

APO-Famciclovir

(for genital herpes)

Famciclovir

Consumer Medicine Information

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

What is in this leaflet

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.

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.

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

Keep this leaflet with the medicine. You may want to read it again.

What this medicine is used for

Famciclovir is used to treat outbreaks of genital herpes and to suppress (prevent) recurrent outbreaks of the condition in adults and adolescents.

It belongs to a group of medicines called antivirals.

How it works

Genital herpes is a viral infection caused by Herpes Simplex 1 (HSV 1) or Herpes Simplex 2 (HSV 2). It is usually transmitted through sexual contact.

Symptoms include tingling, burning or itching of the genitals, followed by blisters that may be painful.

Famciclovir works by stopping the multiplication of the virus that causes genital herpes. 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.

People who have frequent episodes of genital herpes can also take famciclovir to help prevent the attacks.

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.

This medicine is not addictive.

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 an allergy to:

- famciclovir
- penciclovir
- any of the ingredients 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, throat or other parts of the body
- muscle pain or tenderness or joint pain
- 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.

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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- problems with your body's immune system, which helps to fight off infections
- kidney problems
- liver problems

Tell your doctor if you are pregnant or you plan to become pregnant or are breastfeeding.

It is not known whether taking this medicine during pregnancy could affect your baby or whether famciclovir passes into the breast milk. Famciclovir should not be used during pregnancy unless necessary.

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 and to increase blood levels of penicillin-type antibiotics
- raloxifene, a medicine used to treat osteoporosis
- 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 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 differ to 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

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your

condition and whether you are taking any other medicines.

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.

Your doctor may have prescribed a different dose.

To treat an outbreak of genital herpes:

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. Your doctor will tell you which regimen is best for you:

- Take two 500 mg tablets twice daily for one day
- or**
- Take two 250 mg tablets to start with, followed by one 250mg tablet every 12 hours for the next 3 doses
- or**
- Take one 125 mg tablet every 12 hours for 5 days.

For dosing regimens with 12-hourly dosing, 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.

To suppress (prevent) outbreaks of recurrent genital herpes:

The usual dose is one 250 mg tablet taken twice each day.

Continue to take this medicine for as long as your doctor tells you to. Do this even if you do not have an outbreak.

How to take it

Swallow the tablets whole with a full glass of water.

The tablets may be taken with or without food.

When to take it

Take the tablets at about the same time each day.

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.

This medicine helps to control your condition but does not cure it. Your doctor will tell you when you can stop. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, 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 (telephone 13 11 26) for advice, or go to Accident and Emergency 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 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.

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

For suppressing recurrent outbreaks, make sure to 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.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

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

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. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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.

Side effects

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

This medicine helps most people with shingles, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious

but 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 following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist 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 list includes the more common side effects of your medicine. They are usually mild.

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

- 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.

The above list includes serious side effects that may need medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling below the surface of the skin, such as swelling around the face, eye, eyelid or throat
- bruising or bleeding more easily than usual (may indicate that the number of platelets (a type of blood cell responsible for blood clotting) in your blood is reduced)
- widespread red, raised areas, blisters or sores of the lips, eyes, mouth, nasal passages or genitals (signs of a serious skin reaction)

- persistent pain in the upper right abdomen, yellowing of the skin and/or eyes, dark urine or pale bowel motions (signs of a possible liver problem)
- palpitations (signs of abnormal heart beat)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. The above side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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

Storage and disposal

Storage

Keep your medicine in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your medicine in a cool dry place where the temperature stays 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, ask your pharmacist what to do with any medicine that is left over.

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. AUST R 160559.

Bottle pack sizes: 28, 40 or 56 tablets. AUST R 160558.

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. AUST R 160556.

Bottle pack sizes: 14, 20, 21, 28, 40 or 56 tablets. AUST R 160560.

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. AUST R 172443.

Bottle pack sizes: 12, 14, 16, 20, 28, 30, 56 tablets. AUST R 172445.

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:

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

This medicine does not contain gluten, lactose, sucrose, tartrazine and other azo dyes.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street, Cremorne, VIC

3121

Australia

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