

APO-Famciclovir

(for genital herpes)

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.

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. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Famciclovir. It contains the active ingredient, famciclovir.

Famciclovir 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.

How it works

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 famciclovir to help prevent the attacks.

Although famciclovir 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 famciclovir 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 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 under 12 years of age.

Before you take this medicine

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.

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
- problems with your kidneys
- problems with 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 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 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

There are different ways to take famciclovir 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 three ways to take famciclovir to treat an outbreak of genital herpes and your doctor will tell you which regimen is best for you:

- Two 500 mg famciclovir tablets twice daily for one day

or

- Two 250 mg famciclovir tablets to start with, followed by one 250mg tablet every 12 hours for the next 3 doses

or

- One 125 mg famciclovir tablet every 12 hours for 5 days.

Both of these outbreak treatment doses deliver the same total quantity of famciclovir (1250 mg) during the treatment course.

Take the second (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 prescription filled.

Take one 250 mg famciclovir tablet twice each day.

Continue to take one 250 mg famciclovir 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 famciclovir 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 for

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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 this medicine

Things you must do

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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking famciclovir.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking famciclovir.

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.

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 famciclovir affects you.

This medicine can cause dizziness, tiredness or confusion in some people.

Practice "safer sex", including the use of condoms, when symptoms are present, even if you have started taking famciclovir.

This is important to prevent you passing the infection onto 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.

Possible side effects

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

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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.

These may be serious side effects and you may need medical attention.

- 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.

If you experience any of the following tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation.

- 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.

Other side effects not listed above may occur in some patients.

Storage and disposal

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 doctor tells you to stop taking this medicine or the expiry date has passed, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Famciclovir looks like

125 mg tablets

White, round, biconvex, film-coated and engraved "FAM" over "125" on one side and "APO" on the other side.

Blister pack sizes: 10, 28, 40 or 56 tablets.

Bottle pack sizes: 28, 40 or 56 tablets.

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.

500 mg tablets

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

Blister 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 125 mg, 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 125 mg tablets (blister pack): AUST R 160559.

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

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

APO-Famciclovir 125 mg tablets (bottle): AUST R 160558.

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

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

Sponsor

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