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 10 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, valacyclovir, 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).
- If you are a severely immune compromised patient (e.g., AIDS patients or bone marrow transplant recipients) topical application of **BETA-VIRA TOPICAL CREAM** may be inappropriate.
- 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 medicines).

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. It has been established that **BETA-VIRA TOPICAL CREAM** does not have any clinically significant effect on male fertility.

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 and may cause local skin reactions such as contact dermatitis.

BETA-VIRA TOPICAL CREAM contains propylene glycol and 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.

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

In the event of overdosage, or if you or a child accidentally swallow the cream, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the packet/product/container 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 (red inflamed skin).

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 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 **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 ingredient 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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Marketed by:
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PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: **S1**

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

Asiklovir

Lees hierdie hele biljet noukeurig deur, want dit bevat belangrike inligting vir u.

BETA-VIRA TOPICAL CREAM is beskikbaar sonder 'n doktersvoorskrif, vir u om 'n minder ernstige siekte te behandel. Nietemin moet u steeds **BETA-VIRA TOPICAL CREAM** versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Moenie **BETA-VIRA TOPICAL CREAM** met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter spreek indien u simptome vererger, of nie na 10 dae verbeter nie.

Wat is in hierdie biljet

1. Wat **BETA-VIRA TOPICAL CREAM** is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u **BETA-VIRA TOPICAL CREAM** gebruik.
3. Hoe om **BETA-VIRA TOPICAL CREAM** te gebruik.
4. Moontlike newe-effekte.
5. Hoe om **BETA-VIRA TOPICAL CREAM** te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat BETA-VIRA TOPICAL CREAM is en waarvoor dit gebruik word

BETA-VIRA TOPICAL CREAM bevat asiklovir, wat behoort aan 'n klas medisyne wat bekend staan as antivirale middels.

BETA-VIRA TOPICAL CREAM word gebruik in die vroeë behandeling van koorsblare (*Herpes simplex* virus). Dit vertraag die groei van die virus en versnel die genesing van koorsblare.

2. Wat u moet weet voordat u BETA-VIRA TOPICAL CREAM gebruik

Moenie BETA-VIRA TOPICAL CREAM gebruik nie

- Indien u allergies is vir asiklovir, valasiklovir en propileenglikol, of vir enige van die ander bestanddele van **BETA-VIRA TOPICAL CREAM** (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet gedra word met **BETA-VIRA TOPICAL CREAM**

- Indien branderigheid voorkom of u eriteem (rooiheid van die vel) ontwikkel.
- Moenie op slymvliese soos in die mond, oog of vagina gebruik nie, aangesien die room irritasie kan veroorsaak.
- Moenie hierdie room gebruik indien u erge koorsblare het nie; u moet 'n dokter spreek vir advies oor hoe om dit te behandel.
- Vermy toevallige toediening in die oë.
- Daar is verminderde doeltreffendheid van **BETA-VIRA TOPICAL CREAM** in die behandeling van *varicella zoster* virus (virus wat waterpokkies veroorsaak).
- Indien u plaaslike velreaksies ontwikkel, soos kontak dermatitis (jeukerige veluitslag).
- Indien u 'n ernstig immuun-onderdrukte pasiënt is (bv. VIGS-pasiënte of beenmurg oorplantingsontvangers), kan topikale toediening van **BETA-VIRA TOPICAL CREAM** onvanpas wees.
- Ernstige velreaksies soos Geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS) is aangemeld by pasiënte wat **BETA-VIRA TOPICAL CREAM** ontvang. Kombinasie van simptome soos koors, erge veluitslag, vel wat afdop, swelling van die gesig, geswelde limfkliere, griepagtige gevoel, geel vel of oë, kortasem, droë hoes, borspyn of ongemak, voel dors, urineer minder gereeld, minder urien kan gesien word. Indien u enige tekens van ernstige velreaksies soos swelling, jeukerigheid, rooi ernstige veluitslag ervaar, staak onmiddelik die gebruik van **BETA-VIRA TOPICAL CREAM** en kontak u dokter (sien Afdeling 4).

Ander medisyne en BETA-VIRA TOPICAL CREAM

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne gebruik. (Dit sluit alle aanvullende of tradisionele medisyne in).

Probenesied verhoog die gemiddelde halfleeftyd en oppervlakte onder die plasmakonsentrasiekurwe van asiklovir (tyd wat dit neem vir die medisyne in u liggaam om in die helfte verminder te word en werklike liggaamsblootstelling aan die medisyne na toediening).

Ander medisyne wat nierfisiologie (hoe die niere funksioneer) beïnvloed kan moontlik die farmakokinetika (wat die liggaam aan die geneesmiddel doen) van asiklovir beïnvloed.

Geen klinies beduidende interaksies is geïdentifiseer nie.

Swangerskap en borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u **BETA-VIRA TOPICAL CREAM** gebruik.

Swangerskap:
Die veiligheid van **BETA-VIRA TOPICAL CREAM** tydens swangerskap is nie vasgestel nie.

Borsvoeding:
Die veiligheid van **BETA-VIRA TOPICAL CREAM** in laktasie is nie vasgestel nie.
Beperkte menslike data toon dat asiklovir wel in borsmelk uitgeskei word.

