

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

Zovirax Tablets 200 mg

Zovirax Tablets 400 mg

Zovirax Tablets 200 mg – each tablet contains aciclovir 200 mg

Zovirax Tablets 400 mg – each tablet contains aciclovir 400 mg

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

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or 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 Tablets (called 'Zovirax' in this leaflet) contains a medicine called aciclovir. 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
- 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 to any of the additional ingredients contained in this medicine (listed in section 6).

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

Special warnings regarding use of the medicine

Contact your physician or pharmacist before taking Zovirax if:

- you have had experienced **severe skin reactions** with Zovirax or valaciclovir
- you have kidney problems
- you are over 65 years of age.

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

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

Conditions you need to look out for

Zovirax can cause severe skin reactions. You must look out for certain symptoms while you are taking Zovirax to reduce the risk of any problems. If you experience signs or symptoms of severe skin reactions, stop using Zovirax and contact your physician immediately (see 'Side effects').

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 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 may be pregnant or are planning to have a baby, ask your physician for advice before using this medicine.

Driving and using machines

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

Important information about some of the ingredients in the medicine

Zovirax contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially sodium-free.

Zovirax Tablets 200 mg contains lactose. If your physician has told you that you have an intolerance to some sugars contact your physician before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

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

Taking this medicine

- Take this medicine by mouth.
- Zovirax Tablets 200 mg and 400 mg – Swallow the tablet whole, with a little water.
- Make sure to **drink plenty of fluids such as water** while you are being treated with Zovirax.
- Start to take Zovirax as soon as possible.

There is no information regarding crushing/halving/chewing.

The dose that you need to take will depend on the reason Zovirax is being given to you. Your physician will discuss this with you.

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

Your physician may adjust the dose of Zovirax 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.

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

Do not exceed the recommended dose

If you accidentally have taken a higher dosage

Zovirax is usually not harmful unless you take too much over several days. Refer to your physician or pharmacist if you took too much Zovirax. 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, 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 regimen recommended by your physician. Do not stop treatment with the medicine without consulting the physician.

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 use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

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

Conditions you need to look out for

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

If you have an allergic reaction, **stop taking Zovirax 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.

Severe skin reactions: These effects are very rare (may affect **up to 1 in 10,000** people taking Zovirax). The signs include:

- widespread red or scaly rash with blisters (that may contain pus), bumps under the skin or peeling of skin. Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results.

➔ **Contact a physician immediately** if these symptoms appear. **Stop taking Zovirax.**

Additional side effects include:

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 (anemia)
- reduced numbers of white blood cells (leukopenia)
- reduced numbers of blood 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)
- severe skin reactions, such as widespread red or scaly rash with blisters (that may contain pus), bumps under the skin or peeling of skin. Flu-like symptoms accompanied by a rash, fever, swollen glands, and abnormal blood test results. (See '*Conditions you need to look out for*').

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.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store in the original package.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:
Zovirax Tablets 200 mg and 400 mg:
Lactose monohydrate (only in 200 mg tablets), microcrystalline cellulose, sodium starch glycollate, povidone K30, magnesium stearate.
- What the medicine looks like and the contents of the package:
Zovirax Tablets 200 mg is supplied in a carton package containing 25 tablets in blister packages. The tablets are white, round, convex, marked with "GXCL3" on one side and plain on the other.

Zovirax Tablets 400 mg is supplied in a carton package containing 25 tablets in blister packages. The tablets are white, shield-shaped, marked with "GXCM1" on one side and plain on the other.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Trading Services Limited, Dublin, Ireland.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Zovirax Tablets 200 mg: 126-41-30640
Zovirax Tablets 400 mg: 126-40-30639

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