

(GSK logo)

Package leaflet: Information for the user

Zovirax 200 mg Dispersible Tablets
aciclovir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Zovirax is and what it is used for
- 2 What you need to know before you take Zovirax
- 3 How to take Zovirax
- 4 Possible side effects
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1 What Zovirax is and what it is used for

Zovirax 200 mg Dispersible Tablets (called 'Zovirax' in this leaflet) contains the active substance aciclovir. This belongs to a group of medicines called antivirals. It works by stopping the growth of certain viruses.

Zovirax 200 mg Dispersible Tablets can be used to:

- treat herpes simplex virus infections of the skin and mucous membranes (cold sores, genital herpes and other herpes simplex infections)
- prevent recurrences of recurrent herpes simplex infections (stop these problems returning after you have had them)
- prevent herpes simplex infections in immunocompromised patients (stop these problems in people whose immune systems work less well, which means their bodies are less able to fight infections)
- treat chickenpox and shingles

2 What you need to know before you take Zovirax

Do not use Zovirax if:

- you are allergic (hypersensitive) to aciclovir, valaciclovir or any of the other ingredients (listed in Section 6)

Do not take Zovirax if the above applies to you. If you are not sure, check with your doctor or pharmacist before taking Zovirax.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zovirax if:

- you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Zovirax or valaciclovir
- you have kidney problems
- you are over 65 years of age
- you are thirsty. You must make sure you drink plenty of liquids such as water whilst taking this medicine
- your immune system is weak

Take special care with Zovirax

Zovirax can cause severe skin reactions. Stop using Zovirax and seek medical attention immediately if you notice any of the symptoms of severe skin reactions described in section 4.

If you are not sure if the above apply to you, check with your doctor or pharmacist before taking Zovirax.

Zovirax is also available as a liquid suspension.

Children

There is no data available to support the use of this medicine in stopping cold sores or genital herpes returning after having had them and treatment of shingles in children whose immune systems work well.

Other medicines and Zovirax

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

Zovirax with food and drink

Food and drink should not affect the absorption of your medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The ingredients in Zovirax can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take Zovirax.

Driving and using machines

Some side effects such as feeling drowsy or sleepy may impair your ability to concentrate and react. Make sure you are not affected before you drive or operate machinery.

Important information about the contents of Zovirax Tablets

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

3 How to take Zovirax

Your doctor will decide on the correct dose to take, how often and for how long, depending on:

- your age
- the type of infection you have
- whether it is to treat the infection or to stop it coming back

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Dissolve the tablet in a glass of water and stir before drinking.
- If you prefer, the tablet can also be swallowed whole with a little water.
- Start to take Zovirax as soon as possible.
- Drink plenty of liquids such as water while taking this medicine.

The dose that you should take will depend on what you have been given Zovirax for. Your doctor will discuss this with you. An 800 mg tablet is also available.

Treatment of herpes simplex infections (treatment of cold sores, genital herpes and other herpes simplex infections):

Use in adults

The recommended dose is 200 mg, five times daily, during the waking part of the day, approximately every four hours for five days.

Your doctor can adjust the doses as required (e.g. in case you have reduced immune resistance; you are elderly or you have kidney problems). If you are elderly or have kidney problems, it is important to drink plenty of water during treatment.

Use in children

Children under 2 years of age: 100 mg, five times daily, during the waking part of the day, every four hours.

Children over 2 years of age: 200 mg, five times daily, during the waking part of the day, every four hours.

Other form of this medicine may be more suitable for children. **Ask your doctor or pharmacist.**

Prevent recurrences of recurrent herpes simplex infections (stopping these problems returning after you have had them):**Use in adults**

The recommended dose is 200 mg, four times daily, every six hours.

You should take Zovirax until your doctor tells you to stop.

Your doctor can adjust the doses as required (e.g. in case you have reduced immune resistance; you are elderly or you have kidney problems). If you are elderly or have kidney problems, it is important to drink plenty of water during treatment.

Prevent herpes simplex infections in immunocompromised patients (stopping these problems in people whose immune systems work less well, which means their bodies are less able to fight infections):**Use in adults**

The recommended dose is 200 mg, four times daily, every six hours.

You should take Zovirax until your doctor tells you to stop.

Your doctor can adjust the doses as required (e.g. in case you have reduced immune resistance; you are elderly or you have kidney problems). If you are elderly or have kidney problems, it is important to drink plenty of water during treatment.

Use in children

Children under 2 years of age: 100 mg, four times daily, every six hours.

Children over 2 years of age: 200 mg, four times daily, every six hours.

