

Package leaflet: Information for the user

Zovirax

Cold sore 5% w/w cream aciclovir

Please read right through this leaflet before you start using this medicine. This medicine is available without prescription, but you still need to use Zovirax Cold Sore Cream carefully to get the best results from it.

- Keep this leaflet, you may need to read it again.
- If you have any further questions, ask your pharmacist.

In this leaflet:

1. What Zovirax does
2. Check before you use Zovirax
3. How to use Zovirax
4. Possible side effects
5. How to store Zovirax
6. Further information

1. What Zovirax does

Zovirax is used for the treatment of cold sores. The active ingredient is aciclovir, an antiviral agent. **Apply at the first signs of a cold sore** (such as tingling and itching). It can also be used to speed up healing if one has already appeared and shorten the duration of pain.

2. Check before you use Zovirax

Do not use Zovirax:

- If you have ever had an allergic reaction to aciclovir, valaciclovir, propylene glycol or any of the other ingredients (listed in Section 6).
- inside your nose or mouth (e.g. for mouth ulcers), or for anything other than a cold sore.
- in the eyes or genital area.

Take special care with Zovirax

- Always wash your hands before and after applying Zovirax.
- Do not touch your eyes until you have washed your hands after application.
- If you accidentally get cream in your eye, wash out thoroughly with warm water. Consult your doctor if you are concerned.
- Do not swallow the cream. If you accidentally swallow any cream, it is unlikely to cause any ill effects but consult your doctor if you are concerned.
- Avoid touching a cold sore to prevent transferring the infection or making it worse.
- If you have been told by your doctor that you have a weakened immune system, contact your doctor before treating any type of infection.
- If you are in any doubt if you have a cold sore, contact your doctor.
- If your cold sore gets very severe, contact your doctor.

Using other medicines

Tell your doctor or pharmacist before use if you are taking any regular medication on prescription or over the counter products

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before using Zovirax if you are pregnant, trying to become pregnant or are breastfeeding.

Zovirax contains propylene glycol, sodium laurilsulfate and cetostearyl alcohol:

- Contains 200 mg propylene glycol in each daily dose which is equivalent to 400 mg/g.
- Contains 3,75 mg sodium laurilsulfate in each daily dose which is equivalent to 7.5 mg/g. 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.
- Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3. How to use Zovirax

Suitable for all ages:

- Apply at the first signs of a cold sore (such as tingling and itching). • Apply liberally to the affected area 5 times a day.
- Continue treatment for 4 days. If your cold sore hasn't healed after this time, you can use the cream for up to 10 days in total.
- Treat your cold sore for 4 full days to ensure rapid healing.
- If you forget a dose, apply when you remember and continue as before.
- If your cold sore hasn't healed fully after 10 days, or if it gets worse at any time, contact your doctor.
- Never give your Zovirax to others, even if their symptoms are the same as yours.
- The amount of cream inside this pack is enough for one cold sore attack. For any future attacks, start treatment at the first signs of a cold sore developing (such as tingling or itching). It can also be started during the blister stage.
- Do not use more than the recommended dose.

4. Possible side effects

Like all medicines, Zovirax can have side effects, but not everybody gets them.

Stop using the medicine and tell your doctor if you experience:

- Allergy-like reactions, for example swelling of the lips, face and eyelids, or an itchy bumpy rash on your skin (hives).
- The following side effects could also occur:
- Mild burning or stinging after application. This will quickly go away.
- Redness, itching or a mild drying or flaking of the skin, skin rashes or weals.

This does not prevent the cream from working.

Reporting of side effects

If you get any side effects, talk to your doctor pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zovirax

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date (EXP) which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

Active ingredient Aciclovir 5% w/w.

Other ingredients Dimeticone, propylene glycol (E1520), poloxamer 407, cetostearyl alcohol, sodium laurilsulfate, white soft paraffin, liquid paraffin, glycerol monostearate, macrogol stearate 100 and purified water.

Zovirax is a smooth white to off-white cream.

Zovirax is available in a 2g tube or pump.

More about cold sores

A cold sore is an infection which is caused by the herpes simplex virus (HSV), which lies dormant in nerve cells supplying your lips and the surrounding skin.

When does the first infection occur?

The first infection usually occurs in early childhood, probably after being kissed by a person with the infection. The virus passes through the skin, travels up a nerve and stays in a nerve junction indefinitely.

What can trigger the virus?

Various things, including colds, flu, menstruation, fatigue, emotional upset, stress, physical injury, bright sunlight and simply when you are feeling “run down”. Once triggered, the virus travels back down the nerve to the skin on and around the lips where it causes the cold sore to develop. Many cold sore sufferers can recognise when they are about to get a cold sore e.g. tingling, itching.

Remember - cold sores are infectious

The virus is capable of infecting other parts of the body. To reduce the risk of passing the infection on, do not allow others to touch your cold sore, or to share your towel, etc. You should avoid kissing and oral sex if you or your partner has an active cold sore. Always wash your hands before and after touching cold sores.

- Avoid touching your eyes. HSV infection of the eye can lead to ulcers on the window of the eye (cornea).
- Avoid kissing - especially children - when you have a cold sore.
- Don't break the blisters or pick the scabs. Not only could you infect your cold sore with other germs, you may infect your fingers with the virus.
- Don't share your eating and drinking utensils.

The marketing authorisation holder is Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland.

The manufacturer: Haleon Germany GmbH, Barthstrasse 4, D-80339 Munich, Germany.

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