APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S4**

1. NAME OF THE MEDICINE

ADCO ACYCLOVIR TOPICAL CREAM, 5,0 % w/w, cream

2. QUALITATIVE AND QUANTATIVE COMPOSITION

Each 1 g contains acyclovir 0,05 g (5,0 % w/w)

Preservative: Benzyl alcohol 0,75 % m/m

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM:

Cream.

Smooth, white soft cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

S4

Aciclovir is effective in the treatment of viral infections due to *Herpes simplex* type 1 and type 2 of the skin and genitalia in the initial and recurrent situation.

4.2 Posology and method of administration

Adults and children:

The topical cream may be applied five or six times daily every three or 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.

Paediatric population:

As applicable to adults.

Method of administration

Topical application.

4.3 Contraindications

- Hypersensitivity to aciclovir and propylene glycol or to any of the excipients of ADCO-ACYCLOVIR TOPICAL CREAM listed in section 6.1.
- Safety of ADCO-ACYCLOVIR TOPICAL CREAM in pregnancy and lactation has not been established.

4.4 Special warnings and precautions for use

Topical applications of acyclovir may sometimes produce burning or erythema.

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 associate with ADCO-ACYCLOVIR 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 If signs and symptoms suggestive of DRESS appear, ADCO-ACYCLOVIR TOPICAL CREAM should be withdrawn immediately and an alternative treatment considered (as appropriate). If the patient has developed DRESS with the use of ADCO-ACYCLOVIR TOPICAL CREAM, treatment with ADCO-ACYCLOVIR TOPICAL CREAM must not be restarted in this patient at any time.

In severely immune compromised patients (e.g., AIDS patients or bone marrow transplant recipients) oral acyclovir dosing should be considered. Such patients should be encouraged to consult a physician concerning the treatment of any infection.

ADCO-ACYCLOVIR TOPICAL CREAM is not recommended for application to mucous membranes such as in the mouth, eye or vagina, as it may be irritant.

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

ADCO-ACYCLOVIR TOPICAL CREAM contains a specially formulated base and should not be diluted or used as a base for the incorporation of other medicaments.

ADCO-ACYCLOVIR TOPICAL CREAM contains 30 mg per gram of cetostearyl alcohol and may cause local skin reactions (e.g., contact dermatitis).
ADCO-ACYCLOVIR TOPICAL CREAM contains 100 mg per gram of propylene glycol and may cause skin irritation.
ADCO-ACYCLOVIR TOPICAL CREAM contains 7.5 mg per gram of benzyl alcohol and may cause allergic reactions and mild local irritation.

4.5 Interaction with other medicines and other forms of interaction

Probenecid increases the 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 medicines interactions with acyclovir.
No clinically significant interactions have been identified.

4.6 Fertility, Pregnancy and breast-feeding

Pregnancy:

The safety of ADCO-ACYCLOVIR TOPICAL CREAM in pregnancy has not been established.

Breastfeeding:

The safety of ADCO-ACYCLOVIR TOPICAL CREAM in lactation has not been established. Limited human data show that acyclovir does pass into breast milk.

Fertility:

There is no information on the effect of 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

This medicine has no influence on ability to drive or operate machinery.

4.8 Undesirable effects

Tabulated list of adverse reactions

MedDRA system organ Class	Frequency	Side effects
Skin and subcutaneous tissue disorders	*Less frequent*	Transient stinging or burning, erythema. 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 and uricaria.

		Drug reaction with eosinophilia and systemic symptoms (DRESS) (see section 4.4)*

*Post-marketing experience

Reporting of suspected adverse reactions

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

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Class: A 20.2.8 Antiviral agents

Mechanism of action

Aciclovir 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. Aciclovir inhibits viral replication by inhibiting DNA synthesis. This inhibition is due to intracellular conversion of acyclovir by viral thymidine kinase to the monophosphate with subsequent conversion to the diphosphate and the active triphosphate. This active (acyclovir triphosphate) form inhibits the herpes virus DNA polymerase enzyme as well as being incorporated into viral DNA.

Toxicity to mammalian host cells is low.

5.2 Pharmacokinetic properties

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 AR ‘(for pH-adjustment)

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

ADCO-ACYCLOVIR TOPICAL CREAM is packed in aluminium Collapsible tubes of 2 g and 10 g.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF THE CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685,

Republic of South Africa.

Customer care: 0860 ADCOCK I 232625

8 REGISTRATION NUMBER(S)

28/20.2.8/0369

9 DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

01/04/1996

10 DATE OF REVISION OF THE TEXT

23/01/2026

Namibia		
	Product name	**Registration number**
	ADCO-ACYCLOVIR TOPICAL CREAM 2g	05/20.2.8/0114
Kenya		
	ADCO-ACYCLOVIR TOPICAL CREAM 2g	H98/014
Mauritius		
	ADCO-ACYCLOVIR TOPICAL CREAM 2g	R9092/02/14
Botswana		
	ADCO-ACYCLOVIR TOPICAL CREAM 2g	BOT1001636A