

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed with a physician's prescription only

Zovirax Suspension

Each 5 ml suspension contains aciclovir 200 mg.

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – "Important information about some ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Zovirax Suspension contains a medicine called aciclovir. It works by killing or stopping the growth of viruses.

Zovirax Suspension can be used to:

- treat chickenpox and shingles.
- treat cold sores, genital herpes and other herpes simplex infections.
- prevent recurrence of herpes simplex infections in patients with a normal immune system.
- prevent herpes simplex infections in people whose immune system is not functioning so well, which means their bodies are less capable of fighting infections.

Therapeutic group

Antiviral.

2. Before using the medicine

Do not use the medicine if:

- you are sensitive (allergic) to aciclovir or valaciclovir or any of the additional ingredients of this medicine (listed in section 6).

Do not take Zovirax Suspension if the above applies to you. If you are not sure, talk to your pharmacist or physician before taking Zovirax Suspension.

Special warnings regarding the use of the medicine

Refer to your pharmacist or physician before taking Zovirax Suspension if:

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

If you are not sure if these apply to you, talk to your pharmacist or physician before taking Zovirax Suspension.

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

Drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines, herbal medicines and nutritional supplements, tell the physician or the pharmacist.

Especially if you are taking:

- probenecid, used to treat gout
- cimetidine, used to treat stomach ulcers
- mycophenolate mofetil, used to prevent your body from rejecting transplanted organs.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you are pregnant or are planning to become pregnant, consult the physician or pharmacist before using the medicine.

Driving and use of machinery

Certain side effects, such as drowsiness or sleepiness may impair your ability to concentrate and respond. Make sure that you are not affected by these effects before you drive or operate machinery.

With respect to children, caution them against riding a bicycle, playing near a road, and similar activities.

Important information about some ingredients of the medicine

Zovirax Suspension contains:

Methyl parahydroxybenzoate and 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 physician 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 physician 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 should you use the medicine?

Always use the preparation according to the physician's instructions. Check with the physician or the pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

Taking this medicine

- Take this medicine by mouth.
- Shake the bottle well before use.
- Use the spoon provided to carefully measure the dose needed.
- Start to take Zovirax Suspension as soon as possible.

The dose that you should take will depend on the reason for which Zovirax Suspension is being given to you.

The dosage and treatment regimen will be determined by the physician only.

Your physician may adjust the dose of Zovirax Suspension if:

- it is intended 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 Suspension.

If any of these apply to you, talk to your physician before taking Zovirax Suspension.

Do not exceed the recommended dose

Opening instructions: To remove the cap, press down and twist to the left (turning counter-clockwise) at the same time.

Closing instructions: Close the bottle tightly with the cap, twisting to the right (turning clockwise) until fully closed.

If you have accidentally taken a higher dosage

Zovirax Suspension is usually not harmful, unless you take too much over several days. Refer to your pharmacist or physician if you took too much Zovirax Suspension. Bring the package of the medicine with you.

If a child has accidentally swallowed the medicine, refer immediately to a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

- If you forgot to take Zovirax Suspension, 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.

Adhere to the treatment as recommended by the physician. Even if your health condition improves, do not stop treatment with the medicine without consulting the physician, as your symptoms may get worse.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, use of Zovirax Suspension may cause side effects in some of the users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Allergic reactions (These may affect up to 1 in 1,000 people)

If you have an allergic reaction, **stop taking Zovirax Suspension and refer to a physician straight away**. The signs may include:

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

Additional side effects

Common side effects - These may affect up to 1 in 10 people

- headache
- feeling dizzy
- nausea or vomiting
- diarrhea
- stomach pain
- rash
- skin reaction after exposure to light (photosensitivity)
- itching
- feeling tired
- unexplained fever (high temperature) and feeling faint, especially upon standing up.

Uncommon side effects - These may affect up to 1 in 100 people

- itchy, hive-like rash
- hair loss.

Rare side effects - These may affect up to 1 in 1,000 people

- effects on some blood and urine tests

- increase in enzymes that work in the liver.

Very rare side effects - These 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 platelets (cells that help the blood to clot) (thrombocytopenia)
- feeling weak
- feeling agitated or confused
- tremors
- hallucinations (seeing or hearing things that do not exist)
- 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 behavior, 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, in the back area where your kidney is located, or above your pelvis (renal pain).

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.it) that directs you to the online form for reporting side effects, or by entering the link:

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the carton. The expiry date refers to the last day of that month.
- Store below 25°C.
- Discard the suspension at the end of the treatment.

6. Additional information

- In addition to the active ingredient the medicine also contains:
Sorbitol solution 70%, glycerol, dispersible cellulose, methyl parahydroxybenzoate, propyl parahydroxybenzoate, vanillin, banana flavour (contains propylene glycol) and purified water.
- What the medicine looks like and the content of the package:
Zovirax Suspension is supplied 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 is for administration of 5 ml of the suspension and the other is for administration of 2.5 ml.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 018-21-24481

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