

APOHEALTH FAMCICLOVIR ONCE

(for cold sores)

Contains the active ingredient, famciclovir (fam-SYE-klo-veer)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about famciclovir.

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 last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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

Keep this leaflet with your medicine.

You may want to read it again.

What famciclovir is used for

The name of your medicine is APOHEALTH FAMCICLOVIR ONCE. It contains the active ingredient, famciclovir.

Famciclovir 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 APOHEALTH FAMCICLOVIR ONCE 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 prescribed for you.

This medicine is available only from your pharmacist and does not require a prescription.

There is no evidence that this medicine is addictive.

Use in children

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

Before you take famciclovir

When you must not take it

Do not take this medicine if you have had an allergic reaction to famciclovir, penciclovir (a related antiviral medicine) or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

Do not take this medicine 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 this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of

tampering or if it does not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your pharmacist or doctor if:

1. You have allergies to:

- Any other medicines
- Any other substances, such as foods, preservatives or dyes.

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.

2. You have a problem with your kidneys.

3. You are over 50 years of age as you may be at increased risk of kidney problems, or you have any other risk factors for kidney problems, including: diabetes, high blood pressure, heart problems, liver problems or any other medical conditions or signs of an infection other than your cold sore.

If you have any of these conditions your pharmacist may want to take extra precautions or refer you to a doctor to determine if this medicine is suitable for you.

4. You are pregnant, intend to become pregnant or if you are breast-feeding.

APOHEALTH FAMCICLOVIR ONCE should not be used during pregnancy unless necessary. Your pharmacist or doctor will discuss with you the potential risks of taking this medicine during pregnancy, and will also advise you if you should take this medicine while breast-feeding, based on the benefits and risks of your particular situation.

If you have not told your pharmacist or doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist 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 famciclovir 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.
- medicines that can affect your immune system.

These medicines may be affected by famciclovir or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking famciclovir.

Other interactions not listed above may also occur.

How to take this medicine

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, 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, 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.

How to take it

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.

When to take it

Take APOHEALTH FAMCICLOVIR ONCE 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 famciclovir is all that is necessary for treating each episode of cold sores.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for

advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much famciclovir.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Taking too much famciclovir 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 famciclovir

Things you must do

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

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

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

Tell any other doctors, dentists, and pharmacists who are treating you that you sometimes take famciclovir to treat recurring episodes of cold sores.

Things you must not do

Do not take less than the recommended dose of three tablets, unless advised by your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use it 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 famciclovir 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 that causes them 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 can be seen, 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, towels)
- Avoid direct skin-to-skin contact of the area with other people (e.g. kissing) until the cold sore has healed.

Side effects of famciclovir

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

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 doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following:

- headache

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

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

- a rash on other parts of your body, that is separate to 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:

- swelling below the surface of the skin (e.g. swelling around the face, eye, eyelid or throat)
- 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 is 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.

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.

After taking this medicine

Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

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 pharmacist or doctor recommended that you take less than the full dose in this pack, ask your pharmacist what to do with any tablets that you may have left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What APOHEALTH FAMCICLOVIR ONCE looks like

White, oval, biconvex, film-coated and engraved "FAM500" on one side and "APO" on the other side.

Available in blister packs of 3 tablets.

Ingredients

Each tablet contains 500 mg of famciclovir as the active ingredient.

It also contains the following inactive ingredients:

- poloxamer
- stearic acid
- hypromellose
- titanium dioxide
- macrogol 8000.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APOHEALTH FAMCICLOVIR ONCE 500 mg tablets:

AUST R 201911

Sponsor

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This leaflet was prepared in November 2014.