

ACYCLOVIR BIOTECH

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 is 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:

Reduction in blood platelets: 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 "200" on one side, other side plain.

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

ACYCLOVIR BIOTECH 200 tablets are available in:

150 white, opaque HDPE container having white, opaque screw type cap with induction sealing wad.

Pack size: 25, 100, 250, 500 and 1 000 tablets

Clear PVC/Aluminium blisters.

Pack size: 30 tablets

Patient ready packs (PRP)

Pack size: 25 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 pack sizes and pack-types may be available all the time.

Not all strengths may be marketed.

Holder of Certificate of Registration

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ACYCLOVIR BIOTECH

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:

S4

ACYCLOVIR BIOTECH 200, tablette.
ACYCLOVIR BIOTECH 800, tablette.
Asiklovir
ACYCLOVIR BIOTECH 200 bevat suiker (waterryke laktose 190 mg)

Lees die hele pamflet noukeurig deur voordat jy begin om ACYCLOVIR BIOTECH te neem

- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
- Indien jy verdere vrae het, vra asseblie jou dokter, apoteker, verpleegster of ander gesondheidsorgverskaffer.
- ACYCLOVIR BIOTECH is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle skade aan doen, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet

- Wat ACYCLOVIR BIOTECH is en waarvoor dit gebruik word
- Wat jy moet weet voordat jy ACYCLOVIR BIOTECH neem
- Hoe om ACYCLOVIR BIOTECH te neem
- Moontlike newe-effekte
- Hoe om ACYCLOVIR BIOTECH te bewaar
- Inhoud van die pak en ander inligting

1. Wat ACYCLOVIR BIOTECH is en waarvoor dit gebruik word

ACYCLOVIR BIOTECH behoort aan 'n groep medisyne wat antivirale medisyne genoem word. ACYCLOVIR BIOTECH word gebruik vir die behandeling van die volgende:

- Herpes simpleks infeksies van die vel en slymvliese insluitende genitale herpes (aanvanklike en herhalende) indien so gou as moontlik gegee nadat simptome verskyn het;
- Onderdrukking van herhalende herpes simpleks infeksies in pasiënte met 'n onbevoegde immuunstelsel;
- Gordelroos indien die letsel nie ouer as 72 ure oud is nie;
- Varicella zoster of waterpokkievirus (indien gebruik binne 24 uur na die verskyning van tipiese waterpokkiesuitslag);
- Verlaag die risiko om herpes infeksies te ontwikkel in MIV positiewe pasiënte wat ernstig immuunonderdruk is. ACYCLOVIR BIOTECH kan in kombinasie met sidovidin geneem word in pasiënte met gevorderde MIV siekte.

2. Wat jy moet weet voordat jy ACYCLOVIR BIOTECH neem

Moenie ACYCLOVIR BIOTECH neem nie:

- Indien jy hipersensitief (allergies) is vir asiklovir, valasiklovir of enige van die ander bestandele van ACYCLOVIR BIOTECH (gelys in afdeling 6).
- Indien jy swanger is of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met ACYCLOVIR BIOTECH:

- Indien jy nierprobleme het sal jou dosis aangepas moet word;
- Indien jy bejaard is, aangesien jy 'n verhoogde risiko van nierprobleme het;
- Indien jy bejaard is of van nierprobleme het en jyervaar enige neurologiese newe-effekte soos hoofpyn, duiseligheid en verwarring. Hierdie newe-effekte is oor die algemeen omkeerbaar wanneer die behandeling gestaak word.
- Indien jy ander nefrotoksiese medisyne gebruik, aangesien dit jou risiko van niersersaking verhoog.
- Indien jy ooit 'n ernstige veluitslag van velskil, blase en/ of mondres ontwikkel het na gebruik van asiklovir (bv. ACYCLOVIR BIOTECH).

Ernstige velreaksies insluitend geneesmiddelreaksies met eosinofilie en sistemiese simptome (DRESS), en akute veralgemeende eksantematiese pustulose (AGEP) is aangemeld in verband met die gebruik van ACYCLOVIR BIOTECH. Soek onmiddellik mediese hulp as jy enige van die tekenen wat in afdeling 4 beskryf word, opmerk.

