

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

ADCO-ACYCLOVIR TOPICAL CREAM

Acyclovir

Read all of this leaflet carefully because it contains important information for you

ADCO-ACYCLOVIR TOPICAL CREAM is available without a doctor's prescription. Nevertheless, you still need to use ADCO-ACYCLOVIR TOPICAL CREAM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ADCO-ACYCLOVIR TOPICAL CREAM with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What ADCO-ACYCLOVIR TOPICAL CREAM is and what it is used for
2. What you need to know before you use ADCO-ACYCLOVIR TOPICAL CREAM
3. How to use ADCO-ACYCLOVIR TOPICAL CREAM
4. Possible side effects
5. How to store ADCO-ACYCLOVIR TOPICAL CREAM
6. Contents of the pack and other information.

1. What ADCO-ACYCLOVIR TOPICAL CREAM is and what it is used for

ADCO-ACYCLOVIR TOPICAL CREAM is a smooth white soft cream for application

to the lips. It contains acyclovir which belongs to a class of medicine known as antivirals.

ADCO-ACYCLOVIR TOPICAL CREAM is indicated for the treatment of cold sores (Herpes simplex virus infections); it slows the growth of the virus and speeds the healing of cold sore blisters.

2. What you need to know before you use ADCO-ACYCLOVIR TOPICAL CREAM

- if you are hypersensitive (allergic) to acyclovir or any of the other ingredients of ADCO-ACYCLOVIR TOPICAL CREAM (listed in section 6).

Warnings and Precautions

Take special care with ADCO-ACYCLOVIR TOPICAL CREAM

- Serious skin reactions such as Drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in patients receiving ADCO-ACYCLOVIR TOPICAL CREAM. Combination of symptoms such as fever, severe rash, peeling skin, swelling of the face, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinating less often, less urine can be seen. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using ADCO-ACYCLOVIR TOPICAL CREAM immediately and contact your doctor (see section 4).
- do not use the cream if it causes burning, redness of skin.
- do not use on mucous membranes as the cream can cause irritation.
- do not use this cream to treat mouth ulcers or for herpes infections which are in or near your eyes, or in the genital area.
- do not use this cream if your cold sore is severe; you must see a doctor for advice on how to treat it.
- only use ADCO-ACYCLOVIR TOPICAL CREAM to treat blisters on your lips.
- If your immune system is weakened for any reason e.g. HIV infection, a bone marrow transplant or cancer treatment, do not treat yourself with ADCO-ACYCLOVIR TOPICAL CREAM; you must seek advice from your doctor.

While you have a cold sore, avoid spreading the infection to others by washing your hands carefully before and after applying the cream, and avoid touching the infected skin with anything else, especially with your hands or with towels.

Applicant: Adcock Ingram Limited
Proprietary name and dosage form: Adco-Acyclovir topical cream
Strength: Each one gram contains acyclovir 0,05 g

Other medicines and ADCO-ACYCLOVIR TOPICAL CREAM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Driving and using machines

ADCO-ACYCLOVIR TOPICAL CREAM has no influence on the ability to drive or operate machinery.

ADCO-ACYCLOVIR TOPICAL CREAM contains some of the ingredients

ADCO-ACYCLOVIR TOPICAL CREAM contains:

- Cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).
- Propylene glycol which may cause skin irritation. Because this medicine contains propylene glycol, do not use it on open wounds or large areas of broken or damaged skin (such as burns) without checking with your doctor or pharmacist.
- Benzyl alcohol may cause allergic reactions and mild local irritation.

3. How to use ADCO-ACYCLOVIR TOPICAL CREAM

FOR EXTERNAL USE ONLY.

Do not share medicines prescribed for you with any other person.

Always use ADCO-ACYCLOVIR TOPICAL CREAM exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the stated dose.

It is best to apply the product as soon as possible after the start of the infection.

For application to the surface of the skin only:

1. Wash your hands thoroughly before use.
2. Apply a thin layer of the cream to the infected area and the skin immediately next to it, 5 or 6 times a day at intervals of about 3 or 4 hours.

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3. Wash your hands again, to avoid spreading the infection.

4. Use the cream for 5 to 10 days.

If you use more ADCO-ACYCLOVIR TOPICAL CREAM than you should or if you or a child accidentally swallow the cream.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the packet with you to help identification.

If you forget to use ADCO-ACYCLOVIR TOPICAL CREAM

If you miss a treatment, apply the cream as soon as you remember, and apply the remaining doses for that day at evenly spaced intervals.

4. Possible side effects

ADCO-ACYCLOVIR TOPICAL CREAM can have side effects.

Not all side effects reported for ADCO-ACYCLOVIR TOPICAL CREAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO-ACYCLOVIR TOPICAL CREAM, please consult your health care provider for advice.

If any of the following happens, stop using ADCO-ACYCLOVIR TOPICAL CREAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the lips, face and/or eyelids (angioedema)
- rash, itchy skin, weal.
- The adverse reaction of the skin may appear as rashes with or without blisters. Skin irritation, oedema (DRESS) and fever and flu-like symptoms may occur.

These are all very serious side effects. If you have them, you may have had a serious reaction to ADCO-ACYCLOVIR TOPICAL CREAM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

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- A burning or stinging feeling after applying the cream that goes away.
- Itching.
- Mild drying or flaking of your skin.
- Redness of your skin.
- Skin rash.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADCO-ACYCLOVIR TOPICAL CREAM.

5. How to store ADCO-ACYCLOVIR TOPICAL CREAM

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light.
- Do not refrigerate.
- Store in the original package and keep the tube in the outer carton.
- Do not use ADCO-ACYCLOVIR TOPICAL CREAM after the expiry date which is stated on the tube/carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

The active substance is acyclovir and each gram of cream contains acyclovir 0,05 g (5,0 % w/w).

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The other ingredients are Cetomacrogol 1000 (Volpo CS 20), cetostearyl alcohol, hydrochloric acid AR, liquid paraffin, propylene glycol, self-emulsifying glyceryl monostearate, white soft paraffin, benzyl Alcohol (preservative), hydrochloric acid AR (for pH-adjustment).

What ADCO-ACYCLOVIR TOPICAL CREAM looks like and contents of the pack

ADCO-ACYCLOVIR TOPICAL CREAM is a smooth, white soft cream.

ADCO-ACYCLOVIR TOPICAL CREAM is available in tubes of 2 g and 10 g.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685,

Republic of South Africa.

This leaflet was last revised in

23/01/2026

Registration number (s)

28/20.2.8/0369

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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