

Zaviral®

Zaviral 200mg tablets Zaviral 400mg tablets (Acyclovir)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What is **Zaviral** and what it is used for

The name of your medicine is **Zaviral**. This belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses.

Zaviral can be used to:

- treat chickenpox and shingles.
- treat cold sores, genital herpes and other herpes simplex infections.
- stop these problems in people whose immune systems work less well, which means their bodies are less able to fight infections.

2. Before you take **Zaviral**

Do not take **Zaviral and tell your doctor if:**

- you are allergic (hypersensitive) to acyclovir, valacyclovir or any other ingredients in this medicine (see section 6: Further Information).

An allergic reaction can include a rash, itching or shortness of breath.

Do not take this medicine if any of the above apply to you, talk to your doctor or pharmacist before taking **Zaviral**.

Take special care with **Zaviral**

Before you take **Zaviral tell your doctor if:**

- you are elderly.
 - you have kidney problems.
 - you are thirsty. You must make sure you drink plenty of liquids such as water whilst taking this medicine.
 - you have a nervous disorder.
 - you have liver disease or abnormal levels of electrolytes (salts) in your blood.
 - you have severe breathing difficulties.
- If you are not sure if any of the above apply to you, talk to your

doctor or pharmacist before using **Zaviral**.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines bought without a prescription, including herbal medicines.

- In particular tell your doctor if you are taking any of the following medicines:
- probenecid - used for gout.
 - cimetidine - used for stomach acid.
 - mycophenolate mofetil - used in transplant patients.
 - theophylline - used for asthma.
 - zidovudine - used to treat HIV.

Tests

Tell your doctor you are taking this medicine if you are going to have any blood or urine tests.

Pregnancy and Breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding. Driving and using machines

You should not drive or operate machinery until you are sure that the tablets are not affecting your ability to do so.

Zaviral contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take **Zaviral**

Take this medicine as your doctor or pharmacist has told you.

Taking this medicine

- To remove a tablet, press on the tablet from the blister (or bubble) side, pushing it through the foil.
- Do not remove the tablet from the blister until you are ready to take it.
- Unless told otherwise, swallow your tablets whole with plenty of water.
- Drink plenty of liquids such as water while taking this medicine.
- If you feel that the effect of your medicine is too strong or too weak, do not change the dose yourself, but talk to your doctor or pharmacist.

The usual doses are given below. These may be changed by your doctor:

Adults

Herpes Simplex

- Take for at least 5 days
- 200mg, five times each day
- Take every four hours while awake (for example, 6am, 10am, 2pm, 6pm, 10pm).

Shingles

- Take for 7 days.
- 800mg, five times each day.
- Take every four hours while awake (for example, 6am, 10am, 2pm, 6pm, 10pm).

Stopping these problems returning after you have had them

- 200mg four times each day or 400mg twice daily.

Stopping these problems in people whose immune systems work less well and whose bodies are less able to fight infection

- 200mg four times a day.

Elderly and people with kidney problems

Your doctor may decide to lower your dose if you are elderly or have kidney problems.

If you take more **Zaviral than you should**

Talk to your doctor or go to your nearest hospital straight away. Take this leaflet and any tablets you have left to show the doctor or pharmacist.

If you forget to take **Zaviral**

Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, **Zaviral** can cause side effects although not everybody gets them.

Allergic reactions (affects less than 1 in 1,000 people)

If you have an allergic reaction to **Zaviral** see a doctor straight away. An allergic reaction may include:

- any kind of skin rash, flaking skin, boils or sore lips and mouth.
- swelling of the face, lips, tongue or throat or difficulty breathing or swallowing.
- sudden wheezing, fluttering or tightness of the chest or collapse.

Other side effects include:

Common (affects less than 1 in 10 people)

- feeling or being sick.
- diarrhoea.
- stomach pains.
- headaches.
- feeling dizzy.
- feeling very tired.
- itching.
- skin rash that happens in people who are oversensitive to sunlight.
- fever.

Uncommon (affects less than 1 in 100 people)

- skin rashes (causing itchiness or redness).
- hair loss.
- **Rare** (affects less than 1 in 1,000 people)
- shortness of breath.
- changes in blood tests that check the way your liver or kidneys are working.

Very rare (affects less than 1 in 10,000 people)

- blood disorders such as nose bleeds, bruising more easily than usual, sore throat, high temperature or chills, mouth ulcers and unusual tiredness.
 - changes in the results of blood tests such as a fall in the number of white blood cells.
 - liver problems (hepatitis).
 - yellowing of your skin or whites of the eyes (jaundice).
 - kidney failure (which usually returns to normal).
 - pain in your lower back, the kidney area of your back or above your hip (renal pain).
 - feeling weak, dizzy or short of breath. This could be caused by something called 'anaemia'.
 - feeling agitated.
 - shaking.
 - seeing or hearing things that are not there (hallucinations).
 - fits.
 - loss of consciousness.
 - feeling sleepy.
 - feeling confused.
 - difficulty in controlling movements.
 - difficulty in speaking.
 - personality changes and inability to concentrate.
- Frequency not known:**
- tingling or numbness in the hands or feet.
 - muscle pain.
 - swollen glands.
 - serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).

- serious illness with blistering of the skin (toxic epidermal necrolysis).
- swelling of the ankles, feet or fingers.
- changes in vision.

Reporting of side effects

If you get any 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 directly via the national reporting systems listed later.

5. How to store **Zaviral**

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Do not use after the expiry date (month, year) stated on the blister and package.
- If it is out of date or you no longer want it, take it back to the pharmacy.
- Do not use **Zaviral** if you notice anything wrong with the medicine. Talk to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicine no longer required. These measures will help to protect the environment.

6. Further information

What **Zaviral contains**

Zaviral comes in two strengths, 200mg and 400mg.

- The active ingredient is acyclovir.
- The other ingredients are microcrystalline cellulose, povidone, croscarmellose sodium, sodium lauryl sulfate, colloidal silicon dioxide, talc and magnesium stearate.

What **Zaviral look like and contents of the pack**

Zaviral 200 and **Zaviral** 400 tablets are white, oblong tablets. **Zaviral** 200 and **Zaviral** 400 are available in packs containing 4 blisters, each blister contains 14 tablets.

Marketing Authorization holder and manufacturer:

Azal Pharma

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Website: www.azalpharma.com

To report any Side effect
National Medicines and Poisons Board (NMPB)
Fax (+249)18352263
E-mail: info@nmpb.gov.sd
Website: www.nmpb.gov.sd

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consultation your doctor.
- Keep medicament out of reach of children.

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Azal pharma.
Khartoum - Sudan

281216

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