

**PATIENT PACKAGE INSERT IN
ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

FENLIPS

Cream

1 gram of cream contains:

Penciclovir 10 mg

The inactive and allergenic ingredients in the medicine are listed in section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine is intended for children over the age of 12 and adults. Below this age, refer to a doctor. Use the medicine properly. If you need more information, consult a pharmacist. Refer to the doctor if the signs of the illness (symptoms) worsen or do not improve after 4 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for local treatment of cold sores (Herpes labialis).

Therapeutic group: Anti-viral for local use.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient penciclovir, famciclovir, or to any of the additional ingredients contained in the medicine, such as propylene glycol (listed in section 6).
- Do not use the medicine on mucous membranes (e.g., genitals and inside the mouth) and in the eyes.

Special warnings regarding the use of the medicine

- If you have a **weakened immune system**, only use Fenlips upon the doctor's recommendation.
- If you are uncertain **whether your sore is a cold sore**, consult a doctor.
- Fenlips has not been tested in children under 12 years of age. Therefore, do not use the medicine in children under 12 years of age.

Before treatment with Fenlips, tell the doctor if you are suffering from other ailments, or if you are suffering from allergies.

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult the doctor before using the medicine.

Important information regarding some of the ingredients of the medicine

This medicine contains propylene glycol, which may cause skin irritation.

In addition, the medicine contains cetostearyl alcohol, which may cause local skin reactions (contact dermatitis).

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain. It is important to start treatment as close as possible to the onset of early signs such as: irritation and stinging in the lip area.

The usual dosage is generally:

Adults and children over the age of 12 years (this medicine is not intended for children under 12 years of age):

Using a clean finger, apply Fenlips Cream on the affected areas, approximately every two hours throughout the day (approximately 8 times a day). Even if the treatment with Fenlips was started after the sore appeared, the medicine accelerates the healing process, eases the pain and limits the spread of the virus.

The duration of treatment is 4 days. If after four days of treatment the condition worsens or the sore does not heal, refer to the doctor. It is important to adhere to the treatment regimen for 4 days (even if there is an improvement beforehand), since, if the treatment does not persist for a long enough period of time or is prematurely discontinued, the sore may flair up again.

Do not exceed the recommended dose.

Wash your hands before and after each use of the cream.

Do not swallow the medicine.

If you accidentally took a higher dosage, no harmful effects are expected, only mild skin irritation.

If you accidentally swallowed the medicine, no harmful effects are expected, only oral tissue irritation. Contact the doctor if

necessary. In both of these cases, no special treatment is necessary.

If you forgot to apply the cream at the designated time, apply a dose as soon as you remember, but wait two hours between applications. Do not apply a double dose to compensate for a forgotten dose.

How can you contribute to the success of the treatment?

This medicine is intended for **external use only**. Avoid contact with the eyes, since the virus can cause severe conditions if the eyes are infected.

A cold sore is an infectious sore. To avoid infecting others or transferring the infection to other parts of the body, avoid touching the sore or popping blisters (something which may extend the duration of healing) when the sore appears, and avoid sharing a towel, clothing or eating utensils. Avoid kissing and oral intercourse. Wash your hands thoroughly before and after touching the sore.

Do not take medicines in the dark! Check the label and the dose **each time** you take medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Fenlips may cause side effects in some of the users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue use and refer to a doctor immediately if you experience hypersensitivity reactions, such as urticaria, swelling of the face or the area where the cream was applied, skin rash.

Additional side effects

Side effects that occur frequently, at a frequency of up to 1:100: transient burning, stinging or itching sensation, pain or numbness in the area of application.

If a side effect occurred, if a side effect gets worse or when you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects:

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/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

In addition, you can report to Perrigo via the following address:

www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

- Storage conditions: Store below 30°C. Do not freeze. Store in the original package.

6. FURTHER INFORMATION

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

Propylene glycol, purified water, white soft paraffin, cetostearyl alcohol, paraffin liquid, cetomacrogol 1000.

What the medicine looks like and the contents of the package:

Fenlips is a white, smooth cream in a 2 gram tube.

Manufacturer: Omega Pharma UK, London, England.

Registration holder and address: Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 14241.31798

This leaflet was checked and approved by the Ministry of Health in February 2016.