Zovirax Cold Sore Cream

Active ingredient(s): Aciclovir 5% w/w

Information Leaflet

This leaflet provides important information about using ZOVIRAX Cold Sore Cream. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZOVIRAX Cold Sore Cream.

Where to find information in this leaflet:

- 1. Why am I using ZOVIRAX Cold Sore Cream?
- 2. What should I know before I use ZOVIRAX Cold Sore Cream?
- 3. What if I am taking other medicines?
- 4. How do I use ZOVIRAX Cold Sore Cream?
- <u>5.</u> What should I know while using ZOVIRAX Cold Sore <u>Cream?</u>
- 6. Are there any side effects?
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1. Why am I using ZOVIRAX Cold Sore Cream?

ZOVIRAX Cold Sore Cream contains the active ingredient Aciclovir 5% w/w. Aciclovir belongs to a group of medicines called antivirals. They are used for treating infections caused by the Herpes simplex virus.

ZOVIRAX Cold Sore Cream is used to treat cold sores on the lips and face. Cold sores are caused by Herpes simplex virus infection.

ZOVIRAX Cold Sore Cream does not get rid of Herpes simplex virus infection from your body, so it cannot prevent cold sores from coming back. It does, however, reduce the severity and duration of cold sore symptoms when they appear.

You should only use ZOVIRAX Cold Sore Cream if your doctor has already told you that your cold sores are caused by the Herpes simplex virus.

2. What should I know before I use ZOVIRAX Cold Sore Cream?

Warnings

Do not use ZOVIRAX Cold Sore Cream if:

- you have an allergy to aciclovir, valaciclovir, propylene glycol or any other ingredient in the product.
- the product has expired or the packaging is torn or shows signs of tampering, if product has expired or damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your pharmacist or doctor.

Check with your doctor or pharmacist if:

- your cold sore is severe.
- you have had any of the following medical conditions: an underlying condition, which might have weakened your immune system, such as HIV infection, or bone marrow or organ transplant.
- you are in any doubt whether your sore is a cold sore.
- you are pregnant or plan to become pregnant, or breastfeeding. This medicine should not be used if you are pregnant or breastfeeding unless your doctor has told you to.

If you have not told your pharmacist or doctor about any of the above, tell them before you use ZOVIRAX Cold Sore Cream.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant. Do not use ZOVIRAX Cold Sore Cream if you are pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed. ZOVIRAX Cold Sore Cream should only be used if recommended by your doctor.

Children and adolescents

 Do not use ZOVIRAX Cold Sore Cream in children below 12 years of age. ZOVIRAX Cold Sore Cream is available for adolescents and children aged 12 years and over.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ZOVIRAX Cold Sore Cream and affect how it works.

As yet there are no medicines known which affect the way Zovirax Cold Sore Cream works, or which are affected by Zovirax Cold Sore Cream.

However, you should not mix ZOVIRAX Cold Sore Cream with other creams, lotions or ointments and apply them to the affected area.

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4. How do I use ZOVIRAX Cold Sore Cream?

How to use it

- Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the box or tube, ask your pharmacist or doctor for help.
- For external use only.
- Apply a thin layer of cream to the affected area, including the outer edges of the cold sore blisters, if present, five times a day every four hours and miss applying it in the middle of the night.

How long to use it

- Use ZOVIRAX Cold Sore Cream as soon as the first symptoms of a cold sore appear, such as burning, tingling or itching. You can still begin to use it once a blister has appeared.
- Use it for no more than 4 days. If your symptoms do not improve after 4 days of treatment with ZOVIRAX Cold Sore Cream, you should tell your doctor.

If you forget to use it

If you forget to use the cream at any time, use it as soon as you remember. However, if it is almost time for the cream to be used, skip the missed application and go back to your normal routine of using it.

If you use too much (overdose)

Overdosing with ZOVIRAX Cold Sore Cream when it is applied to the skin is unlikely.

