

Cyclovir Cream

Active ingredient and its concentration: Acyclovir
5% w/w

Inactive ingredients: listed 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 is dispensed without a physician's prescription. You must use the medicine in the correct manner. Consult the pharmacist if you need further information. You have to contact the physician if symptoms of the illness worsen or if they do not improve in 10 days.

1. What Cyclovir is intended for

Cyclovir is used for the treatment of cold sores.

The active ingredient is Acyclovir, 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.

2. Before using the medicine

Do not use Cyclovir:

- If you have ever had an allergic reaction to acyclovir, valacyclovir, propylene glycol or any of the other ingredients (listed in Section 6).
- Inside your mouth (e.g. for mouth ulcers) or nose.
- For any skin infection other than a cold sore.
- In the eyes or genital area.

Take special care with Cyclovir

- Always wash your hands before and after applying Cyclovir.
- 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 physician 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 physician that you have a weakened immune system, contact your physician before treating any type of infection.
- If you are in any doubt if you have a cold sore, contact your physician.
- If your cold sore gets very severe, contact your physician.

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

Pregnancy and breast feeding

Talk to your physician or pharmacist before using Cyclovir if you are pregnant, trying to become pregnant or are breast feeding.

Important information about some ingredients of the medicine:

Propylene glycol may cause skin irritation. Cetostearyl alcohol can cause local skin reactions (e.g. contact dermatitis).

3. How should you use the medicine?

Suitable for all ages:

- You should check with the physician or the pharmacist if you are unsure.
- The usual dosage: 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 5 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 5 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 physician.
- Never give your Cyclovir 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.
- Do not swallow the cream. For external use only. If you accidentally swallow any cream, it is unlikely to cause any ill effects but consult your physician if you are concerned. 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.
- 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.

4. Possible side effects

As with any medicine, use of Cyclovir 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.

Stop using the medicine and tell your physician immediately if you experience:

- Allergy-like reactions, for example swelling of the lips, face and eyelids.

Additional side effects:

- Mild burning or stinging after application. This will quickly go away.
- Redness, itching or a mild drying or flaking of the skin, skin rashes, hives or weals.

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.

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://forms.gov.il/qlo/qaldata/getsequence/getsequence.aspx?formType=adverSideEffect/Medic/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 but do not keep it in the refrigerator.

6. Further information

In addition to the active ingredient, the medicine also contains:

Propylene glycol, white soft paraffin, cetostearyl alcohol, liquid paraffin, ariceal 165 (glycerol monostearate, macrogol stearate 100, poloxamer 407, dimeticone 20), sodium laurylsulfate, and purified water.

What does the medicine look like and what is the contents of the package:

Cyclovir is available in a 2 g tube or pump. Not all pack sizes may be marketed.

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.

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.

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Manufacturer: Glaxo Operations (UK) Limited, Barnard Castle, UK.

This leaflet was checked and approved by the Ministry of Health in: August 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

152-54-341D2.