

PATIENT INFORMATION LEAFLET FOR
ACITOP

Scheduling Status

S1

ACITOP 5,0 % w/w, Acyclovir cream

Acyclovir

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

ACITOP is available without a doctor's prescription. Nevertheless, you still need to use ACITOP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACITOP 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 ACITOP is and what it is used for
2. What you need to know before you use ACITOP
3. How to use ACITOP
4. Possible side effects
5. How to store ACITOP
6. Contents of the pack and other information.

1. What ACITOP is and what it is used for

ACITOP is a smooth off-white cream for application to the lips. It contains acyclovir which belongs to a class of medicine known as antivirals.

ACITOP 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 ACITOP

Do not use ACITOP if you:

- are hypersensitive (allergic) to acyclovir, valacyclovir or propylene glycol or any of the other ingredients of ACITOP (see **section 6** and end of **section 2**).

Warnings and Precautions

Take special care with ACITOP:

- do not use on mucous membranes as the cream can cause irritation.
- do not use this cream to treat mouth ulcers.
- 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 ACITOP to treat blisters on your lips.
- if you develop a skin reaction that includes a fever, facial swelling and a rash or small blisters containing pus/liquid.

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.

Other medicines and ACITOP

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ACITOP.

Driving and using machinery

ACITOP has no influence on the ability to drive or operate machinery.

Important information about some of the ingredients

ACITOP contains:

- chlorocresol and may cause allergic reactions.
- 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.

3. How to use ACITOP

FOR EXTERNAL USE ONLY.

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

Always take ACITOP exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

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, 6 times a day at intervals of about 4 hours.
3. Wash your hands again, to avoid spreading the infection.
4. Use the cream for up to 5 days. If the infection has not healed after this time, you can continue to use it for a further 5 days.

If your cold sore gets worse during the treatment period, or if it has not healed after 10 days of treatment, STOP using the cream and seek advice from your doctor.

If you use more ACITOP than you should or if you or a child accidentally swallow the cream, contact your doctor or nearest hospital immediately. Take the packet with you to help identification.

If you forget to use ACITOP

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

Like all medicines, ACITOP can cause side effects, although not everybody gets them.

Not all side effects reported for ACITOP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ACITOP, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using ACITOP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe allergic reaction symptoms which include, sudden wheeziness, fluttering or tightness in the chest, collapse, swelling of eyelids, face, lips or elsewhere, skin rash or weals.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ACITOP. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Uncommon/Less frequent side effects:

- 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, 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 the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafety@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ACITOP.

5. How to store ACITOP

- Store all medicines out of reach of children.
- Do not store above 25 °C.
- Do not refrigerate.
- Store in the original package and keep the tube in the outer carton.
- Do not use ACITOP 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

What ACITOP contains

The active substance is acyclovir and each gram of cream contains 50 mg of Acyclovir (5,0 % w/w Acyclovir).

The other ingredients are disodium EDTA, cetomacrogol 1000, cetostearyl alcohol, dimethicone, liquid paraffin, propylene glycol, chlorocresol, white soft paraffin, self emulsifying glyceryl monostearate.

What ACITOP looks like and contents of the pack

ACITOP is a smooth white to off-white cream and is available in aluminium tubes containing 2 g, 5 g or 10 g of cream.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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