

EZOVIR Cold Sore Relief

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 pharmacist or doctor.

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 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 pharmacist or doctor has weighed the risks of you taking EZOVIR against the benefits it can provide.

If you have any concerns about this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine.

You may need to read it again.

What EZOVIR is used for

EZOVIR is an antiviral medicine used to treat recurrent outbreaks of cold sores in adults 18 years of age and over who have a normal immune system (the body system which fights

against harmful bacteria, viruses and fungi).

Cold sores are an infection caused by a virus called herpes simplex type 1 (HSV- 1). The infection is most commonly acquired as a baby or child from contact with parents or relatives, often from kissing.

Cold sores usually begin on or around the lips, mouth, and nose as small red bumps that turn into fluid-filled blisters. Cold sores can be tender and painful. 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.

After redness and swelling develop, blisters form. The blisters may weep or burst and this can be painful. Then 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. After the initial infection has healed, the virus becomes dormant in nerve cells.

Cold sores can be unpredictable. The virus can become active again in the body, even after many years, resulting in recurrent outbreaks.

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.

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

The best results are obtained if the medicine is started as soon as possible after the onset of symptoms of a cold sore, such as 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 recommended for you.

EZOVIR is only available from your pharmacist and does not require a prescription. It is not addictive.

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

Before you take EZOVIR

When you must not take it

Do not take EZOVIR 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.

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.

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 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 pharmacist or doctor if
you are over 50 years of age, or if
you have:**

- a problem with your body's
immune system, which helps to
fight off infections
- 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.

**Tell your pharmacist or 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 pharmacist or 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.**

He/she will want to know if you are
prone to allergies.

**If you experience an allergic
reaction, inform your pharmacist
or doctor immediately.**

Taking other medicines

**Tell your pharmacist or doctor if
you are taking any other
medicines, including any 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
more brittle and likely to break)
- medicines that can affect your
immune system
- medicines that can affect your
kidney
- You may need to take different
amounts of these medicines or
you may need to take different
medicines or you may need to
take different medicines. Your
pharmacist and doctor 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.**

How to take EZOVIR

**Follow all directions given to you
by your pharmacist or doctor
carefully.**

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

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

How much to take

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

He/she will tell you exactly how
much to take.

When to take it

**Take EZOVIR 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 is all that
is necessary for treating each episode
of cold sores. Each pack of EZOVIR
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, treatment should not be repeated within 7 days.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone number 13 11 26), 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 tablets. 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

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

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

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 periodically take this medicine.

Things you must 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 it to treat any other complaints unless your doctor tells you to.

Things to be careful of

If you are pregnant or breastfeeding, 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.

Things that may you're your Condition

Cold sores are contagious and the virus can be passed on from person to 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 area 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.

Side effects

Tell your pharmacist or doctor 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. Ask your pharmacist or doctor to answer any questions you may have. Tell your pharmacist or 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)
- The above side effects are usually mild.

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

- a rash elsewhere on the body, that is separate from the cold sore
- 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 pharmacist or 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 pharmacist or doctor if you notice anything else that is making you unwell.

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

After taking EZOVIR

Storage

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

Store your EZOVIR tablets in a dry place at room temperature.

Do not store your medicines 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 it 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.

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 that is left over.

Product description

What it looks like

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

Ingredients

Active Ingredient

EZOVIR 500 - contain 500 mg famciclovir per tablet.

Inactive ingredients

EZOVIR tablets

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

Neo Health (OTC) Pty Ltd

Suite 3, 380 Pennant Hills Road,
Pennant Hills, NSW 2120, Australia

Australian Registration Numbers

EZOVIR Cold Sore Relief 500 mg -
AUST R 351702

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