

Patient leaflet in accordance with the Pharmacists'
Regulations (Preparations) – 1986
The medicine is dispensed according
to a physician's prescription only

Zovirax Genital, cream

Contains: aciclovir 5% w/w.

List of the additional ingredients detailed in section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other 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 Genital contains a medicine called aciclovir. It is used to treat genital infections caused by the Herpes simplex virus. It works by killing or stopping the growth of viruses that cause genital herpes.

Therapeutic group

Antiviral.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to aciclovir, valaciclovir, propylene glycol or to any of the additional ingredients contained in the medicine (listed in section 6).

If you are not sure, talk to your physician or pharmacist before using Zovirax Genital.

Special warnings regarding the use of the medicine

Talk to your physician or pharmacist before using Zovirax Genital if:

- you have a condition where your immune system works less well and your body is less able to fight infections (e.g., if you have HIV or AIDS or if you have had a bone marrow transplant).

If you are not sure, talk to your physician or pharmacist before using Zovirax Genital.

Zovirax Genital is not for use in the mouth, eyes or the vagina. Zovirax Genital may cause skin irritation.

If you are not sure, talk to your physician or pharmacist before using Zovirax Genital.

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding consult the physician or the pharmacist before using the medicine.

3. How should you use the medicine?

Always use according to the physician's instructions.

You should check with the physician or the pharmacist if you are unsure.

Applying the cream

- Zovirax Genital is not for use in your mouth, eyes or the vagina.
- You should not mix Zovirax Genital with anything before you use it, not even water.
- Always wash your hands before and after you use the cream.

Zovirax Genital is prescribed for the treatment of genital herpes. Avoid sexual intercourse while under treatment until the sores have completely healed, since genital herpes is transmitted during sexual contact.

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

The usual dosage is:

Adults and children

- Apply a thin layer of cream to the affected area five times a day.
- You should space each application of Zovirax Genital by four hours. Suggested times are: **07:00, 11:00, 15:00, 19:00 and 23:00.**
- If your sore has not healed after 5 days, you may use the cream for 5 more days.
- If the affected area has still not healed after this, stop using the cream and tell your physician.

Do not exceed the recommended dose

If you accidentally have used a higher dosage

Talk to your physician or pharmacist if you use too much Zovirax Genital. Zovirax Genital is for use on the skin; if you swallow any, talk to your physician or pharmacist.

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

If you forgot to use the medicine

- If you forgot to use Zovirax Genital, use it as soon as you remember. However, if it is nearly time for your next application, skip the missed application.
- Do not use a double application to make up for a forgotten application.

Persist with the treatment as recommended by 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 any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

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

Allergic reactions (affects less than 1 in 10,000 people)

If you have an allergic reaction, **stop using Zovirax Genital and see a physician straight away.** The signs may include:

- rash, itching or hives on your skin
- swelling of the face, lips, tongue or other parts of your body
- shortness of breath, wheezing or having trouble breathing
- unexplained fever and feeling faint, especially when standing up.

Additional side effects

Uncommon (affects less than 1 in 100 people)

- a burning or stinging feeling after applying the cream that goes away
- mild drying or flaking of your skin
- itching.

Rare (affects less than 1 in 1,000 people)

- redness of your skin
- skin rash.

If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician.

Adverse events can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" that is located on the Ministry of Health home page (www.health.gov.il), which refers to on-line form for adverse events reporting, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store below 25°C.

The preparation can be used for up to 10 days after first opening, but no later than the expiry date.

Do not store in a refrigerator.

6. Additional information

- **In addition to the active ingredient the medicine also contains –**
Propylene glycol, white soft paraffin, cetostearyl alcohol, liquid paraffin, glycerol monostearate and polyoxyethylene stearate, poloxamer 407, dimeticone 20, sodium laurilsulfate, purified water.
- **What does the medicine look like and what is the content of the package –**
Each carton contains a 10 g tube of Zovirax Genital. The tube has a screw cap and contains a smooth, white cream.
- **License Holder:** GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- **Manufacturer:** Glaxo Operations (UK) Limited, Barnard Castle, UK.
- This leaflet was checked and approved by the Ministry of Health in December 2014.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 046-50-23031

Trade marks are owned by or licensed to the GSK group of companies.

©2018 GSK group of companies or its licensor.

ZovGen PT v4.1A