

SCHEDULING STATUS:

S4

ADCO ACYCLOVIR 200 mg tablets
Acyclovir
Contains sugar (lactose): 170 mg per tablet

Read all of this leaflet carefully before you start using ADCO ACYCLOVIR TABLETS

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

1. What ADCO ACYCLOVIR TABLETS is and what it is used for

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

- Herpes simplex infections of the skin and mucous membranes including initial and recurrent genital Herpes simplex virus infections.
- Suppression of recurrent Herpes simplex infections in immunocompetent patients.
- Prophylaxis of Herpes simplex infections in immunocompromised patients.
- Treatment of Herpes zoster if the lesions are not older than 72 hours.
- Treatment of Varicella zoster (chickenpox) within 24 hours after appearance of the typical chickenpox rash.

2. What you need to know before you take ADCO ACYCLOVIR TABLETS

Do not take ADCO ACYCLOVIR TABLETS:

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

Warnings and precautions

Take special care with ADCO ACYCLOVIR TABLETS:

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- 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.
- If you have kidney problems. Your doctor may prescribe a lower dose of ADCO ACYCLOVIR.
- It is important that you drink plenty of water while taking high doses of ADCO ACYCLOVIR TABLETS.
- Serious skin reactions such as Drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in patients receiving ADCO ACYCLOVIR TABLETS. 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 ADCO ACYCLOVIR immediately and contact your doctor (see Section 4).

Other medicines and ADCO ACYCLOVIR TABLETS

Always tell your healthcare provider if you are taking any other medicine. (This includes all 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.

Fertility, pregnancy and lactation

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 using ADCO ACYCLOVIR TABLETS.

Driving and using machines

ADCO ACYCLOVIR TABLETS can cause dizziness. You should not drive or operate machinery if you experience this effect.

ADCO ACYCLOVIR contains lactose

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

ADCO ACYCLOVIR contains sodium

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

3. How to take ADCO ACYCLOVIR TABLETS

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

Always use ADCO ACYCLOVIR TABLETS exactly as your doctor or pharmacist has told

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you. Check with your doctor or pharmacist if you are not sure.

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

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

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, omitting the night dose

In severe initial infection, your doctor will extend your treatment. In immunocompromised patients, dosage could be increased to 400 mg, or alternatively, intravenous dosing can be considered

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 or alternatively, intravenous dosing can be considered

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, omitting the night dose

Dosage in the elderly:

Adequate hydration in patients taking high doses must be maintained. Patients with kidney problems should be given special attention.

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

200 mg every 12 hours if creatinine clearance 0-10 mL/minute

Treatment of varicella zoster in immunocompromised patients with renal impairment:

800 mg every 12 hours if creatinine clearance 0-10 mL/minute

800 mg every 8 hourly intervals if creatinine clearance 10-25 mL/minute

800 mg 5 times daily with 4 hourly intervals if creatinine clearance > 25 mL/minute.

Patients on haemodialysis should receive their usual appropriate dose after each dialysis

Orally administered acyclovir in children less than 2 years of age has not yet been fully studied

The tablets should be taken by mouth

If you take more ADCO ACYCLOVIR TABLETS than you should

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

If you forget to take ADCO ACYCLOVIR TABLETS

Take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.

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

4. Possible side effects

ADCO ACYCLOVIR TABLETS can have side effects.

Not all side effects reported for ADCO ACYCLOVIR TABLETS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ADCO ACYCLOVIR TABLETS, please consult your health care provider for advice.

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

Frequent side effects include:

- headache
- feeling dizzy
- nausea
- diarrhoea
- vomiting
- stomach pains
- pruritis
- skin rash
- skin reaction after exposure to light (photosensitivity)
- urticaria
- hair loss
- feeling tired
- fever

Less frequent side effects include:

- effects on some blood tests
- anaphylaxis (life-threatening allergic reaction)

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Angioedema (rapid swelling under the skin)

- agitation, confusion, shakiness, impaired coordination, slurred speech hallucinations, psychotic symptoms, fits, drowsiness, brain diseases, coma
- shortness of breath
- Reversible rises in bilirubin and liver related enzymes
- inflammation of the liver (hepatitis)
- yellowing of your skin and whites of your eyes (jaundice)
- Increased blood urea and creatinine
- renal failure, renal pain

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 ADCO ACYCLOVIR TABLETS.

You may also report to Adcock Ingram Limited using the following e-mail address: Adcock.AEReports@adcock.com.

5. How to store ADCO ACYCLOVIR TABLETS

- Store all medicines out of reach of children.
- Store at or below 25°C in dry place. Protect from light and moisture.
- Store in the original package.
- 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 (e.g., toilets).

6. Contents of the pack and other information

What ADCO ACYCLOVIR TABLETS contains

The active ingredient is acyclovir

The other ingredients are colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium lauryl sulphate, sodium starch glycollate and stearic acid.

What ADCO ACYCLOVIR TABLETS looks like and contents of the pack

ADCO ACYCLOVIR TABLETS 200: White, hexagonal shaped tablets, scored on one side.

ADCO ACYCLOVIR TABLETS 200 mg are available in:

Securitainer of 25 tablets.

Blister packs of 25 tablets

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Holder of Certificate of Registration

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