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 APO-Famciclovir. It contains the active ingredient, famciclovir.

Famciclovir is an antiviral medicine used to treat recurrent outbreaks of cold sores in adults who have a normal immune system (the body system which fights against harmful bacteria, viruses and fungi).

How it works

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 famciclovir for cold sores 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 doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed famciclovir for another reason.

This medicine is available only with a doctor's 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 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 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 or have had any medical conditions, especially the following:
   - problems 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.

3. You plan to become pregnant or breast-feed.

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

If you have not told your 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.

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

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines. 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.

The usual dose is 1,500 mg taken as a single dose or two doses of 750 mg, taken 12 hours apart, for one day only.

Doses may be repeated if cold sores recur.

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

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 famciclovir tablets for cold sores 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.

A single dose can also be halved. Take the first half dose and then, 12 hours later, take the second half dose.

**If you forget to take it**

Take a dose as soon as you remember.

If you are not sure what to do, ask your doctor or pharmacist.

**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.

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**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 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.

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.

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**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 and they worry you:

- headache
- dizziness
- nausea (feeling sick) or vomiting
- 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:

- 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.

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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.

**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**

While you are taking famciclovir
• 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.

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.

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.

500 mg tablets

White, round, biconvex, film-coated and engraved "FAM" over "500" on one side and "APO" on the other side.

Blisters pack sizes: 3, 12, 14, 16, 20, 28, 30, 56 tablets.

Bottle pack sizes: 12, 14, 16, 20, 28, 30, 56 tablets.

Not all strengths, pack types and/or pack sizes may be available

Ingredients

Each tablet contains 250 mg or 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

APO-Famciclovir 250 mg tablets (blister pack): AUST R 160556.

APO-Famciclovir 250 mg tablets (bottle): AUST R 160560.

APO-Famciclovir 500 mg tablets (blister pack): AUST R 172443.

APO-Famciclovir 500 mg tablets (bottle): AUST R 172445.

Sponsor

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Australia

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Product description

What APO-Famciclovir looks like

250 mg tablets

White, round, biconvex, film-coated and engraved "FAM" over "250" on one side and "APO" on the other side.

Blister pack sizes: 5, 14, 20, 21, 28, 30 or 56 tablets.

Bottle pack sizes: 14, 20, 21, 28, 40 or 56 tablets.
This leaflet was prepared in December 2011.