Langdurige gebruik of herhaalde kursusse van ACYCLOVIR BIOTECH by pasiënte met 'n gekompromitteerde immuunstelsel kan lei tot die verskeidenheid van virusstamme met verminderde sensitiviteit vir asiklovir behandeling, dit kan veroorsaak dat ACYCLOVIR BIOTECH ondoeltreffend is in die behandeling van jou toestand.

Jy moet seker maak dat jy genoeg water drink indien jy hoë dosisse ACYCLOVIR BIOTECH neem.

Ander medisyne en ACYCLOVIR BIOTECH

Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre en tradisionele medisyne in).

ACYCLOVIR BIOTECH mag interaksies met die volgende medisyne hê:

- medisyne wat ook deur die niere uitgeskei word, soos probenesien en simetidien;
- 'n immuunonderdrukkende medisyne genaamd mikofenoaatmofetil;
- teofilien.

Raadpleeg asseblie jou dokter, apoteker of ander gesondheidsorgverskaffer vir advies.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of borsvoed, dink dat jy swanger mag wees of beplan om 'n baba te hê, raadpleeg asseblie jou dokter, apoteker of ander gesondheidsorgverskaffer vir advies voordat jy ACYCLOVIR BIOTECH neem.

ACYCLOVIR BIOTECH moet nie gedurende swangerskap en borsvoeding gebruik word nie. Die veilige gebruik van ACYCLOVIR BIOTECH gedurende swangerskap en borsvoeding is nog nie vasgestel nie.

Bestuur en die gebruik van masjiene

Daar was geen studies om die effek van ACYCLOVIR BIOTECH op bestuursverrigting of die vermoë om masjinerie te bestuur, te ondersoek nie. ACYCLOVIR BIOTECH kan egter duiseligheid veroorsaak wat die vermoë om te bestuur en masjiene te gebruik kan beïnvloed (sie afdeling 4 "Moontlike newe-effekte").

Dit is nie altyd moontlik om te voorskaf tot watter mate ACYCLOVIR BIOTECH met jou daagliks aktiwiteite kan inmeng nie. Jy moet verzekер dat jy nie betrokke raak by bestuur of masjinerie hanteer totdat jy bewus is van die mate waarin ACYCLOVIR BIOTECH jou beïnvloed nie.

ACYCLOVIR BIOTECH bevat suiker (waterryke laktose)

Indien jy deur jou dokter vertel is dat jy onverdraagsaam is vir sekere suiker, kontak jou dokter voordat jy ACYCLOVIR BIOTECH 200 neem.

Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per dosis-eenheid, dit wil sê in wese 'n natriumvry'.

3. Hoe om ACYCLOVIR BIOTECH te neem

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

Neem altyd ACYCLOVIR BIOTECH presies soos jou dokter jou vertel het. Raadpleeg jou dokter of apoteker indien jy nie seker is nie. Jou dokter sal jou vertel hoe lank jou behandeling met ACYCLOVIR BIOTECH sal aanhou.

Indien jy die indruk het dat die effek van ACYCLOVIR BIOTECH te sterk of te swak is, vertel jou dokter of apoteker.

Die gewone dosisregime, gerangskik volgens toestand wat behandel word, is soos volg:

Dosering in volwassenes:

Aanvanklike en herhalende herpes simpleks infeksies van vel en slymvliese:

200 mg 5 keer daagliks in 4-uurlike intervalle vir 5 dae.

In ernstige aanvanklike infeksies sal jou dokter jou behandeling verleng. By pasiënte met immuunonderdrukking kan die dosis tot 400 mg verhoog word.

Die eerste dosis moet so vroeg as moontlik na die aanvang van infeksie toegedien word.

Onderdrukking van herhalende genitale herpes simpleks infeksies by pasiënte met immuunonderdrukking:

200 mg asiklovir 4 keer daagliks met 6-uurlike intervalle, of 400 mg 12-uurliks.

Sommige pasiënte kan deurbraakinfeksies op 800 mg daagliks hê. Jou dokter sal terapie elke 6 - 12 maande onderbreek om geskiedenis van siekte waar te neem.

