PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ACYCLOVIR BIOTECH 200, tablets.

ACYCLOVIR BIOTECH 800, tablets.

Acyclovir

ACYCLOVIR BIOTECH 200 contains sugar (lactose, hydrous 190 mg)

Read all of this leaflet carefully before you start taking ACYCLOVIR BIOTECH

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ACYCLOVIR BIOTECH has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ACYCLOVIR BIOTECH is and what it is used for

ACYCLOVIR BIOTECH belongs to a group of medicines called antivirals. ACYCLOVIR BIOTECH is used for the treatment of the following:

- Herpes simplex infections of the skin and mucous membranes including genital herpes (initial and recurrent) if given as soon as possible after symptoms appear;
- Suppression of recurrent herpes simplex infections in patients with an incompetent immune system;
- Shingles if the lesion in not older than 72 hours;
- Varicella zoster or chickenpox virus (if used within 24 hours after appearance of typical chickenpox rash);
- Reduce the risk of developing herpes infections, in HIV positive patients who are severely immunocompromised. ACYCLOVIR BIOTECH could be used in combination with zidovudine in patients with advanced HIV disease.

2. What you need to know before you take ACYCLOVIR BIOTECH

Do not take ACYCLOVIR BIOTECH:

- If you are hypersensitive (allergic) to acyclovir, valaciclovir or any of the other ingredients of ACYCLOVIR BIOTECH (listed in section 6).
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with ACYCLOVIR BIOTECH:

- If you have kidney problems, your dosage will need to be adjusted;
- If you are elderly, as you have an increased risk of kidney problems;
- If you are elderly or have kidney problems and you experience any neurological side effects such as headache, dizziness and confusion. These side effects are generally reversible upon discontinuation of treatment.
- If you use other nephrotoxic medicines, as it increases your risk of kidney failure.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after use of acyclovir (e.g., ACYCLOVIR BIOTECH).

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP) have been reported in association with ACYCLOVIR BIOTECH use. Seek medical attention immediately if you notice any of the signs described in section 4.

Prolonged use or repeated courses of ACYCLOVIR BIOTECH in patients with a compromised immune system, may lead to the selection of virus strains with reduced sensitivity to acyclovir treatment, this may cause ACYCLOVIR BIOTECH to be ineffective in the treatment of your condition.

You must ensure that you drink enough water if you take high doses of ACYCLOVIR BIOTECH.

Other medicines and ACYCLOVIR BIOTECH

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

ACYCLOVIR BIOTECH may have interactions with the following medicines:

- medicine that are also excreted via the kidneys, such as probenecid and cimetidine;
- an immunosuppressant medicine called mycophenolate mofetil;
- theophylline.

Please consult your doctor, pharmacist or other healthcare provider for advice.

Pregnancy, 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 healthcare provider for advice before taking ACYCLOVIR BIOTECH.

ACYCLOVIR BIOTECH should not be used in pregnancy and breastfeeding. The safe use of ACYCLOVIR BIOTECH during pregnancy and breastfeeding has not been established.

Driving and using machines

There have been no studies to investigate the effect of ACYCLOVIR BIOTECH on driving performance or the ability to operate machinery. However, ACYCLOVIR BIOTECH may cause dizziness which may influence the ability to drive and use machines (see section 4 “Possible side effects”).

It is not always possible to predict to what extent ACYCLOVIR BIOTECH may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which ACYCLOVIR BIOTECH affects you.

ACYCLOVIR BIOTECH contains sugar (lactose, hydrous)

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking ACYCLOVIR BIOTECH 200.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take ACYCLOVIR BIOTECH

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

Always take ACYCLOVIR BIOTECH exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with ACYCLOVIR BIOTECH will last.

If you have the impression that the effect of ACYCLOVIR BIOTECH is too strong or too weak, tell your doctor or pharmacist.

The usual dosage regimen, arranged according to condition being treated, is as follows:

Dosage in adults:

Initial and recurrent herpes simplex infections of skin and mucous membranes:

200 mg 5 times daily at 4 hourly intervals for 5 days.

In severe initial infection, your doctor will extend your treatment. In immunocompromised patients, dosage could be increased to 400 mg.

The first dose should be administered as early as possible after start of infection.

Suppression of recurrent genital herpes simplex infections in immunocompromised patients:

200 mg acyclovir 4 times daily at 6 hourly intervals, or 400 mg 12 hourly.

Some patients may have breakthrough infections on 800 mg daily. Your doctor will interrupt therapy every 6 – 12 months to observe history of disease.

Prevention of herpes simplex infections in patients with a weakened immune system:

200 mg 4 times daily at 6 hourly intervals.

