

Fenistil[®] Cold Sore 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 pharmacist has 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 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 4 days.

What is in this leaflet

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

1. What Fenistil Cold Sore Cream is and what it is used for

The active ingredient in this medicine is Penciclovir, an antiviral which is used to treat infections caused by viruses. Fenistil Cold Sore Cream can be used to treat cold sores on the lips and around the mouth.

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 Fenistil Cold Sore Cream

Do not use Fenistil Cold Sore Cream

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

Warnings and Precautions

Talk to your doctor or pharmacist before using Fenistil Cold Sore Cream.

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

Avoid applying the cream near your eyes.

Please check with your doctor or pharmacist before using Fenistil Cold Sore Cream:

- if you are unsure that your sore is a cold sore,
- if 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

Fenistil Cold Sore Cream is not recommended for the treatment of children under 12 years of age.

Other medicines and Fenistil Cold Sore Cream

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 using this medicine.

Driving and using machines

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

Take special care

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 Fenistil Cold Sore Cream

The cream contains:

- cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis),
- propylene glycol which may cause skin irritation.

3. How to use Fenistil Cold Sore Cream

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

Start treatment at the earliest sign of a cold sore (symptoms such as, tingling, redness and itching).

Adults and children over 12 years: Apply the cream in a thin layer over the cold sore. Apply the cream every 2 hours during the day, for 4 days. Always wash your hands before and after applying the cream.

If the cold sore gets worse or does not improve after 4 days, talk to your pharmacist or doctor. Use to treat cold sores on the lips and face only. Do not apply this medicine to the inside of your mouth, around the eyes or the genital area.

Use in children

Fenistil Cold Sore Cream is not recommended for the treatment of children under 12 years of age.

If you use more Fenistil Cold Sore Cream 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 Fenistil Cold Sore Cream

Apply the next application as soon as you remember and carry on as before. Do not apply more cream to make up for a forgotten dose.

If you accidentally swallow Fenistil Cold Sore Cream

Fenistil 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 cold sores are infectious.

To prevent the virus infecting other parts of the body, or 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 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 other people, even if their symptoms are the same as yours.

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

4. Possible side effects

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

Some common side effects are: initial itching, burning, stinging or numbness where the cream has been applied (may affect up to 1 in 10 people). Some people have also reported allergic-type reactions such as allergic dermatitis, rash, raised and itchy bumps or swelling of the area where the cream has been applied. If this happens stop using the cream and seek medical advice.

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 to the Medicines and Healthcare products Regulatory Agency (MHRA), through the Yellow Card Scheme; you can make a report by filling in a Yellow Card (available from pharmacies), by phoning Freephone 0800 100 3352. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fenistil Cold Sore Cream

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

Do not use Fenistil Cold Sore Cream after the "Use By" date which is stated on the tube and carton.

The "Use By" date refers to the last day of that month.

Do not store above 30 °C. Store in the original pack. 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 Fenistil Cold Sore Cream contains

The active substance is penciclovir. One gram of Fenistil contains 10 mg Penciclovir.

The other ingredients are white soft paraffin, liquid paraffin, cetostearyl alcohol, propylene glycol, cetomacrogol 1000 and purified water. (See also Section 2 "Important Information about some of the ingredients of Fenistil Cold Sore Cream").

What Fenistil Cold Sore Cream looks like and contents of the pack

Fenistil Cold Sore Cream is a smooth white cream.

Fenistil Cold Sore Cream is available in 2 g aluminium tubes.

Marketing Authorisation Holder and Manufacturer

Novartis Consumer Health UK Limited, Camberley, Surrey, GU15 3YL, UK.

For any information about this medicinal product, please contact the Marketing Authorisation Holder.