

Package leaflet: information for the user

Vectatone 1% cream

penciclovir

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

Always use 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 your symptoms worsen or do not improve within 4 days.

What is in this leaflet:

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

1. What Vectatone is and what it is used for

Vectatone is a beige to light brown cream that is used for the treatment of cold sores (herpes labialis) caused by herpes simplex. The cream should be applied as soon as possible when symptoms appear, when the lips begin to “tingle” and/or when bumps/blisters start to form. It should not be applied once scabs have formed. You must talk to a doctor if your symptoms worsen or do not improve within 4 days.

Vectatone inhibits the ability of the herpes simplex virus to multiply. The time needed for healing and the duration of pain and visible signs of the virus are shortened by up to 24 hours.

2. What you need to know before you use Vectatone

Do not use Vectatone

- if you are allergic to penciclovir or any of the other ingredients of this medicine (listed in section 6).
- if you have previously exhibited hypersensitivity to famciclovir.

Warnings and precautions

Talk to your doctor or pharmacist before using Vectatone:

- if you are unsure about the cause of your cold sore or if the cold sore worsens or does not get better.
- if your immune system is impaired.

The cream must not be applied in or near the eyes, genitals or mucous membranes (e.g. mouth or nose).

Vectatone should only be used on cold sores on the lips or around the mouth.

Other medicines and Vectatone

It is unlikely that the effect of the treatment will be affected if Vectatone cream is used at the same time as other medicines.

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

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 his medicine.

Pregnancy

Experience of use during pregnancy is limited.

Breast-feeding

It is not known whether the active ingredient is passes into mother's milk.

Driving and using machines

Vectatone does not affect your ability to operate a vehicle.

Vectatone contains cetostearyl alcohol

Vectatone contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

Vectatone contains propylene glycol

This medicine contains 416mg propylene glycol per gram of cream which may cause skin irritation

3. How to use Vectatone

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.

For adults and children over 12 years of age

Use as early as possible at the first signs of infection, e.g. itching and tingling sensation. Some people do not notice these symptoms. However, Vectatone cream has an effect and can still be applied when the first bumps/blisters have started to form.



1. Always wash your hands before and after applying the cream.
2. Squeeze a small amount of cream onto the tip of your finger.
3. Apply the cream every two hours throughout the day for 4 days.

If the treatment time is at the same time as a meal, apply the cream after you have eaten.

It may take some time before the cream begins to work. Continue using the cream even if the sore does not feel better immediately. Use the cream for 4 days unless you have received other instructions from your doctor.

Use in children

Vectatone Cream must not be used on children under 12 years of age.

If you use more Vectatone than you should

It is not likely to be any serious problems if you at once, have used a large amount of cream on your skin, although some irritation of the skin may occur.

The cream is not harmful if swallowed, but it may cause some irritation in the mouth. No special treatment is necessary.

If a child has accidentally used the medicine in an inappropriate way please contact your doctor or hospital.

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.

Common (may affect up to 1 in 10 people):

Reactions at the area of application, e.g. burning sensation, pain or numbness.

Not known (frequency cannot be estimated from the available data):

Hypersensitivity, nettle rash and allergic dermatitis (e.g. rash, itching, blisters and swelling).

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. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Vectatone

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Do not freeze.

Do not use this medicine after the expiry date which is stated on the label 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 medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other**information What Vectatone contains**

- The active substance is penciclovir 10 mg/g(1%)
- The other ingredients are white soft paraffin, liquid paraffin, cetostearyl alcohol, propylene glycol, macrogol cetostearyl ether 1000, red and yellow iron oxide (E172) and purified water.

What Vectatone looks like and contents of the pack

Vectatone is a smooth, beige to light brown cream.

Package sizes: 2 g and 5 g tube.

Not all package sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorization holder: [To be completed nationally]

Manufacturer: Omega Pharma International NV, Venecoweg 26, B-9810 Nazareth, Belgium;

Medgenix Benelux NV, Vliegveld 21, B-8560 Wevelgem, Belgium

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