

EZOVIR® Cold Sore Relief

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using EZOVIR® Cold Sore Relief?

EZOVIR® Cold Sore Relief contains the active ingredient Famciclovir. EZOVIR® Cold Sore Relief is an antiviral medicine that is used to treat recurrent outbreaks of cold sores in adults who have a normal immune system (the body system which fights against harmful bacteria, viruses and fungi).

For more information, see Section [1. Why am I using EZOVIR® Cold Sore Relief?](#) in the full CMI.

2. What should I know before I use EZOVIR® Cold Sore Relief?

Do not use if you have ever had an allergic reaction to EZOVIR® Cold Sore Relief or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use EZOVIR® Cold Sore Relief?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EZOVIR® Cold Sore Relief and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use EZOVIR® Cold Sore Relief?

- Follow the instructions provided and use EZOVIR® Cold Sore Relief until your doctor tells you to stop.
- The usual dose is three 500 mg tablets taken together as a single dose

More instructions can be found in Section [4. How do I use EZOVIR® Cold Sore Relief?](#) in the full CMI.

5. What should I know while using EZOVIR® Cold Sore Relief?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using EZOVIR® COLD SORE RELIEF.• Tell your pharmacist or doctor if your cold sore symptoms do not improve within a few days, or if they become worse.
Things you should not do	<ul style="list-style-type: none">• Do not take less than the recommended dose of 3 tablets, unless advised by your doctor.• Do not give this medicine to anyone else even if their condition seems to be the same as yours.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how EZOVIR® Cold Sore Relief affects you.• Be careful driving, operating machinery or doing jobs that require you to be alert until you know how EZOVIR® Cold Sore Relief affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store your EZOVIR® Cold Sore Relief tablets in a dry place where the temperature stays below 25°C.• Keep your medicine in the original container until it is time to take it.

For more information, see Section [5. What should I know while using EZOVIR® Cold Sore Relief?](#) in the full CMI.

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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

EZOVIR® Cold Sore Relief

Active ingredient(s): *Famciclovir*

Consumer Medicine Information (CMI)

This leaflet provides important information about using EZOVIR® Cold Sore Relief. **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 EZOVIR® Cold Sore Relief.**

Where to find information in this leaflet:

- [1. Why am I using EZOVIR® Cold Sore Relief?](#)
- [2. What should I know before I use EZOVIR® Cold Sore Relief?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use EZOVIR® Cold Sore Relief?](#)
- [5. What should I know while using EZOVIR® Cold Sore Relief?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using EZOVIR® Cold Sore Relief?

EZOVIR® Cold Sore Relief contains the active ingredient famciclovir. EZOVIR® Cold Sore Relief is an antiviral medicine that is used to treat recurrent outbreaks of cold sores in adults who have a normal immune system (the body system which fights against harmful bacteria, viruses and fungi).

Cold sores can be unpredictable. Even after many years, some people may experience recurring cold sores due to viral reactivation. Some common triggers to a cold sore may include:

- sun exposure
- stress
- fatigue
- menstrual periods
- fever
- illness
- dry chapped lips
- skin trauma
- a cold

Many people who get cold sores know when one is coming by a tingling, burning, itchy or painful sensation or redness in the area. This can happen very rapidly.

Cold sores are an infection caused by a virus called herpes simplex type 1 (HSV-1). Cold sores usually begin on or around the lips, mouth, and nose. After redness and swelling develop, the small red bumps turn into fluid-filled blisters.

The blisters may weep or burst, and this can be tender and painful. A shallow ulcer and yellow crust form as the cold sore dries. The crust eventually falls off, exposing new pink-coloured skin. Generally, the sores heal without scarring.

The infection is most commonly acquired as a baby or child from physical contact with parents or relatives that have a cold sore, often by kissing. After the initial infection has healed, the virus becomes dormant in nerve cells.

Although EZOVIR® Cold Sore Relief does not cure the viral infection, it helps to relieve the symptoms and shorten their duration of an outbreak.

The best results are obtained if the medicine is started as soon as possible after the onset of symptoms occur. These may include tingling, itching or burning, or the appearance of the first signs, such as redness or swelling. This is when the virus is reproducing rapidly.

