


X

FRONT

Y


6200000083090

Package leaflet: Information for the user

Zovirax Cream

aciclovir

Read all of this leaflet carefully before you start using 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:

- What Zovirax is and what it is used for
- What you need to know before you use Zovirax
- How to use Zovirax
- Possible side effects
- How to store Zovirax
- Contents of the pack and other information

1 What Zovirax is and what it is used for

Zovirax Cream (called 'Zovirax' in this leaflet) contains a medicine called aciclovir. This belongs to a group of medicines called antivirals. It is used to treat cold sores and genital infections caused by the Herpes simplex virus. It works by killing or stopping the growth of viruses that cause cold sores or genital herpes.

2 What you need to know before you use Zovirax

Do not use Zovirax if:

- you are allergic (hypersensitive) to aciclovir, valaciclovir, propylene glycol or any of the other ingredients (listed in Section 6).

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

Warnings and precautions

Talk to your doctor or pharmacist before using Zovirax 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 doctor or pharmacist before using Zovirax.

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

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

Other medicines and Zovirax

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without prescription, including herbal medicines.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before using any medicine.

Zovirax Contains:

Cetostearyl alcohol; The excipient cetostearyl alcohol can cause local skin reactions (e.g. contact dermatitis)

Propylene glycol; this medicine contains 400 mg of propylene glycol per gram of product.

Propylene glycol may cause skin irritation. Do not use this medicine in babies less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns) without talking to your doctor or pharmacist.

Sodium laurilsulfate; this medicine contains 7.5 mg of sodium laurilsulfate per gram of product. Sodium laurilsulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

3 How to use Zovirax

Always use Zovirax exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Applying the cream

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

Adults and children

- Apply a thin layer of cream to the affected area five times a day.
- You should space each application of Zovirax by four hours. Suggested times are: **7am, 11am, 3pm, 7pm and 11pm.**
- If your cold sore has not healed after 4 days, or your genital herpes 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 doctor.

If you use more Zovirax than you should

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

If you forget to use Zovirax

- If you forget to use Zovirax, 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.

4 Possible side effects

Like all medicines, Zovirax can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions (affects less than 1 in 10,000 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 having trouble breathing
- unexplained fever and feeling faint, especially when standing up.

Other side effects include:

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

To report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s, please contact us via: gulf.safety@gsk.com

5 How to store Zovirax

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not store in a refrigerator.
- Do not use Zovirax if more than one month has passed since you first opened the tube.
- Do not use Zovirax after the expiry date which is stated on the carton and tube. The expiry date (EXP.) refers to the last day of that month.
- Do not throw away 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 Cream contains

- The active substance is aciclovir.
- The cream contains 5% w/w aciclovir.
- The other ingredients are poloxamer 407, cetostearyl alcohol, sodium laurilsulfate, white soft paraffin, liquid paraffin, propylene glycol, purified water, glycerol monostearate and polyoxyethylene stearate, dimeticone 20.

What Zovirax looks like and contents of the pack

Each carton contains a 2 g or 10 g tube of Zovirax. The tube has a screw cap and contains a smooth, white to off-white cream. Not all pack sizes may be marketed.

Marketing authorization holder:
The Wellcome Foundation Ltd, 980 Great West Road, Brentford, Middlesex, United Kingdom.

Manufacturer:
Glaxo Operations UK Limited*, Barnard Castle, UK
*Member of the GSK group of companies

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


©2022 GSK group of companies or its licensor.


Version date: November 2020

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



Version: 2		
Harmony AMS Artwork Information Panel		
Manufacturing Site Number: 6200000083090		
Manufacturing Site(s): GSK_BARNARD CASTLE_UNITED KINGDOM		
Product Market Trade Name: ZOVIRAX		
Approving Market(s): MARKET GROUP-Gulf and Near East		
Print Process: N/A		
Colour Standard Reference: N/A		
Technical Drawing (Do NOT include version number): JMF333		
Material Spec. (Do NOT include version number): N/A		
Material Type: N/A	N/A	
Total Colours & Varnishes: 1		
BLACK		
Total Special Finishes: 0		
Body Text Size: 9.5pt		
Smallest Text Size: 9.5pt		
Leading: 11.0pt		
Horizontal Scale: 100%		
Microtext: N		
Additional Info (1): N/A		
Additional Info (2): N/A		
Additional Info (3): N/A		

AIP_Production_V_INDD - 06_2022 - Harmony - Version 3

 200 mm Measuring Bar
 If an e-banner DOES NOT appear on the top of this document, THEN this document has NOT been printed from the Harmony system.

IMPORTANT

GSK LOC is responsible to approve the change documentation, artwork brief and final artwork, ensuring that it is accurate, consistent and complete.

GSK SDC is responsible for site technical requirements and pre-press suitability.

GSK Market is responsible to advise SDC when changes required impact the following:

**Formulation
Tablet embossing
Storage conditions
Shelf Life**

NOTE TO MARKET

Local approvers must ensure that trade mark and copyright statements included in the brief comply with guidance provided by Legal: Global Trade Marks.

Pharma code Ref. No. 7010

