

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

VALACYCLOVIR 500 BIOTECH, 500 mg, film-coated tablets

Valacyclovir

Sugar free

Read this leaflet carefully before you start taking VALACYCLOVIR 500 BIOTECH:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- VALACYCLOVIR 500 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 VALACYCLOVIR 500 BIOTECH is and what it is used for
2. What you need to know before you take VALACYCLOVIR 500 BIOTECH
3. How to take VALACYCLOVIR 500 BIOTECH
4. Possible side effects
5. How to store VALACYCLOVIR 500 BIOTECH
6. Contents of the pack and other information

1. What VALACYCLOVIR 500 BIOTECH is and what it is used for

VALACYCLOVIR 500 BIOTECH belongs to a group of medicines called antiviral agents. VALACYCLOVIR 500 BIOTECH is indicated for:

- Treatment of herpes zoster (shingles). It reduces the duration pain associated with shingles, and pain persisting after an attack (post herpetic neuralgia).
- Herpes genitalis: Treatment of recurrent genital herpes in adult patients with normal immune systems.
- Prevention (suppression) of recurrent herpes simplex infection (skin infection with blisters and rash) of the skin and mucous membrane of the ano-genital area.
- Prevention of cytomegalovirus (CMV) infection and CMV disease and other herpes virus infections following organ transplantation.

VALACYCLOVIR 500 BIOTECH is only available with your doctor's prescription.

2. What you need to know before you take VALACYCLOVIR 500 BIOTECH

Do not take VALACYCLOVIR 500 BIOTECH:

- if you are hypersensitive (allergic) to valacyclovir, acyclovir or any of the ingredients of VALACYCLOVIR 500 BIOTECH (listed in Section 6).
- if you are pregnant or breast-feeding.
- If you have ever developed an extended rash associated with fever, enlarged lymph nodes, increased levels of liver enzymes and or/eosinophilia (drug reaction with eosinophilia and systemic symptoms after taking valacyclovir).

Warnings and precautions

Talk to your doctor, pharmacist or health care provider before taking VALACYCLOVIR 500 BIOTECH if

- you have kidney problems
- you have liver problems
- you have advanced HIV infection
- you are going to have a bone marrow transplant or a kidney transplant.
- you are over 65 years of age

- your immune system is weak

Take special care with VALACYCLOVIR 500 BIOTECH:

- If you have kidney problems, you should be adequately hydrated when taking high doses of VALACYCLOVIR 500 BIOTECH. Care should be taken and your dosage might be adjusted.
- If you have liver problems or a liver transplant, as your body may react differently VALACYCLOVIR 500 BIOTECH. Care should be taken as no data is available for when patients with liver problems are taking high doses or for when liver transplant patients take VALACYCLOVIR 500 BIOTECH.
- As interactions may occur when taking VALACYCLOVIR 500 BIOTECH with other medicinal products/medicines (see Taking other medicines with VALACYCLOVIR 500 BIOTECH)
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported with the use of valacyclovir. DRESS appears initially as flu like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.
- Serious skin reactions have been reported in association with VALACYCLOVIR 500 BIOTECH treatment. You should stop taking and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4
- If you develop a rash associated with a fever and enlarged lymph nodes, stop taking VALACYCLOVIR 500 BIOTECH and contact your doctor or seek medical attention immediately.
- If you are taking VALACYCLOVIR 500 BIOTECH to treat or prevent genital herpes, or you have had genital herpes in the past, you should still practice safe sex, including the use of condoms. This is important to prevent you passing the infection on to others. You should not have sex if you have genital sores or blisters.

Other medicines and VALACYCLOVIR 500 BIOTECH

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

Tell your doctor, pharmacist or other healthcare professional if you are using or receiving any of the following medicines:

- tacrolimus (immunosuppressive medicine used after organ transplant)
- ciclosporin (immunosuppressive medicine used to prevent organ rejection)
- cimetidine (used for stomach problems/ulcers)
- probenecid (mainly used in treating gout)
- mycophenolate mofetil (immunosuppressive medicine used to prevent organ rejection).

Before you begin using any new medicine (prescription or non-prescription) or if you develop any new medical problem while you are using this medicine, check with your doctor, pharmacist, or other healthcare professional.

Pregnancy and breastfeeding:

Do not take VALACYCLOVIR 500 BIOTECH if you are pregnant or breast-feeding your baby.

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 taking this medicine.

Driving and using machinery:

It is not always possible to predict to what extent VALACYCLOVIR 500 BIOTECH may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VALACYCLOVIR 500 BIOTECH affects them.

VALACYCLOVIR 500 BIOTECH should not have an effect on driving and using machinery, but may cause nervous system disorders e.g. dizziness. Do not drive or operate machinery if you are affected by VALACYCLOVIR 500 BIOTECH.

3. How to take VALACYCLOVIR 500 BIOTECH

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

Always take VALACYCLOVIR 500 BIOTECH exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of VALACYCLOVIR 500 BIOTECH is too strong or too weak, talk to your doctor or pharmacist.

VALACYCLOVIR 500 BIOTECH may be taken with or without food.

The usual adult dose is:

Treatment of Herpes zoster (shingles)

- Therapy should be started as soon as possible following the onset of signs and symptoms. Two tablets (1 gram) three times a day for 7 days.

Treatment of recurrent (regular/repeated) genital herpes

- Therapy should be started as soon as possible following the onset of signs and symptoms.
- One tablet (500 mg) twice daily for 5 days.