In severely immunocompromised patients, or impaired absorption from the gut, dosage could be doubled to 400 mg.

Treatment of varicella zoster in adolescents (12-18 years):

800 mg 4 times a day for 5 days.

Treatment of varicella zoster and herpes zoster infections in adults:

800 mg 5 times daily at 4 hourly intervals for 7 days.

Treatment should be started as early as possible. In severely immunocompromised patients, or patients with impaired gut absorption, your doctor will consider a dosage form directly into your veins.

Management of severely immunocompromised patients:

800 mg 4 times daily at 6 hourly intervals.

Dosage in children:

Herpes simplex and prophylaxis of herpes simplex infections in immunocompromised patients 2 years and older:

The doctor will administer the adult dose. Orally administered acyclovir in children less than 2 years of age has not yet been fully studied.

Dosage in the elderly:

Adequate hydration in patients taking high doses must be maintained.

Treatment or prophylaxis of herpes simplex infections in patients with renal impairment:

200 mg every 12 hours if creatinine clearance > 10 mL/minute.

Treatment of varicella zoster, herpes zoster and immunocompromised patients with renal impairment:

800 mg twice daily at 12 hourly intervals (creatinine clearance > 10 mL/minute).

800 mg 3 times daily with 8 hourly intervals (creatinine clearance 10-25 mL/minute).

The tablets should be taken by mouth.

If you take more ACYCLOVIR BIOTECH than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Side effects of an overdosage may include gastrointestinal upset, such as nausea and vomiting, and neurological effects such as headache and confusion.

In the event of an overdosage your doctor will place you on haemodialysis.

If you forget to take ACYCLOVIR BIOTECH

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ACYCLOVIR BIOTECH can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- yellowing of the skin and eyes, also called jaundice

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

The following serious side effects are reported less frequently:

- if you experience more infections than usual, fatigue, sleepiness, fever and headaches, this may be a sign of a blood disorder called leukopenia
- reduction in blood platelets, which increases your risk of bleeding or bruising
- if you experience fits, feeling nervous, confused, trembling, difficulty in controlling your movements, difficulty speaking, hallucinations, psychotic symptoms, sleepiness and coma. These symptoms are generally reported in patients with kidney problems.
- if you have difficulty breathing
- signs of kidney problems including proteins, red and white blood cells, high levels of urea and creatinine in the urine, and abnormally small amounts of urine, kidney pain (pain in your back)

Side effects reported with unknown frequency:

- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever after the imaging procedure (acute generalised exanthematous pustulosis, [AGEP]).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- headache, dizziness
- nausea, vomiting, diarrhoea and abdominal pains
- severe itching, rashes and if your skin is more sensitive to sunlight
- feeling tired

- unexplained fever (high temperature)

The following side effects have been reported less frequently:

- if you experience any symptoms which may be a sign of reduction in your red blood cells, such as pale skin, weakness and shortness of breath
- inflammation of the liver (hepatitis)
- increases in the enzymes that work in the liver
- skin hives
- hair loss
- swelling of the area beneath the skin or mucosa triggered by an allergy

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 "**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 ACYCLOVIR BIOTECH.

5. How to store ACYCLOVIR BIOTECH

Store all medicines out of reach of children.

Store at or below 25 °C in a dry place and protected from light.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6.Contents of the pack and other information

What ACYCLOVIR BIOTECH contains

- The active substance is acyclovir.
- The other ingredients are:

ACYCLOVIR BIOTECH 200: colloidal silicone dioxide, croscarmellose sodium, indigotine lake (CI 73015), lactose, hydrous, magnesium stearate, microcrystalline cellulose.

ACYCLOVIR BIOTECH 800: brilliant blue FCF lake (CI 42090), colloidal silicone dioxide, croscarmellose sodium, indigotine lake (CI 73015), magnesium stearate, microcrystalline cellulose.

What ACYCLOVIR BIOTECH looks like and contents of the pack

ACYCLOVIR BIOTECH 200: Round, blue, flat-faced, bevelled-edged tablets, engraved "APO" over "200" on one side, other side plain.

ACYCLOVIR BIOTECH 800: Oval, blue, biconvex tablets, scored and engraved "APO 800" on one side, other side plain.

ACYCLOVIR BIOTECH 200 tablets are available in white plastic bottles of 100, 250, 500 and 1000 tablets.

ACYCLOVIR BIOTECH 800 tablets are available in white plastic bottles of 100, 250, 500 tablets, and in blister packages of 100 tablets.

Not all strengths may be marketed.

Holder of Certificate of Registration

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