Other form of this medicine may be more suitable for children. **Ask your doctor or pharmacist.**

Treatment of chickenpox and shingles:**Use in adults**

The recommended dose is 800 mg taken five times daily, during the waking part of the day, approximately every four hours for seven days.

Your doctor can adjust the doses as required (e.g. in case you have reduced immune resistance; you are elderly or you have kidney problems). If you are elderly or have kidney problems, it is important to drink plenty of water during treatment.

Use in children

Children under 2 years of age: 200 mg, four times daily.

Children 2 to 6 years of age: 400 mg, four times daily.

Children over 6 years of age: 800 mg, four times daily.

The treatment should be followed for five days. Your doctor can consider dose adjustment according to the body weight.

Other form of this medicine may be more suitable for children. **Ask your doctor or pharmacist.**

If you take more Zovirax than you should

Zovirax is not usually harmful, unless you take too much over several days. Talk to your doctor or pharmacist if you take too much Zovirax. Take the medicine pack with you.

If you forget to take Zovirax

- If you forget to take Zovirax, 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

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Conditions you need to look out for:

➔ **Stop using Zovirax and seek medical attention immediately if you notice any of the following symptoms:**

Allergic reactions (may affect up to 1 in 1000 people)

If you have an allergic reaction, **stop taking Zovirax and see a doctor straight away**. The signs may include:

- bumpy rash, itching or hives on your skin
- swelling of your face, lips, tongue or other parts of your body (angioedema)
- shortness of breath, wheezing or trouble breathing
- unexplained fever (high temperature) and feeling faint, especially when standing up

Serious skin reactions:

These are very rare in people taking Zovirax. Signs include:

- 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. The symptoms usually appear at the initiation of treatment [acute generalised exanthematous pustulosis (AGEP)].
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [Stevens-Johnson syndrome (SJS)/ toxic epidermal necrolysis (TEN)].

Other side effects include:

Common (may affect up to 1 in 10 people)

- headache
- feeling dizzy
- feeling or being sick
- diarrhoea
- stomach pains
- skin reaction after exposure to light (photosensitivity)
- itching
- feeling tired
- fever

Uncommon (may affect up to 1 in 100 people)

- bumpy, itchy, hive-like rash (urticaria)
- hair loss

Rare (may affect up to 1 in 1000 people)

- difficulty breathing
- effects on some blood and urine tests including changes in the levels of liver enzymes and blood count changes
- swelling of your face, lips, mouth, tongue or throat (angioedema).

Very rare (may affect up to 1 in 10000 people)

- nosebleeds and bruising more easily than usual as a result of reduced numbers of blood platelets (thrombocytopenia)

- reduction in the number of red and white blood cells (leukopenia). A reduction in white blood cells may leave a patient more prone to infection.
- feeling agitated or confused
- shaking or tremors
- hallucinations (seeing or hearing things that aren't there)
- fits (seizures)
- feeling unusually sleepy or drowsy
- unsteadiness when walking and lack of coordination (ataxia)
- difficulty speaking or hoarseness (dysarthria)
- inability to think or judge clearly or concentrate
- unconsciousness (coma)
- disturbances of behaviour and speech and bodily movements
- damage or malfunction of the brain (encephalopathy) which is evident by an altered mental state
- inflammation of the liver (hepatitis)
- yellowing of your skin and whites of your eyes (jaundice)
- kidney problems where you pass little or no urine
- pain in your lower back, the kidney area of your back or just above your hip (renal pain).
- fatigue, decreased energy, weakness, shortness of breath, light-headedness, palpitations, looking pale (anaemia)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Zovirax

- Keep out of the sight and reach of children.
- Do not store above 30°C.
- Store in the original package.
- Do not use Zovirax after the expiry date which is stated on the carton. The expiry date (EXP.) refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6 Contents of the pack and other information

What Zovirax 200 mg Dispersible Tablets contain

- The active substance is aciclovir.
- The other ingredients are microcrystalline cellulose, aluminium magnesium silicate, sodium starch glycollate, povidone K30, magnesium stearate, hypromellose, macrogol 400, titanium dioxide [E171], macrogol 8000.

What Zovirax looks like and contents of the pack

Zovirax 200 mg Dispersible Tablets are supplied to you in cartons containing 25 tablets in aluminium foil strips. They are white, round tablets marked "GXCF3" on one side.

Each 200 mg tablet contains 200 mg aciclovir.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

GlaxoSmithKline (Ireland) Ltd., 12 Riverwalk, Citywest Business Campus, Dublin 24, D24 YK11

Manufacturer

GlaxoWellcome S.A., Avenida de Extremadura 3, 09400 Aranda de Duero, Burgos, Spain

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