Vrugbaarheid:
Inligting oor die effek van **BETA-VIRA TOPICAL CREAM** op menslike vroulike vrugbaarheid is nie beskikbaar nie. Daar is vasgestel dat **BETA-VIRA TOPICAL CREAM** geen klinies beduidende effek op manlike vrugbaarheid het nie.

Bestuur en gebruik van masjinerie

BETA-VIRA TOPICAL CREAM het geen invloed op die vermoë om te bestuur of

masjinerie te gebruik nie.

BETA-VIRA TOPICAL CREAM bevat setostearielalkohol en kan plaaslike velreaksies soos kontak dermatitis veroorsaak.

BETA-VIRA TOPICAL CREAM bevat propileenglikol en kan velirritasie veroorsaak.
Omdat hierdie medisyne propileenglikol bevat, moet u dit nie op oop wonde of groot dele van stukkende of beskadigde vel (soos brandwonde) gebruik sonder om dit met u dokter of apteker te bevestig nie.

BETA-VIRA TOPICAL CREAM bevat bensielalkohol en kan allergiese reaksies en minder ernstige plaaslike irritasie veroorsaak.

3. Hoe om BETA-VIRA TOPICAL CREAM te gebruik

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.

VIR EKSTERNE GEBRUIK ALLEENLIK.

Gebruik **BETA-VIRA TOPICAL CREAM** altyd presies soos beskryf in hierdie biljet, of soos u dokter of apteker u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.

BETA-VIRA TOPICAL CREAM kan vyf tot ses keer per dag, of elke drie tot vier uur toegedien word, vir periodes van vyf tot tien dae.

Topikale behandeling van koorsblare (topikale letsels) wat veroorsaak word deur *Herpes simplex* (virusinfeksie) moet so vroeg as moontlik begin word.
In herhalende gevalle van koorsblare, begin die behandeling so gou as moontlik wanneer die koorsblare verskyn.

Indien u meer BETA-VIRA TOPICAL CREAM gebruik as wat u moes
In die geval van oordosering, of indien u of 'n kind per ongeluk die room insluk, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum. Neem die verpakking/produk/houer saam om te help met identifikasie.

Indien u oordoseer, kan newe-effekte meer ernstig wees.

Indien u vergeet om BETA-VIRA TOPICAL CREAM te gebruik
Indien u 'n behandeling mis, smeer die room aan sodra u onthou, en smeer die oorblywende dosisse vir daardie dag met eweredige tussenposes aan.

4. Moontlike newe-effekte

BETA-VIRA TOPICAL CREAM kan newe-effekte hê.

Nie alle newe-effekte wat vir **BETA-VIRA TOPICAL CREAM** aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid vererger of indien u enige ongewenste effekte ervaar terwyl u **BETA-VIRA TOPICAL CREAM** gebruik, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **BETA-VIRA TOPICAL CREAM** en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van die lippe, gesig en/of ooglede.
- veluitslag, jeukerige vel, galbulte (rooi ontsteekte vel).

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige allergiese reaksie op **BETA-VIRA TOPICAL CREAM** gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:

Minder gereelde newe-effekte

- 'n Brandende of steekgevoel na die aanwending van die room, wat verdwyn;
- Eriteem (rooiheid van die vel) of ligte uitdroging en afskilfering van die vel;
- Jeukerigheid;
- 'n Jeukerige veluitslag wat veroorsaak word deur direkte kontak met **BETA-VIRA TOPICAL CREAM;**
- Onmiddellike hipersensitiwiteitsreaksies, insluitend angio-edeem (pynlose swelling onder die vel).

Newe-effekte met onbekende frekwensie

- Ernstige velreaksie wat een of meer organe kan beïnvloed (sien **Afdeling 2**).

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter of apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **BETA-VIRA TOPICAL CREAM** te verskaf.

Nadelige geneesmiddelreaksies kan ook by Adcock Ingram Limited aangemeld word deur die volgende e-pos te gebruik: Adcock.AEReports@adcock.com

5. Hoe om BETA-VIRA TOPICAL CREAM te bêre

Bêre teen of benede 25 °C.
Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS

6. Inhoud van die verpakking en ander inligting

Wat BETA-VIRA TOPICAL CREAM bevat

Elke 1 g **BETA-VIRA TOPICAL CREAM** bevat die aktiewe bestanddeel asiklovir 0,05 g.

Preserveermiddel:
Bensielalkohol 0,75 % *m/m*
Die ander bestanddele is Vloeibare Paraffien, Wit Sagte Paraffien, Self-emulsifiserende Gliserielmonostearaat, Setostearielalkohol, Setomakrogol 1000 (“Volpo” CS 20), Propileenglikol, Bensielalkohol, Soutsuur, Gesuiwerde water.

Hoe BETA-VIRA TOPICAL CREAM lyk en die inhoud van die verpakking
Gladde, wit, sagte room.

BETA-VIRA TOPICAL CREAM is verpak in opvoubare aluminiumbuise, wat 2 g room bevat.

PASIËNT INLIGTINGSBILJET

Houer van Sertifikaat van Registrasie

Adcock Ingram Limited

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Midrand, 1685

Kliëntediens: 0860 ADCOCK/232625

Bemark deur: Unicorn Pharmaceuticals.

Hierdie biljet is mees onlangs hersien op

02 Desember 2024

Registrasienommer

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adcock ingram

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