

viruderm
aciclovir

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. Nevertheless, you still need to use viruderm carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

In this leaflet:

1. What viruderm is and what it is used for.
2. Before you use viruderm.
3. How to use viruderm.
4. Possible side effects.
5. Storing viruderm.

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aciclovir

Each 100 g of cream contain:

Aciclovir (INN): 5 g

The other ingredients are: Macrogol 4000 and macrogol 400

Marketing authorization holder:

LABORATORIOS CINFA, S.A.

C/ Olaz-Chipi, 10 – Polígono Industrial Areta

31620 Huarte – Pamplona (Navarra), Spain

1. WHAT VIRUDERM IS AND WHAT IT IS USED FOR

Cream. Each tube contains 2 g of cream.

Aciclovir, the active ingredient of this product, is an antiviral substance active against herpes simplex virus (HSV).

Local symptoms relief in labial herpes (cold sore), including pricking, burning or itching.

2. BEFORE YOU USE VIRUDERM

Labial herpes or cold sore appears as a result of infection by a virus called herpes simplex.

A first infection usually occurs within the mouth (usually in childhood), and may go unnoticed, though in the case of children it should be diagnosed by a physician in order to avoid confusion with dentition disorders or other oral processes. Following this first infection, the herpes simplex virus remains in the body without causing symptoms. The infection often develops new outbreaks at other moments in the lifetime of the patient; these outbreaks typically appear as a consequence of sunburn, colds, fever, emotions, anxiety, oral lesions, menstruation, surgical and dental interventions, or drug allergies. These outbreaks produce itching or pricking sensations in the lips, followed after one or two days by the appearance of small blisters that develop into open lip wounds and finally form crusts.

Until the crusts appear (indicating healing of the lesions), the blisters or open sores are contagious.

It should be taken into account that:

At the time when the itching, burning or pricking appears (before the development of blisters) the virus is multiplying, and treatment is more effective during this stage.

In order to avoid the risk of viral transmission, strictly follow the indications provided under the section “Take special care with viruderm”.

Do not use viruderm:

- If you are hypersensitive (allergic) to aciclovir or any of the other ingredients of viruderm.

Take special care with viruderm:

- This medicine should only be used for cold sore. Avoid contact of the cream with the eyes; if such contact were to occur, wash with abundant water and consult your physician. Do not apply within the mouth, nose or vagina, since local irritation would result.
- Immunodepressed patients (e.g., AIDS patients, transplant patients or persons receiving radiotherapy or chemotherapy) should consult their physician before using this medication.
- To avoid contagion:
 - * Wash your hands after applying the product.
 - * Avoid contact between the lip sores and other parts of the body or skin of other persons, especially nursing infants and children. For the duration of the lesions, do not rub the lip sores with the bed linen when sleeping with another person; do not share towels, and use paper napkins to avoid reinfecting yourself.
- If the lesions worsen or fail to heal within 10 days, discontinue the treatment and consult your physician.
- This medication does not prevent posterior outbreaks or reappearance of the symptoms.

Pregnancy:

Pregnant women should not use this medicine.

Important for women:

If you are or might be pregnant, ask your doctor for advice before using this medicine. The administration of drugs during pregnancy may be hazardous for the embryo or fetus, and should be supervised by a physician.

Breastfeeding:

Nursing women should not use this medicine. Ask your doctor or pharmacist for advice before using this medicine.

Use in children:

Ask your doctor for advice before using this medicine in children under 12 years of age.

Taking other medicines:

Although no interactions have been described for this drug when administered via this route, other products should not be simultaneously applied to the cold sore area while this treatment is used, without first consulting your physician or pharmacist.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO USE VIRUDERM

Follow these instructions unless your physician has indicated otherwise.

It is advisable to wash your hands before and after treating cold sore; avoid unnecessary rubbing of the lesions with the hands.

Use a finger to apply sufficient product to cover the affected zone with a thin layer of cream; repeat the procedure approximately every four hours (except while sleeping), and for up to 5 times a day.

For labial topical use only.

Treatment should be started as soon as the symptoms appear. The start of the cold sore period can easily be recognized by the itching and pricking sensation.

Continue treatment for 5 days. If the cold sore fails to resolve after this time, treatment can be continued another 5 days.

Do not use viruderm for more than 10 days without consulting your physician.

If you use more viruderm than you should:

Aciclovir is not hazardous if swallowed. Although it can cause some irritation in the mouth, no treatment is required in the event of accidental ingestion.

In the event of overdose or accidental ingestion of an important amount of product, report to a medical center indicating the drug taken and the amount administered.

If you forget to take viruderm:

Apply the product as soon as you remember.

4. POSSIBLE SIDE EFFECTS

Like all medicines, viruderm can have side effects.

Some patients have developed burning or itching immediately after application of the product, though this sensation soon disappears. A small proportion of patients have developed mild drying or desquamation of the skin, as well as reddening and itching.

Rare cases of contact dermatitis following application of the product have been reported.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING VIRUDERM

Do not store above 25°C.

Do not use after the expiry date stated on the container.

WITHOUT MEDICAL PRESCRIPTION

This leaflet was approved in November 2000.

KEEP ALL MEDICATION OUT OF THE SIGHT AND REACH OF CHILDREN.

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Additional recommendations for patients with cold sores

Cold sores, or fever blisters, appear due to an infection by a virus called herpes simplex. Usually, the initial infection occurs inside the mouth (usually in childhood) and may go unnoticed but, in the case of children, should be diagnosed by the doctor so as not to confuse it with teeth disorders or other oral processes. After this initial infection, the herpes simplex virus remains in the body without showing any symptoms. The infection then often leads to new outbreaks at other times in life, which usually appear as a result of sunburn, colds, fever, overexcitement, anxiety, mouth wounds, menstruation, dental or surgical interventions or allergies to medication. These outbreaks consist of a tingling sensation or itching of the lips followed after one or two days by the appearance of several small blisters that later develop into an open sore on the lips, which eventually becomes a scab. The blisters or sores are contagious until the scab appears, which is a sign that the lesion has healed.

The following must be taken into account:

Before the blisters appear, when there is a sensation of itching, tingling or stinging, this is when the virus is multiplying and when treatment is most effective.

To avoid the risk of spreading the virus, observe the indications given in the section **Take special care with Viruderm.**