Voorcoming van herpes simpleks-infeksies by pasiënte met 'n verswakte immuunstelsel:

200 mg 4 keer daagliks in 6-uurlike intervalle.

By pasiënte met ernstige immuunonderdrukking, of verswakte absorpsie uit die ingewande, kan die dosis verdubbel word tot 400 mg.

Behandeling van varicella zoster by adolessente (12-18 jaar):

800 mg 4 keer 'n dag vir 5 dae.

Behandeling van varicella zoster en herpes zoster infeksies in volwassenes:

800 mg 5 keer daagliks in 4-uurlike intervalle vir 7 dae.

Behandeling moet so vroeg as moontlik begin word. By pasiënte met ernstige immuunonderdrukking, of pasiënte met verswakte dermabsorpse, sal jou dokter 'n doseervorm direk in jou ore oorweeg.

Bestuur van ernstige immuunonderdrukte pasiënte:
800 mg 4 keer daagliks in 6-uurlike intervalle.

Dosering in kinders:

Herpes simpleks en voorcoming van herpes simplex infeksies in immuunonderdrukte pasiënte 2 jaar oud en ouer:
Die dokter sal die volwasse dosis toedien. Oraal toegedien asiklovir in kinders jonger as 2 jaar is nog nie volledig bestudeer nie.

Dosering in die bejaarde:

Voldoende hidrasie by pasiënte wat hoë dosisse neem, moet gehandhaaf word.

Behandeling of voorcoming van herpes simplex infeksies in pasiënte met niversaking:

200 mg elke 12 ure indien kreatininopruiming > 10 mL/minut.

Behandeling van varicella zoster, herpes zoster en immuunonderdrukte pasiënte met verswakte nierfunksie:

800 mg twee keer daagliks in 12-uurlike intervalle (kreatininopruiming > 10 mL/minut).

800 mg 3 keer daagliks in 8-uurlike intervalle (kreatininopruiming 10-25 mL/minut).

Die tablette moet per mond geneem word.

Indien jy meer ACYCLOVIR BIOTECH neem as wat jy moet

In die geval van 'n oordosis, raadpleeg jou dokter of apoteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Newe-effekte van 'n oordosis mag gastro-intestinale ontsteltenis, soos naarheid en braking, en neurologiese effekte soos hoofpyn en verwarring insluit.

In die geval van 'n oordosis sal jou dokter jou op hemodialise plaas.

Indien jy vergeet om ACYCLOVIR BIOTECH te neem

Moenie 'n dubbele dosis neem om op te maak vir vergeete individuele dosisse nie.

4. Moontlike newe-effekte

ACYCLOVIR BIOTECH kan newe-effekte hê.

Nie alle newe-effekte wat vir ACYCLOVIR BIOTECH aangemeld is word in hierdie pamflet bevat nie. Sou jou algemene gesondheid versleg of indien jy enige ongewenste effekte ervaar terwyl jy ACYCLOVIR BIOTECH neem, raadpleeg asseblie jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om ACYCLOVIR BIOTECH te neem en vertel jou dokter onmiddellik of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat moeilike sluk en moeilike asemhaling kan veroorsaak
- veiluifslag of jeuk
- floute
- vergeling van die vel en oë, genaamd geelsug

Hierdie is almal ernstige newe-effekte. Indien jy hulle het mag jy dalk 'n ernstige reaksie vir ACYCLOVIR BIOTECH gehad het. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter onmiddellik of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:

Die volgende ernstige newe-effekte is minder gereeld aangemeld:

