 times daily at four-hourly intervals. Therapy should be initiated as soon as possible following the onset of signs and symptoms of herpes simplex infection. This is particularly important in the treatment of recurrent episodes. Treatment should be continued for 5 days. If healing has not occurred, the treatment may be prolonged for up to 10 days. Do not exceed the recommended dose.

Method of administration

Cover all lesions adequately.

Use a finger cot or a rubber glove to prevent auto inoculation.

4.3 Contraindications

ACITOP is contraindicated in:

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

4.4 Special warnings and precautions for use

In severely immune compromised patients (e.g., AIDS patients or bone marrow transplant recipients) topical ACITOP may be inappropriate.

ACITOP is intended for cutaneous use only and is not recommended for application to mucous membranes, such as in the mouth, eye or vagina.

Particular care should be taken to avoid accidental introduction into the eye.

Resistance has been reported with varicella zoster virus.

ACITOP contains chlorocresol and may cause allergic reactions.

ACITOP contains cetostearyl alcohol and may cause local skin reactions (e.g., contact dermatitis).

ACITOP contains propylene glycol and may cause skin irritation.

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. However, clinical experience has not identified other drug interactions with acyclovir.

No clinically significant interactions have been identified.

Dilution: ACITOP contains a specially formulated base and should not be diluted or used as a base for incorporation of other medicaments.

4.6 Fertility, pregnancy and lactation

The safety of ACITOP in pregnancy and lactation has not been established. Limited human data show that acyclovir does pass into breast milk.

There is no information on the effect of ACITOP on human female fertility. In a reported study of 20 male patients with normal sperm count, oral acyclovir administered at doses of up to 1 g per day for up to six months has been shown to have no clinically significant effect on sperm count, motility or morphology.

4.7 Effects on ability to drive and use machines

The medicinal product has no influence on the ability to drive or operate machinery.

4.8 Undesirable effects

Tabulated summary of adverse reactions

The following adverse reactions have been classified according to the following categories, frequent, less frequent and frequency unknown.

MedDRA system organ Class	Frequency	Side effects
Skin and subcutaneous tissue disorders	*Less frequent*	Transient stinging, burning or erythema may occur. Mild drying and flaking of the skin may occur. Itching. 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 acyclovir.
Immune system disorders	*Less frequent*	Immediate hypersensitivity reactions including angioedema.

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 asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 and to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

Treatment is symptomatic and supportive if accidental ingestion has occurred. Acyclovir is dialysable (See **section 4.8** and **section 4.4**)

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification

Pharmacotherapeutic group

A 20.2.8. Antiviral agent.

Acyclovir is an acyclic guanine nucleoside analogue that lacks the 3'-hydroxyl on the side chain.

It is active against herpes simplex virus type 1 and 2.

Toxicity to mammalian host cells is low.

5.2 Pharmacokinetic properties

Acyclovir is phosphorylated intracellularly by viral thymidine kinase to the active triphosphate that inhibits viral DNA synthesis and replication by inhibiting the viral DNA polymerase enzymes. The active triphosphate is also incorporated into the herpes virus 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

Cetomacrogol 1000

Cetostearyl alcohol

Chlorocresol

Dimethicone

Disodium EDTA

Liquid paraffin

Propylene glycol

Self emulsifying glyceryl monostearate

White soft paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

- Store at or below 25 °C.

6.5 Nature and contents of container

ACITOP is packed in pure aluminium collapsible tubes, containing 2 g, 5 g or 10 g of cream.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

8. REGISTRATION NUMBER(S)

32/20.2.8/0719

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 August 2000

10. DATE OF REVISION OF THE TEXT

06 June 2023

Namibia: NS2 06/20.2.8/0099