Ask your pharmacist or doctor if you have any questions about why this medicine has been prescribed for you.

EZOVIR® Cold Sore Relief is only available from your pharmacist. The cold sores pack may be purchased without a doctor's prescription. It is not addictive.

Use in Children

This medicine is not recommended for use in infants, children or adolescents under 18 years of age.

2. What should I know before I use EZOVIR® Cold Sore Relief?

Warnings

Do not use EZOVIR® Cold Sore Relief if:

- you are allergic to famciclovir (the active ingredient), penciclovir or a related antiviral medicine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have a problem with your body's immune system, which helps fight off infections.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing;
- swelling of the face, lips, tongue or other parts of the body;
- rash, itching or hives on the skin.

Do not take this medicine if you have a problem with your body's immune system, which helps to fight off infections. Your pharmacist will refer you to your doctor in that case.

Check with your doctor if you:

Are over 50 years of age or if you have or have had any medical conditions especially the following:

- A problem with your kidneys.
- Diabetes, high blood pressure, heart problems, liver problems or other medical conditions.
- Signs of an infection other than your cold sore.
- Your pharmacist may want to take extra precautions or refer you to a doctor to determine if this medicine is suitable for you.
- if you are prone to allergies or allergic to any other medicines, foods, dyes or preservatives.
- take any medicines for any other condition

If you experience an allergic reaction, stop using the medicine and inform your doctor or pharmacist immediately.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

EZOVIR® Cold Sore Relief should not be used during pregnancy unless necessary.

Your pharmacist or doctor will discuss with you the potential risks of taking this medicine during pregnancy and will also advise you if you should take this medicine while breast-feeding, based on the benefits and risks of your particular situation.

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 and EZOVIR® Cold Sore Relief may interfere with each other. These include:

- probenecid, a prescription medicine used to treat gout (a disease with painful, swollen joints caused by uric acid crystals) and to increase levels of penicillin-type antibiotics
- raloxifene, a medicine used to treat osteoporosis (a disease which causes bones to become less dense, gradually making them weaker, more brittle and likely to break)
- medicines that can affect your immune system
- medicines that can affect your kidneys
- You may need to take different amounts of these medicines or may need to take different medicines.
- Your doctor and pharmacist have more information.

- If you have not told your pharmacist or doctor about any of these things, tell him/her before you start taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EZOVIR® Cold Sore Relief.

4. How do I use EZOVIR® Cold Sore Relief?

How much to use

- Follow the instructions provided and use EZOVIR® Cold Sore Relief until your doctor tells you to stop.
- The usual dose is three 500 mg tablets taken together as a single dose

However, if you have problems with your kidneys and your pharmacist has referred you to your doctor to see if this medicine is suitable for you, your doctor may have recommended a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

Follow the instructions that they give you.

Do not change the dose yourself, without your doctor's advice, regardless of how well you may feel.

When to use EZOVIR® Cold Sore Relief

- Take EZOVIR® Cold Sore Relief tablets as soon as possible after the first symptoms (e.g. tingling, itching or burning) or signs (e.g. redness or swelling) of a cold sore appear.
- Do not take the tablets if a hard crust has already formed on the cold sore.

Keep the tablets for the next episode.

How to take it

Swallow the tablets whole with a full glass of water. They may be taken with or without food. It is not necessary to chew or crush the tablet.

How long to take it

A single dose of EZOVIR® Cold Sore Relief is all that is necessary for treating each episode of cold sores. Each pack of EZOVIR® Cold Sore Relief contains enough medicine for one dose. A repeat dose during this episode is not recommended.

If another episode of cold sores recurs, another dose may be taken. However, do not repeat this treatment within 7 days.

If you use too much EZOVIR® Cold Sore Relief

If you think that you have used too much EZOVIR® Cold Sore Relief, you may need urgent medical attention.

Immediately telephone your doctor or the Poisons Information Centre (Australia telephone 13 11 26) for

advice or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much EZOVIR® Cold Sore Relief. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

Taking too much EZOVIR® Cold Sore Relief may affect the kidneys. In people who already have kidney problems it may, rarely, lead to kidney failure if their dose is not correctly lowered.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 EZOVIR® Cold Sore Relief?

