

EZOVIR[®] for genital herpes

famciclovir

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about EZOVIR.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page.

Some more recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking EZOVIR against the benefits it can provide.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What EZOVIR is used for

EZOVIR is an antiviral medicine for adults and adolescents. It is used to treat outbreaks of genital herpes and also to suppress (prevent) recurrent outbreaks of the condition.

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 blisters that may be painful.

People who have frequent episodes of genital herpes can also take EZOVIR to help prevent the attacks.

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.

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

Your doctor may have prescribed it for another reason.

EZOVIR is only available with a doctor's prescription. It is not addictive.

This medicine is not recommended for use in children under 12 years of age.

Before taking EZOVIR

When you must not take it

Do not take EZOVIR if you have an allergy to:

- famciclovir, the active ingredient

- penciclovir, a related antiviral medicine
- any of the other ingredients of EZOVIR listed at the end of this leaflet (see 'Product Description')

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 EZOVIR 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.

Before you start to take it

Tell your doctor if you have a problem with:

- your body's immune system, which helps to fight off infections
- your kidneys
- your liver

Your doctor may want to take extra precautions in that case.

Tell your doctor if you are pregnant, intend to become pregnant or if you are breast feeding.

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 particular situation.

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

Your doctor will want to know if you are prone to allergies.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a 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.

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

How to take EZOVIR

Swallow the tablets whole with a full glass of water.

These 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 label, 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 it

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

1. 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 three ways to take EZOVIR to treat an outbreak of genital herpes and your doctor will tell you which regimen is best for you:

- Two 500 mg EZOVIR tablets twice daily for one day

or

- 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.

Take the second dose (and subsequent doses, if applicable) 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.

2. 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

Continue taking EZOVIR every day for as long as your doctor tells you.

To help clear up your infection, you must take the full course of treatment, even if your symptoms begin to clear up 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 a dose as soon as you remember. Take your next tablet at the usual time, and then go back to taking it as you would normally.

Do not take two doses within a timeframe of less than one hour. In that case, skip the missed dose.

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

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

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

If you take too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australian telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much EZOVIR. Show them the pack of EZOVIR. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

You may need urgent medical attention.

Taking too much EZOVIR 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.

While you are taking EZOVIR

Things you must do

If you become pregnant while taking EZOVIR, tell your doctor.

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 are taking EZOVIR.

Tell any other doctor, dentist or pharmacist who treats you that you are taking EZOVIR.

Things you must not do

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.

Do not stop taking your tablets or change the dosage without checking with your doctor first.

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

Things to be careful of

If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking any medicine.

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

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

Practice "safer sex", including the use of condoms when symptoms are present, even if you have started taking EZOVIR.

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

Things that may help your condition

Take the following precautions to avoid spreading the virus:

- 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 rash.
- Avoid touching or scratching the sore area as you may spread the virus on your fingers.

Side effects

Tell your 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 treatment if you get some of the side effects.

Do not be alarmed by the below lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache
- dizziness
- nausea (feeling sick) or vomiting
- abdominal pain
- diarrhoea
- itching or an itchy rash (urticaria)
- abnormal liver function test results

The above side effects are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- 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)

The above side effects may need medical attention.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following side effects happen:

- 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 cough, light-headedness, changes in alertness, skin reddening, facial/throat swelling, blue discolouration of the lips, tongue or skin (signs of severe allergic reaction).

The above side effects are very rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed here or not yet known may happen in some people.

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

After taking EZOVIR

Storage

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

If you take the tablets out of the pack they may not keep well.

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

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

Do not leave the tablets in the car or on window sills.

Heat and dampness can destroy some medicines. EZOVIR tablets will keep best if they are stored cool and dry.

Keep the medicine where children cannot reach it.

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

Disposal

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 you have left over.

Product description

What it looks like

EZOVIR comes in three tablet strengths for the treatment of genital herpes:

EZOVIR 125 mg tablets are white, round, film-coated tablets, marked with "FM" on one side and "125" on the other. Each carton contains 2, 10, 40 or 56 tablets.

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.

Ingredients

The active ingredient in EZOVIR is famciclovir.

Each EZOVIR 125 tablet contains 125 mg of famciclovir.

Each EZOVIR 250 tablet contains 250 mg of famciclovir.

Each EZOVIR 500 tablet contains 500 mg of famciclovir.

The tablets also contain the following inactive ingredients:

- microcrystalline cellulose
- crospovidone
- silicone dioxide
- copovidone
- sodium stearyl fumarate
- OPADRY II complete film coating system YS-22-18096 White

Supplier

EZOVIR is supplied in Australia by:
Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatrix.com.au
Phone: 1800 274 276

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