

PATIENT INFORMATION LEAFLET

COLD SORE CREAM Aciclovir 50 mg/g

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

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

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 10 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Cold Sore Cream is and what it is used for
2. Before you use Cold Sore Cream
3. How to use Cold Sore Cream
4. Possible side effects
5. How to store Cold Sore Cream
6. Further information

1. WHAT COLD SORE CREAM IS AND WHAT IT IS USED FOR

Cold Sore Cream is a smooth off-white cream for application to the lips and face. It contains aciclovir which belongs to a group of medicines called antivirals.

This cream is used for the treatment of cold sores (Herpes simplex virus infections); it slows the growth of the virus, and speeds the healing of cold sore blisters.

2. BEFORE YOU USE COLD SORE CREAM

Do not use Cold Sore Cream if you:

- are allergic to aciclovir, valaciclovir, propylene glycol or to any of the ingredients of Cold Sore Cream (see Section 6 and end of Section 2).

Take special care with Cold Sore Cream:

- **do not use** on mucous membranes as the cream can cause irritation. The areas to avoid include the inside of the mouth and nose, the eyes and inside the vagina.
- **do not use** this product to treat mouth ulcers, or for herpes infections which are in or near your eyes, or in the genital area.
- **do not use** this cream if your cold sore is severe; you must see a doctor for advice on how to treat it.
- **only use** Cold Sore Cream to treat blisters on your lips and face.

If your immune system is weakened for any reason e.g. HIV infection, a bone marrow transplant or cancer treatment, **do not treat yourself** with Cold Sore Cream; you must seek advice from your doctor.

While you have a cold sore, avoid spreading the infection to others by washing your hands carefully before and after applying the cream, and avoid touching the infected skin with anything else, especially with your hands or with towels.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor or pharmacist if you are or may be pregnant. Ask your doctor for advice before taking any medicine during pregnancy. The active ingredient aciclovir has been found to pass into breast milk.

Important information about some of the ingredients

Cold Sore Cream contains:

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

23LF01468PW

3. HOW TO USE COLD SORE CREAM

FOR EXTERNAL USE ONLY

Always use Cold Sore Cream exactly as instructed in this leaflet. If you are not sure, ask your doctor or pharmacist.

Do not exceed the stated dose.

It is best to apply the product as soon as possible after the start of the infection.

For application to the **surface of the skin** only:

1. Wash your hands thoroughly before use.
2. Apply a thin layer of the cream to the infected area and the skin immediately next to it, 5 times a day at intervals of about 4 hours. Take care not to rub the infected skin any more than you need to.
3. Wash your hands again, to avoid spreading the infection.
4. Use the cream for up to 5 days. If the infection has not healed after this time, you can continue to use it for a further 5 days.

If your cold sore gets worse during the treatment period, or if it has not healed after 10 days of treatment, STOP using the cream and seek advice from your doctor.

If you use more Cold Sore Cream than you should or if you or a child accidentally swallow the cream, contact your doctor or nearest hospital immediately. Take the packet with you to help identification.

If you forget to use Cold Sore Cream

If you miss a treatment, apply the cream as soon as you remember, and apply the remaining doses for that day at evenly spaced intervals.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cold Sore Cream can cause side effects, although not everybody gets them.

If you notice the following: rash, itchy skin, weal, swelling of the lips, face and/or eyelids, they may be signs of an allergic reaction. Stop using Cold Sore Cream and seek medical advice immediately.

Other side effects include:

Uncommon (affects less than 1 in 100 people)

- a burning or stinging feeling after applying the cream that goes away
- itching
- mild drying or flaking of your skin

Rare (affects less than 1 in 1,000 people)

- redness of your skin
- skin rash

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE COLD SORE CREAM

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package and keep the tube in the outer carton. Do not refrigerate.

Do not use Cold Sore Cream after the expiry date which is stated on the tube/carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Cold Sore Cream contains:

- The **active substance** is aciclovir and the cream contains 50 mg in every 1 g (5%).
- The **other ingredients** are stearyl macroglycerides, dimeticone, cetyl alcohol, liquid paraffin, white soft paraffin, propylene glycol and purified water (see end of Section 2 for further information).

What Cold Sore Cream looks like and contents of the pack

The product is a smooth white to off-white cream and is available in aluminium tubes containing 2 g.

Marketing Authorisation Holder: Pinewood Laboratories Ltd., Ballymacarby, Clonmel, Co. Tipperary, Ireland. PL 04917/0066

Manufacturer: CP Pharmaceuticals Ltd., Ash Road North, Wrexham, LL13 9UF or Pinewood Laboratories Ltd., Ballymacarby, Clonmel, Co. Tipperary, Ireland.

This leaflet was last updated in 01/2017

23LF01468PW