

Package leaflet: information for the user
Cold Sore Cream HTP Aciclovir 50 mg/g, cream aciclovir

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

This medicine is available without a prescription. However, use it carefully to achieve the best results.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your pharmacist.
- If your symptoms do not improve after 10 days, or if they worsen, contact your doctor.
- If you experience any side effects listed in section 4, or any side effects not mentioned in this leaflet, contact your doctor or pharmacist.

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1. What is Cold Sore Cream HTP Aciclovir 50 mg/g and what is it used for?

Cold Sore Cream HTP Aciclovir 50 mg/g contains aciclovir, an antiviral agent against herpes viruses, and it inhibits the multiplication of herpes viruses in the skin.

Cold Sore Cream HTP Aciclovir 50 mg/g is used for the treatment of cold sores caused by a herpes virus.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- If you are allergic to the active substance aciclovir, valaciclovir, propylene glycol, or any of the other ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

When applying the cream. Avoid any contact with mucous membranes, such as the mouth, eye, or vagina, as irritation may occur.

Unintentional administration in the eye should be avoided.

If you have a severely reduced immune system function (for example, if you are an AIDS patient or a recipient of a bone marrow transplant). You may need to be treated with Aciclovir tablets. Consult your doctor about the treatment of any infection.

The excipient propylene glycol can cause skin irritations and the excipient cetyl alcohol can cause local skin reactions (e.g., contact dermatitis).

Contact your doctor or pharmacist before using this medicine.

Are you using any other medicines?

No interactions with other medicines are known.

Are you using any other medicines besides Cold Sore Cream HTP Aciclovir 50 mg/g, have you recently used any, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Pregnancy and breastfeeding

Pregnancy

When using this medicine during pregnancy, no harmful effects are expected on your health or that of your unborn child.

Breastfeeding

If you are breastfeeding, you should only use this medicine after consulting your doctor. The active substance is excreted in breast milk. However, the amount that babies can ingest is negligible.

Due to the risk of infecting the baby, you should be extra careful when breastfeeding during a cold sore outbreak. Since the immune system of babies is not fully developed, herpes infections can be very severe for them. It is therefore very important to wash your hands beforehand and wear a face mask while feeding and caring for your baby. The same rules apply to your partner and family members.

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Driving ability and the use of machines

As far as is known, this medicine has no effect on driving ability or the ability to use machines.

Cold sore cream HTP Aciclovir 50 mg/g contains propylene glycol

This medicine contains 150 mg of propylene glycol per gram of cream. Propylene glycol can cause skin irritation. Do not use this medicine on newborns younger than 4 weeks with open wounds or large damaged skin surfaces (such as burns) without first consulting your doctor or pharmacist.

Cold sore cream HTP Aciclovir 50 mg/g contains cetyl alcohol

Cetyl alcohol can cause local skin reactions (e.g., contact dermatitis).

3. How do you use this medicine?

When you notice that parts of your lips become painful, numb, burning, or itchy, these are signs of cold sore blisters. If you regularly suffer from cold sore blisters, you will recognize these signs and can feel the outbreak coming. Then apply Aciclovir cream to these blisters as soon as possible according to the prescription. However, treatment can also be started at a later stage.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Dosage

Adults and children

Apply the cream five times a day at intervals of about 4 hours. You do not need to apply cream at night.

Start treatment as soon as possible at the onset of the cold sore. Continue the treatment for at least 4 days. If healing is not complete after ten days from the start of treatment, you are advised to consult a doctor.

Method of use

- Apply Aciclovir cream by squeezing a little cream onto your fingertip and then applying it to the affected areas. The affected areas are those parts, including the lips, where the infection is active, so where blisters are about to form or have already appeared.
- To prevent the transmission of the virus to other parts of the body (e.g., the eyes) or to other people (e.g., through kissing), it is important to avoid touching the blisters as much as possible and to wash your hands after touching the blisters.

Have you used too much of this medicine?

If you have used too much of this medicine, you are unlikely to experience any unwanted effects.

Did you forget to use this medicine?

Apply this medicine anyway and continue the treatment as indicated above.

If you stop using this medicine

You can stop using this medicine without adverse consequences.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some side effects occur more frequently than others. Therefore, the side effects below are divided into the following categories:

Very common: occur in more than 1 in 10 users
Common: occur in less than 1 in 10 users
Uncommon: occur in less than 1 in 100 users
Rare: occur in less than 1 in 1,000 users
Very rare: occur in less than 1 in 10,000 users

Skin and subcutaneous tissue disorders

Sometimes

- Mild burning or stinging sensation at the application site
- A mild form of dry skin or flaking
- Itching

Rarely

- Redness of the skin
- Inflammation of the skin due to hypersensitivity to aciclovir or any of the other ingredients of the cream

- Immune system disorders

Very rarely

- Hypersensitivity reaction including angioedema (sudden fluid accumulation in the skin and mucous membranes (e.g., throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction).

If breathing difficulties occur, stop using Aciclovir cream and contact your doctor immediately.

- Rash with severe itching (hives) and formation of welts (urticaria)

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Store below 25°C. Do not refrigerate or freeze.

Do not use this medicine after the expiry date. You can find it on the box or the tube after "Do not use after" or "EXP". It includes a month and a year. The last day of that month is the expiry date.

After opening the tube, this medicine is usable for 12 months.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information What substances are in this medicine?

- The active substance in this medicine is aciclovir. One gram of cream contains 50 mg of aciclovir.
- The other ingredients in this medicine are: PEG-5-glycerol stearate, dimethicone, cetyl alcohol, liquid paraffin, petroleum jelly, propylene glycol (E1520), purified water.

What does Cold Sore Cream HTP Aciclovir 50 mg/g look like and how much is in a package? Cold Sore Cream HTP Aciclovir 50 mg/g is a medicine in the form of a white to off-white cream. Cold Sore Cream HTP Aciclovir 50 mg/g is supplied in an aluminum tube with a polyethylene cap. The tubes contain 2 or 3 grams of cream.

Marketing authorization holder and manufacturer

Marketing authorization holder Healthypharm B.V. Van de Reijtstraat 31-E 4814 NE Breda Netherlands

Manufacturer

Centrafarm Services B.V. Van de Reijtstraat 31-E 4814 NE Breda Netherlands

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