- indien jy meer infeksies ervaar wat normaalweg, moegheid, slapereigheid, koers en hoofpyn, dit kan 'n teken wees van 'n bloedafwyking genaamd leukopenie
 - verlaging in bloedplaatjies wat jou kans vir bloeding of kneusing verhoog
 - indien jy aanvalle ervaar, seruweaagtige voel, verward, bewe, moeilikhede om jou bewegings te beheer, probleme met praat, hallusinasiës, psigotiese simptome, slapereigheid en koma. Hierdie simptome is oor die algemeen aangemeld in pasiënte met nierprobleme.
 - indien jy moeilike asemhaling
 - tekens van nierprobleme insluitend proteïene, rooi- en witbloedselle, hoë vlakke van urea en kreatinin in die urine en abnormale klein volumes urine, nierpyn (pyn in jou rug)
- Newe-effekte wat aangemeld is niet 'n onbekende frekwensie:
- wydverspreide veluitslag, hoë liggaamstemperatuur en vergrote limfekliere (DRESS sindroom of geneesmiddel hipersensitiviteit sindroom)
 - 'n rooi, skubberige, wydverspreide veluitslag met bulle onder die vel en blasies vergesel deur koers na die beeldvormingsprocedure (akute veralgemeende eksantematiese pustulose, [AGEP]).
- Hierdie is almal ernstige newe-effekte. Jy mag dalk dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:

Die volgende newe-effekte is minder gereeld aangemeld:

- hoofpyn, duiseligheid
- naarheid, braking, diarree en maagpyn
- ernstige jeuk, veluitslag en indien jou vel meer sensitief is vir sonlig
- moeg gevoel
- onverklaarbare koers (hoë temperatuur)

Die volgende newe-effekte is minder gereeld aangemeld:

- indien jy enige simptome ervaar wat 'n teken kan wees van 'n verlaging in jou rooibloedselle soos 'n bleek vel, swakheid en kort van asem wees
 - inflammasië van die lever (hepatitis)
 - verhoging in die ensiem wat in die lever werk
 - velkorwe
 - haarverlies
 - swelling van die area onder die vel of slymvlies veroorsaak deur 'n allergie
- Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, lig asseblie jou dokter daarvan in.

Aanmelding van newe-effekte

Indien jy newe-effekte kry, praat met jou dokter, apoteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA aanmeld deur die vorm "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn onder SAHPRA se publikasies gevind kan word: <https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld kan jy help om meer inligting oor die veiligheid van ACYCLOVIR BIOTECH te verskaf.

5. Hoe om ACYCLOVIR BIOTECH te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar nie teen benede 25 °C in 'n koel, droë plek en beskerm teen lig.

Gee alle ongebruikte medisyne terug aan jou apoteker.

Moenie ongebruikte medisyne in drieën en riuolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat ACYCLOVIR BIOTECH bevat

- Die aktiewe bestanddeel is asiklovir.
- Die ander bestanddeel is:

ACYCLOVIR BIOTECH 200: kolloïdale silikoondioksied, natriumkroskarmellose, indigotine lake (CI 73015), waterryke laktose, magnesiumstearaat, mikrokristalline cellulose.

ACYCLOVIR BIOTECH 800: briljante blou FCF lake (CI 42090), kolloïdale silikoondioksied, natriumkroskarmellose, indigotine lake (CI 73015), magnesiumstearaat, mikrokristalline cellulose.

Hoe ACYCLOVIR BIOTECH lyk en die inhoud van die pak

ACYCLOVIR BIOTECH 200: Ronde, blou, platgesig, afgeskuinsde rant tablette, met "200" aan die een kant gedruk en ongedruk aan die ander kant.

ACYCLOVIR BIOTECH 800: Ovaal, blou, bikonveksie tablette met 'n breeklyn en "800" aan die een kant gedruk en ongedruk aan die ander kant.

ACYCLOVIR BIOTECH 200 tablette is beskikbaar in:

150cc wit, ondeursigtige HDPE-houer met wit, ondeursigtige skroeftipe doppie met induksie verseëling.

Pakgrootte: 25, 100, 250, 500 en 1 000 tablette

Deursigtige PVC/Aluminium stuifstroke.

Pakgrootte: 30 tablette

Pasiëntgereepte pakkies (PRP)

Pakgrootte: 25 tablette

ACYCLOVIR BIOTECH 800 tablette is beskikbaar in:

Wit plastiekbottels van 100, 250, 500 tablette, en in stuifverpakings van 100 tablette.

Nie alle pakgroottes en pakkietes is dalk heeltyd beskikbaar nie.