However, if you think that someone has accidentally use too much or swallowed the cream, you should immediately:

- phone the Poisons Information Centre (telephone: Australia 13 11 26; New Zealand 0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ZOVIRAX Cold Sore Cream?

Things you should do

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to use the medicine.

Tell your pharmacist or doctor if you become pregnant while using Zovirax Cold Sore Cream.

You should wash your hands thoroughly before and after applying ZOVIRAX Cold Sore Cream to avoid making the cold sore worse or infecting someone else.

Avoid rubbing your cold sores or touching them with a towel. These measures will help to avoid aggravating your own infection and reduce the risk of giving it to others.

Avoid contact with eyes. If you accidentally get Zovirax Cold Sore Cream in your eyes, wash out thoroughly with warm water. Consult your pharmacist or doctor if you are concerned.

Things you should not do

- Do not mix ZOVIRAX Cold Sore Cream with other creams, ointments or lotions for application to the affected area.
- Do not use ZOVIRAX Cold Sore Cream more often or for longer than your pharmacist or doctor has told you to
- Do not use ZOVIRAX Cold Sore Cream for any skin infection other than a cold sore.
- Do not use ZOVIRAX Cold Sore Cream inside your mouth or nose or near your eyes.
- Do not use ZOVIRAX Cold Sore Cream to treat genital herpes infection.
- Do not give ZOVIRAX Cold Sore Cream to anyone else even if they appear to have the same condition as you.

Product tampering

 If you find that the carton seals have been broken or are missing, do not use the product and return it to the place of purchase.

Looking after your medicine

- Store below 25°C.
- Keep out of reach and sight of children. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.
- Do not use ZOVIRAX Cold Sore Cream after the expiry date which is stated on the outer pack and on the immediate container. The expiry date refers to the last day of that month.
- Store in the original package.
- Always screw the cap or lid down tightly after using ZOVIRAX Cold Sore Cream. If the cream is exposed to air for too long it may not work as well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. Do not throw away your medicine in your household waste.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Ask your pharmacist or doctor to answer any questions you may have.

If any of the following happen, stop using the product, tell your pharmacist or doctor immediately or go to Accident and Emergency at your nearest hospital:

- Severe skin rash, itching or hives
- Swelling of the face, lips, mouth or throat
- Difficulty breathing or swallowing
- Fever
- Low blood pressure (feeling faint or dizzy)

The above list includes very serious side effects. You may need urgent medical attention or hospitalization. These side effects are very rare for low doses of this medicine when used for a short period of time.

ZOVIRAX Cold Sore Cream can occasionally cause temporary burning, stinging, itching, redness, drying and flaking at the area where it is applied. These side effects are usually mild. Check with your pharmacist or doctor if they continue to be troublesome.

As with many other products applied to the skin, allergic contact dermatitis (a hot, itchy rash where the cream has been applied) can occur very occasionally. This is usually caused by one of the inactive ingredients in ZOVIRAX Cold Sore Cream, rather than the active ingredient, aciclovir. If any of these symptoms occur and they worry you, contact your doctor or pharmacist.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects your child experiences, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

What ZOVIRAX Cold Sore Cream contains

Active ingredient	Aciclovir 5% w/w
(main ingredient)	

Other ingredients (inactive ingredients)

- Propylene glycol
- Paraffin soft white
- Cetostearyl alcohol
- Paraffin liquid
- Arlacel 165
- Dimethicone 20
- Poloxamer
- Sodium lauryl sulphate
- Water purified

Do not use this medicine if you are allergic to any of these ingredients.

What ZOVIRAX Cold Sore Cream looks like

ZOVIRAX Cold Sore Cream is a smooth white cream and comes in either a 2g aluminium tube or a 2g pump dispenser pack.

Who distributes ZOVIRAX Cold Sore Cream

Haleon

Sydney, NSW, Australia & Auckland, New Zealand

AU: 1800028533 NZ: 0800 540 144

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