APO-Famciclovir

(for cold sores)

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 used to treat recurrent outbreaks of cold sores in adults who have a normal immune system (the body system which fights against infections).

It belongs to a group of medicines called antivirals.

How it works

Cold sores are an infection caused by a virus called herpes simplex type 1 (HSV-1), commonly acquired as a child from contact with parents or relatives.

Cold sores usually begin on or around the lips, mouth, and nose as small red bumps that turn into fluid-filled blisters.

Famciclovir works by stopping the production of the virus causing the cold sore. Although famciclovir for cold sores does not cure the viral infection, it helps to relieve the symptoms and shorten the duration of an outbreak.

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. As the cold sore dries, a shallow ulcer and yellow crust forms which will eventually fall off to expose new lighter-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. E

Some common triggers to a cold sore may include:

- sun exposure
- stress
- fatigue
- menstrual periods
- fever or illness, such as a cold
- dry chapped lips or skin trauma

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 or adolescents under 18 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 or pharmacist.

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
- kidney problems
- liver problems

Tell your doctor if you are pregnant, 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, used to treat gout and to increase blood levels of penicillin-type antibiotics
- raloxifene, 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 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.

The usual dose is three 500 mg tablets taken as a single dose or two doses of 750 mg (one 250 mg tablet and one 500 mg tablet), 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.

When to take it

Take this medicine as soon as possible after the first signs of a cold sore appear, such as tingling, itching or burning, redness or swelling.

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 for

A single dose of famciclovir is all that is necessary for treating each episode of cold sores.

If you forget to take it

Take the missed 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 (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

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 immediately.

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 they have the same condition as you.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not take less than the recommended dose unless advised by your doctor.

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.

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 shed and 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

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 cold sores, 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.

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 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, 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 list includes serious side effects that may require 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 and 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 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.

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 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

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park, NSW 2113

Australia

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