

PACKAGE LEAFLET: INFORMATION FOR THE USER**Vectavir Cold Sore Cream**
Penciclovir

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What Vectavir is and what it is used for
2. What you need to know before you use Vectavir
3. How to use Vectavir
4. Possible side effects
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1. What Vectavir is and what it is used for

Vectavir is used for the treatment of cold sores (Herpes labialis). A cold sore is caused by a viral infection. The virus can remain inactive for extended periods of time, but when triggered the virus multiplies and a cold sore develops. This can occur, for example when you are run-down, when you have a cold or flu, or when you have been out in strong sunlight. The virus causes painful blistering of the lips.

Vectavir contains penciclovir and is an antiviral medicine which stops the virus multiplying. Applying Vectavir means your cold sore heals faster and the duration of pain will be shorter. The time your cold sore is infectious will also be shorter, although applying Vectavir will not stop you spreading your cold sores to another person.

You must talk to a doctor if you do not feel better or if you feel worse after 4 days.

2. What you need to know before you use Vectavir**Do not use Vectavir:**

- If you are allergic to penciclovir, famciclovir or any of the other ingredients of Vectavir (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Vectavir.

Vectavir should only be used on cold sores on the lips and around the mouth. It is not recommended for application to mucous membranes (i.e. inside the mouth or nose or on genital areas). Avoid application in or near the eyes.

Please check with your doctor or pharmacist before using Vectavir:

- if you have a condition or are receiving treatment which weakens your immune system (i.e. the way your body fights infection is reduced), for example HIV infection, a bone marrow transplant or cancer treatment.

Children

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

Other medicines and Vectavir

There are no known interactions with other medicines.

However, tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Pregnancy, breast-feeding and fertility

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 taking this medicine. No data on human fertility is available.

Driving and using machines

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

Important information about some of the ingredients of Vectavir

Vectavir contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). It also contains 416 mg of propylene glycol per gram of cream, which may cause skin irritation.

3. How to use Vectavir

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

Use the cream as early as possible after early symptoms (tingling and itching) appear. However, the cream can still be applied at the first sign of a cold sore. Always wash your hands before and after applying the cream. Squeeze a small amount onto your finger and apply to the affected area. Optionally, for packs which are supplied with clean, single use applicators, these may be used instead of your finger, if desired. Apply every 2 hours throughout the day (approximately 8 times a day) for 4 consecutive days.

You should see your doctor if your symptoms persist or worsen at any time, or if your cold sore does not improve after 4 days of treatment.

Use in children

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

If you use more Vectavir than you should

There are unlikely to be any harmful effects if you have used a large amount of cream on your skin all at once, although some irritation of the skin may occur.

If you forget to use Vectavir

If you forget to use your cream, apply it as soon as you remember, then continue as before.

If you accidentally swallow the cream

Vectavir is not harmful if accidentally swallowed and no treatment is necessary but it may cause irritation in the mouth. Please contact your doctor or pharmacist if you are concerned.

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

Remember that cold sores are infectious.

To avoid the virus infecting other parts of the body, and passing the virus to other people 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 do not share cutlery, cups, glasses, etc.
- Avoid breaking the blisters or picking the sores, 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 give this cream to others, even if their symptoms are the same.

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

4. Possible side effects

Like all medicines, Vectavir can cause side effects, although not everybody gets them. The side effects caused by Vectavir are usually mild in intensity.

Some common side effects (may affect up to 1 in 10 people) are: burning, stinging or numbness when the cream is applied. The effects will usually go away quickly.

Some people have also reported allergic-type reactions such as allergic dermatitis, rash, hives, itching and swelling.

Reporting 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 any side effects directly (see details below) to the national reporting system via the internet at www.mhra.gov.uk/yellowcard. By reporting side effects you can help to provide more information on the safety of this medicine.

5. How to store Vectavir

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the “expiry date” which is stated on the tube and the carton. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not freeze.
- 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 protect the environment.

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

The active substance in your cream is penciclovir. One gram of Vectavir contains 10 mg penciclovir.

The other ingredients are white soft paraffin, liquid paraffin, cetostearyl alcohol, propylene glycol, cetomacrogol 1000 and purified water.

What Vectavir looks like and contents of the pack

Vectavir is a smooth white cream. It is available in 2g and 5g aluminium tubes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorization holder: Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland.

Manufacturer: Omega Pharma International NV, Venecoweg 26, B-9810 Nazareth, Belgium OR Medgenix Benelux NV, Vilegveld 21, Wevelgem, 8560, Belgium.

This medicinal product is authorized in the Member States of the EEA under the following names:

Belgium	Vectavir 1% crème
Finland	Vectavir 1% emulsiovoide
Greece	Fenivir
Ireland	Vectavir Cold Sore Cream
Luxembourg	Vectavir 1%, crème
Portugal	Fenivir 10 mg/g, Creme
Spain	Fenivir 10 mg/g crema

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