

# EZOVIR<sup>®</sup> for cold sores

contains the active ingredient famciclovir

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## CONSUMER MEDICINE INFORMATION

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### What is in this leaflet

This leaflet answers some common questions about EZOVIR<sup>®</sup>.

It does not contain all the available information and 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<sup>®</sup> 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 this medicine.**

You may need to read it again.

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### What EZOVIR<sup>®</sup> is used for

EZOVIR<sup>®</sup> is an antiviral medicine that is used to treat recurrent outbreaks of cold sores in adults and adolescents 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 I (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.

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.

Although EZOVIR<sup>®</sup> 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 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<sup>®</sup> is only available with a doctor's prescription. It is not addictive.

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

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### Before taking EZOVIR<sup>®</sup>

**When you must not take it**

**Do not take EZOVIR<sup>®</sup> if you have an allergy to:**

- famciclovir, the active ingredient
- penciclovir, a related antiviral medicine
- any of the EZOVIR<sup>®</sup> ingredients 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.
- You have a problem with your kidneys or 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.**

It is not known whether taking this medicine during pregnancy could affect your baby or whether the active ingredient in EZOVIR® passes into the breast milk. Your doctor can discuss with you the benefits and risks involved.

**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 get 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)
- 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 doctor about any of these things, tell him/her before your start taking this medicine.**

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## **How to take EZOVIR®**

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**Swallow the tablets whole with a full glass of water.**

They may be taken with or without food.

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

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

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

### ***How much to take***

The usual dose is three 500 mg tablets taken together as a single dose. However, your doctor may have prescribed a different dose.

Patients whose immune system does not work as well as it should may need a different dose for a longer period of time.

**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.**

For people who have reduced kidney function, the dose may need to be reduced.

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

### ***When to take it***

**Take EZOVIR® 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 long to take it***

A single dose of EZOVIR® for cold sores is all that is necessary for treating each episode of cold sores. The dose may be repeated if cold sores recur. Each pack of EZOVIR® contains enough medicine for one dose.

### ***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 you or anyone else may have taken too much EZOVIR®. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.**

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## **While you are taking EZOVIR®**

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### ***Things you must do***

**Tell your pharmacists or doctors if your cold sore symptoms do not improve within a few days, or if they become worse.**

**If you become pregnant, tell your doctor before taking any further doses of this medicine to treat recurring episodes 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®.**

### ***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 this medicine to treat any other complaints unless your doctor tells you to.**

### ***Things to be careful of***

**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.

### ***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.

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## **Side effects**

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**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
- diarrhoea

The above side effects are usually mild.

**Tell your 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

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:**

- bruising 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
- signs of a serious skin or mouth reaction, which may include widespread red, raised areas, blisters or sores
- 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

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.**

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## **After taking EZOVIR®**

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### ***Storage***

**Keep your medicine in the original container until it is time to take it. Store your EZOVIR® tablets dry place where the temperature stays below 25°C.**

**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.**

Australian registration numbers:

EZOVIR® 500 mg - AUST R 157787

This leaflet was prepared on

26 May 2010.

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## **Product description**

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### **What it looks like**

EZOVIR® tablets are available in 500mg - white, oval shape, biconvex, film coated, debossed with "FAM 500" on one side and "G" on other side in blister packs of 3.

### **Ingredients**

The active ingredient in EZOVIR® is famciclovir.

Each EZOVIR® 500 tablet contains 500 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

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[www.alphapharm.com.au](http://www.alphapharm.com.au)

Medical Information

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