

## **Package leaflet: information for the user**

### **Viruderm 50 mg/g ointment**

Acyclovir

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 10 days.

#### **What is in this leaflet**

1. What Viruderm is and what it is used for.
2. What you need to know before you use Viruderm.
3. How to use Viruderm.
4. Possible side effects.
5. How to store Viruderm.
6. Contents of the pack and other information

#### **1. What Viruderm is and what it is used for**

Viruderm is an ointment containing the active substance acyclovir. Acyclovir belongs to the group of drugs called antivirals and is active against the herpes simplex virus.

It is indicated for local relief of the symptoms caused by cold sores, such as itching, stinging and tingling in adults and adolescents over 12 years of age.

You must talk to a doctor if you do not feel better or if you feel worse after 10 days.

#### **How Viruderm works**

Cold sores, or herpes labialis, occur as the result of infection by a virus called herpes simplex.

Normally, there is a primary infection inside the mouth (usually during childhood) that can go unnoticed, but in the case of children it should be diagnosed by a doctor so that it is not confused with teething or other oral conditions. After this primary infection, the herpes simplex virus remains in the body without showing any symptoms. Patients will often have further outbreaks of this infection at other times in their life, which tend to occur as a consequence of sunburn, colds, fever, emotions, anxiety, mouth ulcers, menstruation, dental or surgical interventions, or drug allergies.

These outbreaks consist of a tingling or itching sensation on the lips followed by the appearance of several small blisters after one or two days, which then develop into an open sore on the lips that eventually forms a scab.

Until the scab forms, a sign that the lesion has healed, the blisters or sores are contagious.

#### **2. What you need to know before you use Viruderm**

## **Do not use Viruderm**

- If you are allergic to acyclovir or any of the other ingredients of this medicine (listed in section 6).
- In children under 12 years of age.

## **Warnings and precautions**

Talk to your doctor or pharmacist before using Viruderm.

Immunocompromised patients (e.g. patients with AIDS, transplant recipients or people who are being treated with radiotherapy or chemotherapy) must talk to their doctor before using this medication.

This medication should only be used on cold sores on the lips.

- Avoid the ointment coming into contact with the eyes; should this occur, rinse thoroughly with water and seek medical attention.

Do not apply the product to the inside of the mouth, nose or vagina, as it would cause local irritation. Do not use for treating genital herpes.

To avoid spreading the virus:

- Wash your hands after applying the product.
- Avoid contact between the cold sore and other areas of the body or the skin of other people, especially infants and children. While you have the sore, try not to rub the bed linen with your lips if you sleep with another person, do not share towels and use paper napkins and tissues to avoid reinfecting yourself.

If the sore gets worse or has not healed in 10 days, stop the treatment and talk to your doctor.

This medicine does not prevent subsequent outbreaks or recurrence of the symptoms.

## **Other medicines and Viruderm**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Although no interactions have been described for this medicine by this route of administration, you should not simultaneously apply any other preparations to the area of the cold sore during treatment with this medicine without talking to your doctor or pharmacist.

## **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

The use of medicines during pregnancy can be dangerous for the embryo or foetus and must be monitored by your doctor.

## **Driving and using machines**

No effects on the ability to drive or use machines have been described.

## **3. How to use Viruderm**

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Topical use on the lips.

The moment you notice the itching, tingling or stinging sensation, before blisters appear, is when the virus is multiplying and is therefore when the treatment is most effective.

To avoid the risk of transmitting the virus, follow the instructions given in the “Warnings and precautions” section.

Treatment should be started as soon as the symptoms begin. The onset of a cold sore can be recognised easily by the itching and tingling sensation.

Apply 5 times a day, approximately every 4 hours except when you are sleeping. Use your finger to apply a sufficient amount of product to cover the affected area of the lip with a thin layer.

Continue treatment for 5 days. If complete healing has not occurred in 5 days, treatment can be prolonged for a further 5 days, up to a total of 10 days.

After applying this medication, wash your hands to avoid spreading the virus to other areas of the body or to other people.

Viruderm contains a specially formulated base and should not be diluted or used as a base for incorporating other medicines.

If you think the effects of Viruderm are too strong or too weak, tell your doctor or pharmacist.

### **Use in children**

Do not administer this medicine to children under 12 years of age (see “Do not use Viruderm” section).

### **If you use more Viruderm than you should**

Symptoms of intoxication are unlikely to occur as a result of its external use, but consult your doctor or pharmacist immediately.

In case of overdose or accidental ingestion, consult your doctor or pharmacist immediately or call the Toxicology Information Service, telephone +34 91 562 04 20, specifying the medicine and the amount ingested.

### **If you forget to use Viruderm**

Do not administer a double dose to make up for forgotten doses, just continue with the usual treatment as soon as possible. Do not exceed the recommended frequency of application or duration of treatment.

### **If you stop using Viruderm**

You should not stop treatment before your doctor tells you, as the sore may not be fully healed and the disease may reoccur.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Uncommon (may affect up to 1 in 100 patients):

- Temporary burning or itching after application of Viruderm.
- Dryness or peeling of the skin or lips.
- Itching.

Rare (may affect up to 1 in 1,000 patients):

- Reddening of the skin
- Contact dermatitis (a type of localised allergy) after application. The substances that cause it are generally ingredients of the ointment other than acyclovir, which is the active substance.

Very rare (may affect up to 1 in 10,000 patients):

- Immediate allergic reactions, including angioedema, which manifests with inflammation of the throat or difficulty swallowing or breathing. If this effect is very intense, you should seek medical attention, as it requires emergency measures.

The prolonged use of this ointment may lead to sensitivity; should this occur, stop the treatment and talk to your doctor.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Viruderm**

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Once the tube has been opened and the treatment has been completed, discard the tube.

Do not use this medicine after the expiry date which is stated on the container after EXP.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away containers and medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Viruderm contains**

-The active substance of Viruderm is acyclovir. Each gram of ointment contains 50 milligrams of acyclovir.

-The other ingredients are macrogol 4000 and macrogol 400.

### **What Viruderm looks like and contents of the pack**

Viruderm is a homogeneous off-white ointment packaged in an aluminium tube—with a plastic cap containing 2 g of ointment. The tube is packaged in a cardboard box.

### **Marketing Authorisation Holder and Manufacturer**

Laboratorios Cinfa, S.A.

Carretera Olaz-Chipi, 10. Polígono Industrial Areta

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