Things you should do

Tell your pharmacist or doctor if your cold sore symptoms do not improve within a few days, or if they become worse.

Call your doctor straight away if you:

- If you become pregnant, tell your doctor before taking any further doses of this medicine to another episode of cold sores.
- Your doctor can discuss with you the risks of taking it while you are pregnant.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you periodically take this medicine to treat recurring episodes of cold sores.

Tell any other doctor, dentist or pharmacist who treats you that you are taking EZOVIR® Cold Sore Relief. Remind any doctor, dentist or pharmacist you visit that you are using EZOVIR® Cold Sore Relief.

Things you should not do

- Do not take less than the recommended dose of 3 tablets, unless advised by your doctor.
- Do not give this medicine to anyone else even if their condition seems to be the same as yours.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

Things that may help your condition

- Cold sores are contagious, and the virus can be passed on from an infected person to an uninfected person through close physical contact or saliva, even when blisters are not present.
- The risk is much higher when the cold sore is visible, as the virus can be shed, making it easy to infect other people.

- Take the following precautions to avoid spreading the virus:
- Keep the areas affected by the virus as clean and dry as possible.
- Avoid touching or scratching the sore areas as you may spread the virus on your fingers.
- Do not share any objects that have been in contact with a cold sore (e.g. drinking glasses, eating utensils, or towels).
- Avoid direct skin-to-skin contact of the area with other people (e.g. kissing) until the cold sore has healed.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how EZOVIR® Cold Sore Relief affects you.

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how EZOVIR® Cold Sore Relief affects you.

EZOVIR® Cold Sore Relief may cause dizziness, sleepiness or confusion in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store your EZOVIR® Cold Sore Relief tablets in a dry place where the temperature stays below 25°C.
- Keep your medicine in the original container until it is time to take it.
- Heat and dampness can destroy some medicines. EZOVIR® Cold Sore Relief tablets will keep best if they are stored cool and dry.

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.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

When to discard your medicine (as relevant)

If your pharmacist or doctor recommended that you take less than the full dose in this pack, told you to stop taking your medicine or if it has expired, ask your pharmacist what to do with any tablets that you may have left over.

Do not take EZOVIR® Cold Sore Relief after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

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 use this medicine after the expiry date.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">headachedizzinessnausea (feeling sick) or vomitingdiarrhoeaitching or an itchy rash (urticaria)	<p>Speak to your doctor if you have any of these less mild side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">a rash elsewhere on the body, that is separate from the cold soreextreme sleepiness or confusion, usually in older peoplehallucinations (seeing or hearing things that are not really there)painful or swollen jointsaching muscles or muscle tenderness or weakness that is not caused by exerciseyellowing of the skin or eyes (signs of jaundice)palpitations (signs of abnormal heart beat)	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Very Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">swelling below the surface of the skin (e.g. swelling around the face, eye, eyelid or throat)unexplained bruising or purplish patches on the skin or bleeding more easily than usual, as it may indicate that the number of platelets (a type of blood cell responsible for blood clotting) in your blood are reducedsevere blistering of the skin or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (signs of a serious skin reaction)purple patches, itching, burning of the skin (signs of inflamed blood vessels)seizures or fitsdifficulty breathing or swallowing, wheezing or cough, light-headedness, changes in alertness, skin reddening, facial/throat swelling, blue discolouration of the lips, tongue or skin (signs of severe allergic reaction)signs of a possible liver problem such as persistent pain in the upper right abdomen, yellowing of the skin and/or eyes, dark urine or pale bowel motions	<p>Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following side effects happen.</p> <p>The mentioned side effects are very rare.</p>

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 you experience, 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.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What EZOVIR® Cold Sore Relief contains

Active ingredient (main ingredient)	Famciclovir
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• microcrystalline cellulose• crospovidone• silicon dioxide• copovidone• sodium stearyl fumarate• Opadry II complete film coating system YS-22-18096 White

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

What EZOVIR® Cold Sore Relief looks like

EZOVIR® Cold Sore Relief 500 mg tablets are white, oval, film-coated tablets with "FM" on one side and "500" on the other. Each carton contains 3 tablets.

AUST R 351702

Who distributes EZOVIR® Cold Sore Relief

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street,

Cremorne VIC 3121

Australia

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