

Package Leaflet : Information for the User

ZOVIRAX® 800 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
5. How to store Zovirax
6. Contents of the pack and other information

1. What Zovirax is and what it is used for

Zovirax 800mg Dispersible Tablets (called 'Zovirax' in this leaflet) contain a medicine called aciclovir. This belongs to a group of medicines called antivirals. It works by stopping the growth of viruses.

Zovirax 800mg Dispersible Tablets can be used to:

- treat chickenpox
- treat shingles, and when started right after the rash appears, it can help reduce the nerve pain that can exist after the shingles rash has cleared

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

Check with your doctor or pharmacist before taking Zovirax if:

- 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

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 the treatment and prevention of cold sores and 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

Always take this medicine exactly as your doctor 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.
- Your doctor may decide to give you your dose by intravenous infusion.

The dose that you should take will depend on what you have been given Zovirax for. Your doctor will discuss this with you.

In elderly patients and in patients whose immune system works less well, the doctor may decide to vary the dose given.

Adults

Treatment of chickenpox and shingles

- The usual dose is one 800 mg tablet taken five times a day.
- You should space each dose by 4 hours.
- Suggested times are: **7am, 11am, 3pm, 7pm and 11pm.**
- You should take Zovirax for seven days.

Children

Your doctor may adjust the dose of Zovirax if it is for a child.

Other forms of this medicine (e.g. 200 mg dispersible tablets or a suspension form) may be more suitable for children; ask your doctor or pharmacist.

Treatment of chicken pox

- 6 years and over: 800 mg four times a day
- 2-5 years: 400 mg four times a day
- Under 2 years: 200 mg four times a day
- You should try to space each dose by 5 hours. Suggested times are: **7am, 12noon, 5pm and 10pm.**
- Your child should take Zovirax for five days

Your doctor may adjust the dose of Zovirax if:

- you are over 65 years of age
- you have kidney problems.

People over 65 years of age or with kidney problems:

It is very important while you are taking Zovirax that you drink water regularly during the day. This will help to reduce side effects that can affect the kidney or nervous system. Your doctor will closely monitor you for signs of these. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy. Talk to your doctor before taking Zovirax if any of the above apply.

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:

Allergic reactions (may affect up to 1 in 1,000 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.

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 (fatigue)
- 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 1,000 people)

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

Very rare (may affect up to 1 in 10,000 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. A reduction in white blood cells may leave a patient more prone to infection (leukopenia).
- 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 this medicine out of the sight and reach of children.
- Do not store above 30° C.
- Keep the blisters in the outer carton in order to protect from light and moisture.
- 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.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment.

6. Contents of the pack and other information

What Zovirax 800 mg Dispersible Tablets contain

The active substance is aciclovir.

Each dispersible tablet contains 800 mg aciclovir.

The other ingredients are: microcrystalline cellulose, aluminium magnesium silicate, sodium starch glycolate, povidone K30, magnesium stearate, hypromellose, polyethylene glycol 400, titanium dioxide (E171), polyethylene glycol 8000.

What Zovirax looks like and contents of the pack

Zovirax 800 mg Dispersible tablets are supplied to you in cartons containing 35 tablets. They are white, oval tablets marked "GXCG1" on one side.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer:

Zovirax 800 mg Dispersible tablets are manufactured by: Glaxo Wellcome, S.A., Aranda de Duero, Burgos, Spain.

Parallel Product Authorisation number: PPA 465/038/7

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