

EZOVIR

Treatment of Genital Herpes

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?

EZOVIR contains the active ingredient famciclovir. It is an antiviral medicine that is used to treat outbreaks and prevent recurrent outbreaks of genital herpes in adults and adolescents.

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

2. What should I know before I use EZOVIR?

Do not use if you have ever had an allergic reaction to EZOVIR 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?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EZOVIR 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?

- Your doctor will give you instruction on how to take EZOVIR tablets.

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

5. What should I know while using EZOVIR?

Things you should do	<ul style="list-style-type: none">Tell your doctor if you become pregnant, make sure you tell your doctor or pharmacist before taking any further doses of EZOVIR.Tell your doctor if you are about to be started on any new medicine.Tell any other doctor or dentist you visit that you are using EZOVIR.For more information on "Things you should do" can be found in Section 5 in the full CMI.
Things you should not do	<ul style="list-style-type: none">Do not stop taking EZOVIR or lower the dose without checking with your doctor.Do not use EZOVIR to treat any other medical complaints unless your doctor tells you to.Do not give EZOVIR to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how EZOVIR affects you.This medicine can cause dizziness, sleepiness or confusion in some people.
Drinking alcohol	<ul style="list-style-type: none">Avoid drinking alcohol
Looking after your medicine	<ul style="list-style-type: none">Store EZOVIR tablets in original carton at below 25°C until ready for use.

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

6. Are there any side effects?

- Side effects of this medicine may include headache; dizziness; abdominal pain or bloating; nausea; vomiting; diarrhoea; itching or an itchy rash (urticaria); abnormal liver function test results; extreme sleepiness; hallucinations; painful or swollen joints; aching muscles; yellowing of the skin or eyes; palpitations; a rash on other parts of your body; swelling below the surface of the skin; severe blistering of the skin; unexplained bruising; purple patches, itching, burning of the skin; seizures or fits; difficulty breathing or swallowing, wheezing or coughing.

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

Active ingredient(s): *famciclovir*

Consumer Medicine Information (CMI)

This leaflet provides important information about using EZOVIR. **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.**

Where to find information in this leaflet:

1. Why am I using EZOVIR?
2. What should I know before I use EZOVIR?
3. What if I am taking other medicines?
4. How do I use EZOVIR?
5. What should I know while using EZOVIR?
6. Are there any side effects?
7. Product details

1. Why am I using EZOVIR?

EZOVIR is an antiviral medicine that is used to treat outbreaks and prevent recurrent outbreaks of genital herpes in adults and adolescents.

Genital herpes is a viral infection caused by herpes simplex 1 or herpes simplex 2. It is usually transmitted through sexual contact.

Symptoms include tingling, burning or itching of the genitals, followed by the appearance of blisters which may be painful.

People can also take EZOVIR to help prevent frequent episodes of genital herpes.

Although EZOVIR does not cure the viral infection, it helps to relieve the symptoms and shorten their duration.

The best results are obtained if the medicine is started as soon as possible after the first symptoms begin to appear.

Taking EZOVIR does not prevent you from spreading the herpes virus to another person.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any

questions about why EZOVIR has been prescribed for you.

2. What should I know before I use EZOVIR?

Warnings

Do not use EZOVIR if you are allergic medical conditions:

- Famciclovir, the active ingredient
- Penciclovir, a related antiviral medicine
- Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, wheezing or troubled breathing.

Do not use EZOVIR if:

- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack has passed.

Tell your doctor or pharmacist if you are allergic to any other medicines, foods, preservatives, or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- problems with your immune system (which helps fight off infections)
- kidney disease
- liver disease.

Your doctor may want to take special care if you have any of these conditions.

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 should not be used during pregnancy unless necessary. Your doctor will discuss with you the potential risks of taking EZOVIR during pregnancy, and will also advise you if you should take EZOVIR while breast-feeding, based on the benefits and risks of your personal situation.

Talk to your doctor or pharmacist if you are not sure whether you should start taking this medicine.

If you have not told them about any of the above, tell him/her before you start taking EZOVIR.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking EZOVIR against the benefits they expect it will have for you.

There is no evidence that EZOVIR is addictive.

EZOVIR is not recommended for use in children or adolescents under 18 years of age.

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 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 blood 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 kidneys.

You may need to take different amounts of these medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

Your doctor OR Pharmacist can tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

4. How do I use EZOVIR?

Swallow the tablets whole with a full glass of water.

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

The tablets may be taken with or without food. It is not necessary to chew or crush the tablet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Follow your doctor's instructions on how many EZOVIR tablets to take.

These instructions may differ from the information contained in this leaflet.

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

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

For people whose immune system does not work as well as it should, the dose and duration of treatment may need to be increased.

For people who have kidney problems, your doctor may decide to give you a lower dose.

When to take EZOVIR

There are different ways to take EZOVIR depending on your condition.

To treat an outbreak of genital herpes

To treat an outbreak, take the tablets as soon as possible after the first symptoms of genital herpes appear.

The tablets are best taken within 6 hours of the first symptoms of genital herpes appearing.

There are two ways to take EZOVIR to treat an outbreak of genital herpes and your doctor will tell you which regimen is best for you:

- Two 250 mg EZOVIR tablets to start with, followed by one 250 mg tablet every 12 hours for the next 3 doses

Or

- One 125 mg EZOVIR tablet every 12 hours for 5 days

Both of these outbreak treatment doses deliver the same total quantity of famciclovir (1250 mg) during the treatment course.

