

EZOVIR[®] for genital herpes

contains the active ingredient 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 if it 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 lactose intolerant.

EZOVIR® tablets contain lactose.

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.

The tablets may be taken with or without food.

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 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.

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 keep taking this medicine, 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 time frame 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 Australian Poisons Information Centre (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 your pack of EZOVIR®. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

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.

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 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

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 these lists of possible side effects.

You may not experience any of them.

Tell your doctor if you notice any of the following side effects 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 to you:

- 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)

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 medicine in the original container until it is time to take it.

Store it 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® tablets are available in the following strengths for the treatment of genital herpes:

125mg - white, oval shape, biconvex, film coated, debossed with "FAM 125" on one side and "G" on other side in blister packs of 40.

250mg - white, oval shape, biconvex, film coated, debossed with "FAM 250" on one side and "G" on other side in blister packs of 20, 21 and 56.

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.

The tablets also contain the following inactive ingredients:

- hydroxypropylcellulose
- sodium starch glycollate
- cellulose - microcrystalline
- silicon dioxide
- magnesium stearate
- Opadry II white OY-L-28900

Supplier

EZOVIR® is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

GLEBE NSW 2037

AUSTRALIA

Phone: (02) 9298 3999

www.mylan.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

EZOVIR® 125 mg - AUST R 157789

EZOVIR® 250 mg - AUST R 157788

This leaflet was prepared on 15 Sept 2016.

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