Prevention (suppression) of recurrences of (regular/repeated) Herpes simplex infection

- Dosing should begin as early as possible, immediately the first signs or symptoms appear.
- Patients with compromised immune system: One tablet (500 mg) twice daily

- Patients with normal immune system function: One tablet (500 mg) once daily

To stop you being infected with CMV (Cytomegalovirus) in organ transplantation

- Adults and adolescents (from 12 years of age): A dose of 2 gram (4 tablets) four times daily is recommended.
- Dosage should begin as early as possible and is usually continued for 90 days.

Speak to your doctor if you suffer from kidney or liver disease for information on how this medicine should be taken, as the above dosages may not be appropriate for you.

If you take more VALACYCLOVIR 500 BIOTECH than you should:

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

Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take VALACYCLOVIR 500 BIOTECH:

If you forget to take a dose, take the missed dose as soon as possible and then go on as before. Do not take the missed dose if it is almost time for the next dose and do not take two doses at the same time.

Effects when treatment with VALACYCLOVIR 500 BIOTECH is stopped:

Do not stop taking VALACYCLOVIR 500 BIOTECH, as your doctor will tell you for how long you have to take your tablets.

4. Possible side effects

VALACYCLOVIR 500 BIOTECH can have side effects.

Not all side effects reported for VALACYCLOVIR 500 BIOTECH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VALACYCLOVIR 500 BIOTECH, please consult your health care provider for advice.

If any of the following happens, stop taking VALACYCLOVIR 500 BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- skin rashes or redness. The adverse reaction of the skin may appear as rashes with or without blisters. Skin irritation, oedema (DRESS syndrome) and fever and flu like symptoms may occur.

These are all very serious side effects. If you have them, you may have had a serious reaction to VALACYCLOVIR 500 BIOTECH. You may need urgent medical attention or hospitalisation.

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

- liver problems (with symptoms such as abdominal or stomach pain; chills; clay-coloured stools; dark urine; diarrhoea; dizziness; fever; headache; itching; loss of appetite; nausea; rash; unpleasant breath odour; unusual tiredness or weakness; vomiting of blood; yellowing of the eyes and skin),
- frequent infections such as fever, severe chills, sore throat or mouth ulcers,
- bleeding or bruising more easily than normal,
- decrease in number of red blood cells which can make the skin pale and cause weakness or breathlessness,
- painful, blistering or peeling skin rash (such as Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme);

- a red, scaly rash with bumps under the skin and blisters (acute generalised exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).
- low back pain (kidney pain,
- kidney problems where you pass little or no urine,
- blood in urine (haematuria).

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

Nervous system side effects

- feeling confused,
- seeing or feeling things that are not there (hallucinations),
- feeling very drowsy,
- tremors,
- feeling agitated,
- unsteadiness when walking and lack of coordination,
- slow, slurred speech,
- fits (convulsions),
- altered brain function (encephalopathy),
- unconsciousness (coma),
- confused or disturbed thoughts (delirium).

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of VALACYCLOVIR 500 BIOTECH

Frequent side effects

- nausea (feeling sick,
- vomiting (being sick),

- diarrhoea,
- stomach pains,
- skin reaction after exposure to sunlight (photosensitivity),
- itching rash (pruritus)
- sleepiness (somnolence)
- headache,
- dizziness.

Less frequent side effects

- gastrointestinal (stomach and intestine) discomfort,
- increase in substances produced by the liver,
- diffuse hair loss,
- wheals, hives or welts, itching, redness of skin, skin rash (urticaria),
- pruritus (itching rash),
- difficulty in breathing (dyspnoea).

Frequency unknown

- Drug Reaction with Eosinophilia and Systemic Symptoms also known as DRESS or drug reaction hypersensitivity syndrome, which is characterised by widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs (See also section 2)
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).
- An inflammation of the kidneys (tubulointerstitial nephritis)

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 doctor or nurse. You can also report side effects 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 **VALACYCLOVIR 500 BIOTECH**

5. How to store VALACYCLOVIR 500 BIOTECH

Store all medicines out of reach of children.

Store in the original package (in the carton) at or below 30 °C.

Do not store your medicine in the bathroom.

Do not use VALACYCLOVIR 500 BIOTECH after the expiry date printed on the label, container or blister.

Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VALACYCLOVIR 500 BIOTECH contains:

The active substance is valacyclovir

The other inactive ingredients are: Calcium hydrogen phosphate dehydrate, sodium starch glycolate Type A, hydroxypropyl cellulose (HPC-L), purified talc, magnesium stearate (vegetable grade), Opadry white OY-LS-28908.

What VALACYCLOVIR 500 BIOTECH looks like and contents of the pack

White, oblong, biconvex film-coated tablets.

Approximately 19,4 mm long, 7,8 mm wide and 5,3 mm thick.

Packs of 10, 30 or 42 film-coated tablets packed in white opaque PVC/PE/PVDC/Aluminium blisters in a cardboard

Biotech Laboratories (Pty) Ltd.

1.3.2.1 PIL - Approved

Valacyclovir 500 Biotech (43/20.2.8/0766)

Each film-coated tablet contains Valacyclovir hydrochloride
equivalent to 500 mg Valacyclovir

Date of approval: 27 August 2025

carton.

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd.

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Access to the corresponding Professional Information

(A QR code will be included here for electronic access to the professional information)