
SCHEDULING STATUS

S4

ACYCLOVIR 200 PHARMC, 200 mg tablets.

ACYCLOVIR 400 PHARMC, 400 mg tablets.

Acyclovir

Sugar free

Read all of this leaflet carefully before you start taking ACYCLOVIR PHARMC.

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

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

ACYCLOVIR PHARMC contains a medicine called acyclovir. This belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses.

ACYCLOVIR PHARMC can be used to:

- Treat herpes simplex (type of virus) infections such as cold sores, genital herpes and other herpes simplex infections.
- Stop these infections returning after you have had them.
- Prevent these infections in people whose immune systems work less well, which means their bodies are less able to fight infections.
- Treat other viral infections such as chickenpox and shingles.

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

Do not take ACYCLOVIR PHARMC

- If you are hypersensitive (allergic) to acyclovir or valacyclovir or any of the other ingredients of ACYCLOVIR PHARMC (listed in section 6).

Warnings and precautions

Take special care with ACYCLOVIR PHARMC. Tell your doctor before you take ACYCLOVIR PHARMC:

- If you have kidney problems. Your doctor may prescribe a lower dose of ACYCLOVIR PHARMC.
- If you are pregnant or breastfeeding your baby.
- If you are elderly or have kidney problems, you may have a higher risk of side-effects and your doctor may watch you more closely.

- Severe blistering skin reactions called drug reaction with eosinophilia and systemic symptoms (DRESS) or acute generalised exanthematous pustulosis (AGEP) have been reported with the treatment of ACYCLOVIR PHARMC. Stop using ACYCLOVIR PHARMC and contact your doctor immediately or go to the nearest hospital if you experience a serious skin reaction described in section 4.

You should take plenty of water while taking ACYCLOVIR PHARMC:

Other medicines and ACYCLOVIR PHARMC

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

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- probenecid, used to treat gout
- cimetidine, used to treat stomach ulcers
- mycophenolate mofetil, used to stop your body rejecting transplanted organs.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking ACYCLOVIR PHARMC.

Driving and using machines

It is not always possible to predict to what extent ACYCLOVIR PHARMC may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which ACYCLOVIR PHARMC affects you.

ACYCLOVIR PHARMC contains sodium

ACYCLOVIR PHARMC contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take ACYCLOVIR PHARMC

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

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

The usual dose is:

Adults and children who can swallow tablets: every four hours, five times per day (omitting the night-time dose) for 5 days.

Your doctor may decide to increase the dose or for a longer period depending on the severity of the infection.

Stopping herpes simplex infections returning after you have had them

Adults: 200 mg four times per day.

Your doctor may also change the dosage to 400 mg two times a day or 200 mg three times a day. You may be asked to visit your doctor regularly to monitor how well your treatment is working.

Prevention of herpes simplex infection

Adults and children who can swallow tablets: 200 mg four times per day.

Your doctor may also change the dosage to 400 mg four times a day. You should take ACYCLOVIR PHARMC until your doctor tells you to stop.

Treat other viral infections such as chickenpox and shingles

Adults: 800 mg every four hours, five times per day (omitting the night-time dose) for 7 days.

Adolescents (12-18 years): 800 mg four times per day for 5 days.

Children (immunocompromised): 200 mg/kg (not to exceed 800 mg) four times a day for 5 days.

Your doctor will adjust the dose if you are elderly or have kidney problems.

- Swallow the tablet with water with or without a meal.
- If possible, take the tablet at the same time of the day.
- Start to take ACYCLOVIR PHARMC as soon as possible.

Your doctor will tell you for how long you should take ACYCLOVIR PHARMC.

Do not stop the treatment early because the ACYCLOVIR PHARMC treatment will be less effective to stop the infection and/or prevent the infection to start again.

If you take more ACYCLOVIR PHARMC than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of ACYCLOVIR PHARMC

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

ACYCLOVIR PHARMC can have side effects.

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

If any of the following happens, stop taking ACYCLOVIR PHARMC 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.
- Severe skin reactions
 - A red, scaly rash with bumps under the skin and blisters, called exanthematous pustulosis (AGEP).
 - Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

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

Tell your doctor if you notice any of the following

Frequent side effects

- headache, dizziness
- nausea, vomiting, diarrhoea, abdominal pains
- red, itchy dry skin, skin rash, blistering when your skin is exposed to the sun
- feeling tired, fever.

Less frequent side effects

- feeling tired, pale skin, increase in nose bleeds or unusual bleeding (blood test shows changes in your blood cell counts)
- feeling agitated or confused, hallucinations (seeing or hearing things that aren't there), shaking or tremors, unsteadiness when walking and lack of coordination, difficulty speaking, fits, feeling unusually sleepy or drowsy, unconsciousness (coma), disturbances of behaviour
- difficulty to breath
- liver problems e.g. inflammation of the liver (hepatitis), yellowing of your skin and whites of your eyes (jaundice)
- itchy, hive-like rash, hair loss, swelling underneath the skin (angioedema).
- kidney problems where you pass little or no urine, or blood in the urine, pain in the kidney area of your back.

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. This includes any possible side effects not listed in this leaflet. 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 PHARMC.

5. How to store ACYCLOVIR PHARMC

Store all medicines out of reach of children.

- Store at or below 25 °C in a dry place.
- Protect from light.
- Store in the original package / container.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems.

6. Contents of the pack and other information

What ACYCLOVIR PHARMC contains

The active substance is acyclovir

ACYCLOVIR 200 PHARMC: Each tablet contains 200 mg acyclovir.

ACYCLOVIR 400 PHARMC: Each tablet contains 400 mg acyclovir.

The other ingredients are colloidal silicon dioxide; isopropyl alcohol; microcrystalline cellulose; magnesium stearate; polyvinyl pyrrolidone; sodium starch glycolate

What ACYCLOVIR PHARMC looks like and contents of the pack

ACYCLOVIR 200 PHARMC: White, circular flat tablets with bevelled edges having a break-line on one face and plain on the other face.

ACYCLOVIR 400 PHARMC: White, circular flat tablets with bevelled edges having a break-line on one face and plain on the other face.

ACYCLOVIR 200 PHARMC

Clear PVC/aluminium foil blister packs (10 tablets/blister) containing 30 tablets, in an outer cardboard carton.

White HDPE Securitainer fitted with white LDPE tamper evident closure containing 100 to 500 tablets.

ACYCLOVIR 400 PHARMC

Clear PVC/aluminium foil blister packs (10 tablets/blister) containing 60 or 70 tablets in an outer cardboard carton.

White HDPE Securitainer fitted with white LDPE tamper evident closure containing 100 to 500 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACORP (PTY) LTD

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

This leaflet was last revised on

16 August 2023

Registration numbers

ACYCLOVIR 200 PHARMC: A39/20.2.8/0343.

ACYCLOVIR 400 PHARMC: A39/20.2.8/0344.

Access to the corresponding Professional Information

To be confirmed.