

PHARMACEUTICALS

ANTIVIRAL COLD SORE 5%w/w Cream

Aciclovir

Package Leaflet: Information for the user

The name of this medicine is Antiviral Cold Sore 5% w/w Cream which will be referred as Cold Sore Cream throughout the leaflet.

Read all of this leaflet carefully because it contains important information for you. This medicine is available without a prescription. However, you still need to use Cold Sore Cream carefully to get the best results from it.

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

What is in this leaflet:

- 1. What Cold Sore Cream is and what it is used for
- 2. What you need to know 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. Contents of the pack and other information

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

Cold Sore Cream is used for the treatment of cold sores. The active ingredient is aciclovir, an antiviral agent. Apply at the first signs of a cold sore (such as tingling and itching). It can also be used to speed up healing if one has already appeared.

2. What you need to know before you use Cold Sore Cream

Do not use Cold Sore Cream:

- If you have ever had an allergic reaction to Aciclovir, valaciclovir, propylene glycol or any other ingredients of the preparation (see section 6 for a complete list of ingredients).
- Inside your mouth (e.g. for mouth ulcers) or nose.
- For any skin infection other than a cold sore.
- In the eyes or genital area.

Take special care with Cold Sore Cream:

- Always wash your hands before and after applying Cold Sore Cream.
- Do not touch your eyes until you have washed your hands after application.
- If you accidentally get cream in your eye, wash out thoroughly with warm water. Consult your doctor if you are concerned.
- Do not swallow the cream. If you accidentally swallow any cream, it is unlikely to cause any ill effects but consult your doctor if you are concerned.
- Avoid touching a cold sore to prevent transferring the infection or making it worse.
- If you have been told by your doctor that you have a weakened immune system, contact your doctor before treating any type of infection.
- If you are in any doubt if you have a cold sore, contact your doctor.
- If your cold sore gets very severe, contact your doctor.
- Tell your doctor or pharmacist before use if you are taking any regular medication on prescription or over the counter products.

Pregnancy and Breast-feeding:

Talk to your doctor or pharmacist before using Cold Sore Cream if you are pregnant, trying to become pregnant or are breast-feeding.

Important information about some of the ingredients of Cold Sore Cream

Cold Sore Cream contains cetyl alcohol and propylene glycol which may cause local skin reactions (skin irritation and redness).

3. How to use Cold Sore Cream:

Suitable for all ages:

- Apply at the first signs of a cold sore (such as tingling and itching).
- Apply liberally to the affected area S times a day.
- Continue treatment for 4 days. If your cold sore hasn't healed after this time, you can use the cream for up to I0 days in total.
- Treat your cold sore for 4 full days to
- ensure rapid healing.
- If you forget a dose, apply when you remember and continue as before.
- If your cold sore hasn't healed fully after I0 days, or if it gets worse at any time, contact your doctor.
- Never give your Cold Sore Cream to others, even if their symptoms are the same as yours.
- The amount of cream inside this pack is enough for one cold sore attack. For any future attacks, start treatment at the first signs of a cold sore developing (such as tingling or itching). It can also be started during the blister stage.
- Do not use more than the recommended dose.

4.Possible side effects:

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

Stop using the medicine and tell your doctor if you experience:

• Allergy-like reactions, for example swelling of the lips, face and eyelids.

The following side effects could also occur:

- Mild burning or stinging after application. This will quickly go away.
- Redness, itching or a mild drying or flaking of the skin, skin rashes, hives or weals.

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 via the yellow card scheme at http://www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card on Google Play or Apple App Store. 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 use Cold Sore Cream after the expiry or 'use by' date shown on the container.

Use within 6 weeks of opening. Keep Cold Sore Cream in its original container and store at a temperature below 25°C but do not refrigerate or freeze.

6. Contents of the pack and other information

What the cream contains:

The active ingredient is Aciclovir. Each gram of the cream contains SO mg of Aciclovir.

The other ingredients are stearoyl macrogolglycerides, dimeticone, cetyl alcohol, liquid paraffin, white soft paraffin, propylene glycol and purified water.

What Cold Sore Cream looks like and contents of the pack

Cold Sore Cream is available from your pharmacist without prescription in a 2 g tube.

Produced for:

The Boots Company PLC, Nottingham, NG2 3AA. UK.

Marketing Authorisation Holder:

Relonchem Limited,

Cheshire House, Gorsey Lane, Widnes,

Cheshire, WAS 0RP

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