

Package leaflet: Information for the user
Zovirax 200 mg/5 mL Oral Suspension

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 200 mg/5 mL Oral Suspension (called 'Zovirax' in this leaflet) contains a medicine called aciclovir. This belongs to a group of medicines called antivirals. It works by stopping the growth of viruses. Zovirax 200 mg/5 mL Oral Suspension can be used to:

- treat chicken-pox
- 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
- treat cold sores, genital herpes and other herpes simplex infections (but not to be used to treat herpes simplex infections in newborn infants or severe herpes simplex infections in children whose immune systems work less well which means their bodies are less able to fight infections)
- stop cold sores and genital herpes returning after you have had them
- prevent cold sores and genital herpes in people whose immune systems work less well.

2. What you need to know before you take Zovirax

Do not use Zovirax if:

- you are allergic (hypersensitive) to aciclovir or 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.

Children

There is no data available to support the use of this medicine in stopping cold sores and 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

Taking 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.

Zovirax contains

Methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Liquid Sorbitol solution (non-crystallising) (E420); This medicine contains Liquid Sorbitol solution (non-crystallising) (E420). Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Propylene glycol (E1520); This medicine contains propylene glycol (E1520).

If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

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.
- Use the spoon provided to carefully measure the dose needed.
- 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.

Adults

Treatment of chickenpox and shingles

- The usual dose is four 5 ml spoonfuls 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.

Treatment of cold sores and genital herpes

- The usual dose is one 5 ml spoonful 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 five days, or longer if your doctor tells you to.

Stopping these problems returning after you have had them

- The usual dose is one 5 ml spoonful four times a day.
- You should try to space each dose by 6 hours.
- You should take Zovirax until your doctor tells you to stop.

Preventing these problems in people whose immune systems work less well

- The usual dose is one 5 ml spoonful four times a day. Your doctor may decide to double the dose to two 5 ml spoonfuls four times daily in people whose immune systems are severely impaired.
- You should try to space each dose by 6 hours.
- You should take Zovirax until your doctor tells you to stop.
- Your doctor may decide to increase the dose or give a different form of this medicine by intravenous infusion

Children

Your doctor may adjust the dose of Zovirax if it is for a child. There is no data available to support the use of this medicine in stopping cold sores and genital herpes returning after having had them and treatment of shingles in children whose immune systems work well.

Treatment of cold sores and genital herpes:

- 2 years and over: one 5 ml spoonful five times a day.
- Under 2 years: one 2.5 ml spoonful five times a day

Preventing these problems in children whose immune systems work less:

- 2 years and over: one 5 ml spoonful four times a day
- Under 2 years: one 2.5 ml spoonful four times a day

Treatment of chicken pox

- 6 years and over: four 5 ml spoonfuls four times a day
- 2-5 years: two 5 ml spoonfuls four times a day
- Under 2 years: one 5 ml spoonful 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 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 in blood platelets (thrombocytopenia)
- reduction in the number of red blood cells (anaemia) and white blood cells (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 co-ordination (ataxia)
- difficulty speaking or hoarseness (dysarthria)
- inability to think or judge clearly or concentrate
- unconsciousness (coma)
- disturbances of behaviour, 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 HPRC 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 25°C.
- Do not use this medicine after the expiry date which is stated, after "EXP" on the carton. The expiry date 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/5 mL Oral Suspension contains

- The active substance is aciclovir.
- The other ingredients are Sorbitol liquid (non-crystallising), glycerol, microcrystalline cellulose, carmellose sodium, vanillin, banana flavour (contains propylene glycol [E1520]), purified water, methyl parahydroxybenzoate and propyl parahydroxybenzoate.

What Zovirax looks like and contents of the pack

Zovirax 200 mg/5 mL Oral Suspension is supplied to you in an amber-coloured glass bottle, containing 62.5 mL of an off-white suspension. The medicine comes with a double-ended measuring spoon. One end of the spoon will give you 5 mL of the suspension and the other will give you 2.5 mL.

Each 5 mL of Zovirax 200 mg/5 mL Oral Suspension contains 200 mg aciclovir.

The pack contains 2 x 62.5 mL bottles.

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:

Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany Parallel Product Authorisation number:

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