

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zovirax® 5% w/w Cream (aciclovir)

This product is imported from Spain under the name of 'Zovirax Crema' but is marketed as 'Zovirax 5% w/w Cream' in Ireland.

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.

What is in this leaflet:

1. What Zovirax is and what it is used for
2. What you need to know before you use Zovirax
3. How to use 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 5% w/w 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, genital herpes and other skin infections caused by the Herpes simplex virus. It works by 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 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).

Zovirax Cream is not for use in the mouth, eyes or the vagina.

If you are not sure, talk to your doctor or pharmacist before using 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 prescription, including herbal medicines.

Zovirax with food and drink

Food and drink should not affect the absorption of your medicine.

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 doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Zovirax should not affect your ability to drive or use machines.

Zovirax contains cetosteraryl alcohol and propylene glycol

Zovirax contains cetosteraryl alcohol; this may cause local skin reactions (e.g. contact dermatitis). Zovirax also contains propylene glycol; this may cause skin irritation.

3. How to use Zovirax

Always use this medicine exactly as your doctor has told you. 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. Zovirax cream should only be applied externally for the treatment of cold sores and genital herpes.

- 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 up to 10 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, 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 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 (may affect up to 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 (may affect up to 1 in 1,000 people)

- redness of your skin
- skin rash.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2;
Tel: +353 1 6764971 Fax +353 1 6762517.
Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zovirax

- Do not use any cream after the expiry date printed on the tube and carton label. The expiry date (Exp.) refers to the last day of that month.
- Put the lid back on the tube after each time that you have used it.
- Keep your cream in a safe place out of the reach and sight of children.
- Do not store the cream above 25°C.
- Do not refrigerate.
- If this product appears to be discoloured or show any other signs of deterioration, please return this to your pharmacist who will advise you further.
- If you have any left over/unused product, please return this to your pharmacist for safe disposal.
- Only a doctor can prescribe this Zovirax Cream. Do not let anyone else use your cream even if they have the same symptoms as you.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment.

6. Contents of the pack and other information

What Zovirax 5% w/w Cream contains

Each gram contains 50mg (5% w/w) aciclovir.

There are also some other ingredients in Zovirax Cream. These are propylene glycol (E1520), sodium laurilsulfate, cetostearyl alcohol, poloxamer 407, white soft paraffin, liquid paraffin, dimeticone 20, arlancel 165 and purified water. Zovirax Cream does not contain any preservatives.

What Zovirax looks like and contents of the pack

Zovirax Cream is a smooth, odourless, white to off-white cream.

Zovirax Cream is available in 2g tubes.

Manufacturer

Manufactured by: Glaxo Wellcome Operations,
Barnard Castle, Durham, DL12 8DT, UK.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall,
Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park,
Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business
Park, Santry, Dublin 9.

PPA No: 1151/28/1

Leaflet revision & issue date (ref): 21.10.15

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