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Front Page

1200000117540

Package leaflet: Information for the user



Zovirax Suspension aciclovir 200 mg/5 ml

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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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.

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 Suspension (called 'Zovirax' in this leaflet) contains a medicine called aciclovir. This belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses.

Zovirax can be used to:

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

2 What you need to know before you take Zovirax

Do not use Zovirax:

- if you are allergic to aciclovir or valaciclovir or any of the other ingredients of this medicine (listed in Section 6).
- Do not take Zovirax if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Zovirax.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zovirax if:

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

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

It is important that you drink plenty of water while taking Zovirax.

Other medicines and Zovirax

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

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.

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

Sorbitol: This medicine contains 1575 mg sorbitol per 5 mL. 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: This medicine contains less than 1 mg propylene glycol per 5 mL of oral solution.

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. 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.

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

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.

Suppressing cold sores and genital herpes 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.

Suppressing cold sores and genital herpes in people whose immune systems work less well and whose bodies are less able to fight infections

- 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.

Your doctor may adjust the dose of Zovirax if:

- it is for a child
- you are over 65 years of age
- you have kidney problems. If you have kidney problems, it is important to drink plenty of water while you are being treated with Zovirax.

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:

- rash, itching or hives on your skin
- swelling of your face, lips, tongue or other parts of your body
- shortness of breath, wheezing or trouble breathing
- collapse.

Other side effects include:

Common (may affect up to 1 in 10 people)

- headache
- feeling dizzy
- feeling or being sick
- diarrhoea
- stomach pains
- rash
- skin reaction after exposure to light (photosensitivity)
- itching
- feeling tired
- unexplained fever (high temperature) and feeling faint, especially when standing up.

Uncommon (may affect up to 1 in 100 people)

- itchy, hive-like rash
- hair loss.

Rare (may affect up to 1 in 1,000 people)

- effects on some blood and urine tests
 - increases in the enzymes that work in the liver.
- Very rare** (may affect up to 1 in 10,000 people)
- reduced numbers of red blood cells (anaemia)
 - reduced numbers of white blood cells (leukopenia)
 - reduced numbers of blood platelets (cells that help blood to clot) (thrombocytopenia)
 - feeling weak
 - feeling agitated or confused
 - shaking or tremors
 - hallucinations (seeing or hearing things that aren't there)
 - fits

- feeling unusually sleepy or drowsy
- unsteadiness when walking and lack of coordination
- difficulty speaking
- inability to think or judge clearly
- unconsciousness (coma)
- paralysis of part or all of your body
- disturbances of behaviour, speech and eye movements
- stiff neck and sensitivity to light
- 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).

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.

To report Product Complaints or Adverse Events associated with the use of GSK products, please contact us via: gulf.safety@gsk.com

5 How to store Zovirax

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Do not use this medicine after the expiry date which is stated on the carton after Exp. 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 Suspension contains

- The active substance is aciclovir.
- The other ingredients are sorbitol solution, glycerol, dispersible cellulose, methyl parahydroxybenzoate, propyl parahydroxybenzoate, banana flavour (contains propylene glycol), vanillin and purified water.

What Zovirax looks like and contents of the pack

Zovirax Suspension is supplied to you in an amber-coloured glass bottle, containing 125 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 Suspension contains 200 mg aciclovir.

Marketing authorisation holder

The Wellcome Foundation Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS

Manufacturer

Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany

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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 the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
 - Do not by yourself interrupt the period of treatment prescribed for you.
 - Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

IMPORTANT

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Artwork Studio is responsible for site technical requirements and pre-press suitability.

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Formulation
Tablet embossing
Storage conditions
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ASPEN BAD OLDESLOE

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