

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

The medicine is dispensed without a doctor's prescription

FENLIPS COLOR

Cream

1 gram of cream contains:
Penciclovir 10 mg

Inactive ingredients and allergens in the medicine are listed in section 6.

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

Use the medicine according to the instructions in the dosage section of this leaflet. Consult a pharmacist if you need more information. Refer to the doctor if the symptoms of illness worsen or do not improve after 4 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

Fenlips Color 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 hypersensitive (allergic) to the active ingredient penciclovir, to famciclovir or to any of the other ingredients the medicine contains (mentioned in section 6).

Special warnings regarding the use of the medicine

- Do not use the medicine inside your mouth, in or near your eyes, nose or on your genital area. Avoid applying the cream near your eyes.

Talk to the doctor or pharmacist before starting to use Fenlips Color.

Before treatment with Fenlips Color, consult the doctor if:

- you are unsure that your sore is a cold sore.
- you have a condition, or are receiving treatment which weakens your immune system (i.e. the way your body fights infection), for example, HIV infection, a bone marrow transplant or cancer treatment.
- you need to treat ulcers or blisters which appear around your eyes or genital area.

Contact your doctor if your cold sore gets worse or is severe.

Children and adolescents

- Fenlips Color is not recommended for the treatment of children under 12 years of age.

Drug interactions

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

There are no known interactions between Fenlips Color and other medicines. However, tell the doctor or pharmacist if you are taking or have recently taken any other medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult the doctor before using the medicine.

Driving and using machines

Adverse effects on the ability to drive or operate machinery have not been observed.

Additional warnings

To prevent transferring the infection or making it worse, do not touch your cold sore (See also section 3 "**What general precautions should you take when you have a cold sore?**").

Important information about some of the ingredients of the medicine

The cream contains:

- cetostearyl alcohol which may cause local skin reactions (such as contact dermatitis).
- propylene glycol which may cause skin irritation.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

It is important to start treatment at the earliest sign of a cold sore: tingling, redness and itching near the lips.

The usual recommended dosage is:

Adults and children over 12 years of age:

Using a clean finger apply Fenlips Color cream on the affected areas approximately every 2 hours during the day (about 8 times a day). Even if the treatment with Fenlips Color started after the appearance of the sore, the medicine accelerates the recovery process, relieves the pain and limits the spread of the virus.

The duration of treatment is 4 days. If the cold sore gets worse or does not improve after four days of treatment, refer to the doctor.

It is important to adhere to the treatment for 4 days (even if there is an improvement beforehand), for if the treatment does not last long enough or if it is stopped before the required time, 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. This medicine is intended **for external use only**.

Use in children

Fenlips Color is not recommended for the treatment of children under 12 years of age.

If you applied a large amount of cream on your skin at once, there are unlikely to be any harmful effects- although some irritation of the skin may occur.

If you accidentally swallowed the medicine, there are unlikely to be any harmful effects but it may cause irritation in the mouth. Contact the doctor if necessary. In both of these cases no special treatment is necessary.

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

What general precautions should you take when you have a cold sore?

Remember that a cold sore is an infectious sore.

To prevent the virus from infecting other parts of the body, it is important when you have a cold sore to:

- avoid kissing, especially children.
- avoid oral sex.
- use only your own towel and face cloth and avoid sharing cutlery, cups, glasses, etc.
- avoid popping the blisters or picking the sore, as this may prolong the healing process.
- avoid touching your eyes, as the virus can cause a serious condition if it gets into the eyes.
- do not pass this medicine to others, even if their symptoms are the same as yours.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, the use of Fenlips Color can cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them. The side effects caused by using Fenlips Color are usually mild.

Discontinue use of the medicine and refer to a doctor immediately if hypersensitivity (allergic) reactions appear such as allergic dermatitis, rash, raised and itchy bumps or swelling of the area where the cream has been applied.

Additional side effects

Common side effects, which occur in up to 1 in 10 users: initial stinging, burning, itching or numbness at the application site.

If a side effect appears, if any of the side effects worsens, or if you suffer from a side effect not mentioned in this 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 website (www.health.gov.il), which directs to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

Additionally, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

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

Storage conditions: store below 25°C. Do not freeze. Store in the original package.

Medicines should not be disposed of via wastewater or household waste. Consult the pharmacist about how to dispose of medicines no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

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

Propylene glycol, purified water, white soft paraffin, cetostearyl alcohol, paraffin liquid, macrogol cetostearyl ether, red iron oxide (E-172), yellow iron oxide (E-172).

(see in section 2 "**Important information about some of the ingredients of the medicine**").

What the medicine looks like and contents of the package:

Fenlips Color is a smooth cream which includes color (beige to brown), in a 2 gram aluminum tube.

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

Manufacturer: Omega Pharma Ltd., London, UK.

Revised in January 2020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 15366.34008

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