Take the second and subsequent doses 12 hours after the first dose, or as close as possible to 12 hours during waking hours.

If you take the first dose in the late morning or early afternoon, you can take the next dose before going to bed, but do not take any doses less than 6 hours apart.

During normal waking hours, take any remaining doses at 12 hourly intervals.

Your doctor may have prescribed a different dose so follow their instructions carefully.

To suppress (prevent) outbreaks of recurrent genital herpes

Start suppressive treatment to prevent outbreaks of recurrent genital herpes as soon as possible after you have your EZOVIR prescription filled.

Take one 250 mg EZOVIR tablet twice each day.

Continue to take one 250 mg EZOVIR tablet twice each day for as long as your doctor tells you to. Do this even if you do not have an outbreak.

This medicine helps to control your condition but does not cure it. Your doctor will tell you when you can stop.

Fill your next repeat prescription before using all of the tablets in your current carton. This will ensure that your treatment can be continued and give you the best results.

Try to take the tablets at about the same times each day, as directed by your doctor or pharmacist.

Taking your tablet at the same times each day will have the best effect. It will also help you remember when to take the tablets.

How long to take it for

Continue taking your medicine for the full course of treatment or for as long as your doctor tells you to.

To help clear up your infection, you must take the full course of treatment, even if you feel your condition has improved after a few days.

To prevent recurrent episodes of genital herpes, you must take the tablets each day, even if you have no symptoms.

It is important to keep taking your medicine even if you feel well.

If you forget to take it

Take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (Overdose)

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) for advice, 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.

You may need medical attention.

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

5. What should I know while using EZOVIR?

Things you should do

If you become pregnant, make sure you tell your doctor or pharmacist before taking any further doses of EZOVIR.

They can discuss with you the risks of taking it while you are pregnant.

Remind your doctor and pharmacist that you are taking EZOVIR if you are about to be started on any new medicine.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking EZOVIR.

Things you should not do

Do not stop taking EZOVIR, or lower the dose without checking with your doctor.

If you stop your tablets suddenly, your condition may worsen or you may have unwanted side effects.

Do not take it to treat any other conditions unless your doctor tells you to.

Do not give EZOVIR to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how EZOVIR affects you.

This medicine can cause dizziness, sleepiness or confusion in some people.

Avoid sexual intercourse when symptoms are present, even if you have starting taking EZOVIR, because the risk of infecting your partner is increased.

This is important to prevent you passing the infection on to others.

Things that may help your condition

Take the following precautions to help manage your condition:

- use condoms between episodes to reduce the risk of infecting your partner
- keep the areas affected by the virus as clean and dry as possible

- wear loose-fitting clothing to avoid irritating the blisters
- avoid touching or scratching the sore area as you may spread the virus on your fingers.

Looking after your medicine

Keep your tablets in the blister pack, until it is time to take them.

If you take the medicine out of the pack it may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store EZOVIR or any other medicines in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep EZOVIR where children cannot reach it.

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

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

6. Are there any side effects?

Tell the doctor or pharmacist as soon as possible if you do not feel well while you are taking EZOVIR.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

Less serious side effects

Less Serious Side effects	What to do
<ul style="list-style-type: none">• headache• dizziness	Speak to your doctor or

<ul style="list-style-type: none"> • nausea (feeling sick) or vomiting • diarrhoea • itching or an itchy rash (urticaria) • abnormal liver function test results. 	Pharmacist if you have any of these less side effects and they worry you.
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These side effects are usually mild.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • a rash on other parts of your body • extreme sleepiness or confusion, usually in older people • hallucinations (seeing or hearing things that are not really there) • painful or swollen joints • aching muscles or muscle tenderness or weakness that is not caused by exercise. • yellowing of the skin or eyes (signs of jaundice) • palpitations (signs of abnormal heart beat) • swelling below the surface of the skin (e.g. swelling around the face, eye, eyelid or throat) • unexplained bruising, reddish 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 reduced • severe 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 fits • difficulty breathing or swallowing, wheezing or coughing, light-headedness, changes in alertness, skin reddening, facial/throat 	<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>

swelling, blue discoloration of the lips, tongue or skin (signs of severe allergic reaction).	
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These are serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

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

This medicine is only available with a doctor's prescription.

What EZOVIR 125 mg and 250 mg tablet contains

Active ingredient (Main ingredient)	<ul style="list-style-type: none"> • Each EZOVIR 250 mg – 250 mg of famciclovir • Each EZOVIR 500 mg – 500mg of famciclovir
Other ingredients (Inactive ingredients)	<ul style="list-style-type: none"> • microcrystalline cellulose • crospovidone • silicone dioxide • copovidone • sodium stearyl fumarate • OPADRY II complete film coating system YS-22-18096 White

What EZOVIR looks like

EZOVIR 250 mg tablets are white, round, film-coated tablets, marked with "FM" on one side and "250" on the

other. Each carton contains either 3, 5, 14, 20, 21, 30 or 56 tablets.

EZOVIR 500 mg tablets are white, oval, film-coated tablets with "FM" on one side and "500" on the other. Each carton contains 3, 4, 9, 12, 14, 16, 20, 30 or 56 tablets.

Some of pack sizes and/or pack types may not be marketed

Australian registration numbers:

EZOVIR 250 mg - AUST R 343761

EZOVIR 500 mg - AUST R 343762

Who distributes EZOVIR

Arrotex Pharmaceuticals Pty Ltd

15 -17 Chapel Street; Cremorne

VIC 3121

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