

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

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

Acyclovir

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

BETA-VIRA TOPICAL CREAM is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **BETA-VIRA TOPICAL CREAM** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **BETA-VIRA 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 7 days.

What is in this leaflet

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

1. What BETA-VIRA TOPICAL CREAM is and what it is used for

BETA-VIRA TOPICAL CREAM contains acyclovir, which belongs to a class of medicine known as antivirals.

BETA-VIRA TOPICAL CREAM is used in the early treatment of cold sores (Herpes simplex virus). It slows the growth of the virus and speeds up the healing of cold sore blisters.

2. What you need to know before you use BETA-VIRA TOPICAL CREAM

Do not use BETA-VIRA TOPICAL CREAM

- If you are allergic to acyclovir and propylene glycol or to any of the other ingredients of **BETA-VIRA TOPICAL CREAM** (listed in section 6).

Warnings and precautions

Special care should be taken with **BETA-VIRA TOPICAL CREAM**

- If burning occurs or you develop erythema (redness of the skin).
- Do not use on mucous membranes such as in the mouth, eye or vagina as the cream can cause irritation.
- Do not use this cream if you have severe cold sores; you must see a doctor for advice on how to treat it.
- Avoid accidental introduction into the eyes.
- There is reduced effectiveness of **BETA-VIRA TOPICAL CREAM** in treating varicella zoster virus (virus causing chickenpox).
- If you develop local skin reactions, such as contact dermatitis (itchy rash).

- Serious skin reactions such as Drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in patients receiving **BETA-VIRA 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 **BETA-VIRA TOPICAL CREAM** immediately and contact your doctor (see **Section 4**).

Other medicines and BETA-VIRA TOPICAL CREAM

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

Probenecid increases the acyclovir mean half-life and area under the plasma concentration curve (time taken for the medicine in your body to be reduced in half and actual body exposure to the medicine after administration).

Other medicines affecting renal physiology (how the kidneys function) could potentially influence the pharmacokinetics (what the body does to the drug) of acyclovir.

No clinically significant interactions have been identified.

Pregnancy and, breastfeeding and fertility

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 using **BETA-VIRA TOPICAL CREAM**.

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. No clinical significance of the effect **BETA-VIRA TOPICAL CREAM** on male fertility has been established.

Driving and using machines

BETA-VIRA TOPICAL CREAM has no influence on the ability to drive or operate machinery.

BETA-VIRA TOPICAL CREAM contains cetostearyl alcohol

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

BETA-VIRA TOPICAL CREAM contains propylene glycol

BETA-VIRA TOPICAL CREAM contains propylene glycol and may cause skin irritation.

BETA-VIRA TOPICAL CREAM contains benzyl alcohol

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

3. How to use BETA-VIRA TOPICAL CREAM

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

FOR EXTERNAL USE ONLY.

Always use **BETA-VIRA TOPICAL CREAM** exactly as described in this leaflet, or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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 cold sore blisters (topical lesions) caused by Herpes simplex (viral infection) should be started as early as possible.

In repeated cases of cold sore blisters, start treatment as soon as possible when the cold sore blisters appear.

If you use more BETA-VIRA TOPICAL CREAM than you should

If you use more **BETA-VIRA TOPICAL CREAM** 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 with identification.

If you overdose, side-effects can be of increased severity.

If you forget to use BETA-VIRA 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

BETA-VIRA TOPICAL CREAM can have side effects.

Not all side effects reported for **BETA-VIRA TOPICAL CREAM** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using **BETA-VIRA TOPICAL CREAM**, please consult your health care provider for advice.

If any of the following happens, stop using **BETA-VIRA 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.
- rash, itchy skin, weal.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **BETA-VIRA TOPICAL CREAM**. You may need urgent medical attention or hospitalization.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- A burning or stinging feeling after applying the cream that goes away;
- Erythema (reddening of the skin) or mild drying and flaking of the skin;
- Itching;

- An itchy rash caused by direct contact with **BETA-VIRA TOPICAL CREAM**;
- Immediate hypersensitivity reactions including angioedema (painless swelling under the skin).

Frequency unknown side effects:

- Serious skin reaction that may affect one or more organs (see **Section 2**).

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. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **BETA-VIRA TOPICAL CREAM**.

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

5. How to store BETA-VIRA TOPICAL CREAM

Store at or below 25 °C.

Protect from light.

KEEP OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What BETA-VIRA TOPICAL CREAM contains

Each 1 g of **BETA-VIRA TOPICAL CREAM** contains the active substance Acyclovir 0,05 g.

Preservative:

Benzyl alcohol 0,75 % *m/m*

The other ingredients are Liquid Paraffin, White Soft Paraffin, self-Emulsifying Glyceryl Monostearate, Cetostearyl Alcohol, Cetomacrogol 1000 (Volpo CS 20), Propylene Glycol, Benzyl Alcohol, Hydrochloric Acid, Purified water.

What BETA-VIRA TOPICAL CREAM looks like and contents of the pack

Smooth, white, soft cream.

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

Holder of Certificate of Registration

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Access to the corresponding professional information

It is contained in the packaging of the medicine.