

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Famciclovir Sandoz.

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 taking 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 need to read it again.

WHAT FAMCICLOVIR SANDOZ IS USED FOR

Famciclovir Sandoz 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.

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 Sandoz to help prevent the attacks.

Although Famciclovir Sandoz 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 Sandoz 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 to you.

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription. It is not addictive.

This medicine is not recommended for use in children under 12 years of age.

BEFORE YOU TAKE FAMCICLOVIR SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- famciclovir, the active ingredient, Penciclovir, a related antiviral medicine.
- penciclovir, a related antiviral medicine
- any of the other 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 or other parts of the body
- 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.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you have a problem 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

Tell your doctor if you are lactose intolerant.

Famciclovir Sandoz 250 mg tablets contain lactose. Famciclovir 500mg tablets do not contain lactose.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Famciclovir Sandoz 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.

You may need to take different amounts of these medicines or you may need to take different medicines.

Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

HOW TO TAKE FAMCICLOVIR SANDOZ

Swallow the tablets whole with a full glass of water.

The tablets may be taken with or without food. It is not necessary to chew or crush the tablets.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Follow your doctor's instructions on how many Famciclovir Sandoz tablets to take. 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.

For people whose immune system does not work as well as it should, the dose and duration of treatment may be increased.

For people who have kidney problems, your doctor may decide to give you a lower dose.

When to take Famciclovir Sandoz

There are different ways to take Famciclovir Sandoz depending on your condition.

1. TO TREAT AN OUTBREAK OF GENITAL HERPES

To treat an outbreak, take your medicine 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 two ways to take Famciclovir Sandoz to treat an outbreak of genital herpes and your doctor will tell you which regimen is best for you:

- Two 500mg Famciclovir tablets twice daily for one day or
- Two 250 mg Famciclovir Sandoz tablets to start with, followed by one 250 mg tablet every 12 hours for the next 3 doses.

Take the second dose (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 Famciclovir Sandoz prescription filled.

Take one 250 mg Famciclovir Sandoz tablet twice each day.

Continue to take one 250 mg Famciclovir Sandoz 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 your medicine 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 Famciclovir

Continue taking Famciclovir Sandoz 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

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 two doses within a time frame of less than an hour. In that case, skip the missed dose.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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 Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) 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 Sandoz. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

Taking too much Famciclovir Sandoz may affect your 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 SANDOZ

Things you must do

If you become pregnant while taking this medicine, 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 Sandoz.

Tell any other doctors, dentists or pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not give your medicine to anyone else even if their condition seems to be the same as 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 breast feeding, 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 Sandoz affects you.

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

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

This is important to prevent you passing the infection on to 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 Sandoz.

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.

Tell your doctor or pharmacist if you notice any of the following side effects and they worry you:

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

- 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
- yellowing of the skin or eyes (sign of jaundice)
- palpitation (signs of abnormal heart beat)

The above side effects may require medical attention.

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

- swelling below the surface of the skin (e.g. swelling around the face, eye, eyelid or throat)
- unexplained bruising, reddish or purplish patches on the skin 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 are reduced
- severe blistering of the skin or mucous membranes of the lips, eyes, mouth, nasal passages of genitals (signs of a serious skin reaction)
- purple patches, itching, burning of the skin (signs of inflamed blood vessels)
- seizure of fits
- difficulty breathing or swallowing, wheezing or cough, light-headedness, changes in alertness, skin reddening, facial/ throat swelling, blue discoloration of the lips, tongue or skin (signs of severe allergic reactions).

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.

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

AFTER TAKING FAMCICLOVIR SANDOZ

Storage

- Keep your medicine in the original container until it is time to take it.
- Store in a dry place at room temperature.
- Do not store Famciclovir Sandoz or any other medicine in the bathroom or near a sink.
- Do not leave the tablets on a window sill or in the car.
- Heat and dampness can destroy some medicines. Famciclovir Sandoz tablets will keep best if they are stored cool and dry.

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 it looks like

Famciclovir Sandoz 250mg - white, round film-coated tablets with "FV" on one side and "250" on the other.

Famciclovir Sandoz 500mg - white, oval film-coated tablets with "FV 500" on one side.

Famciclovir Sandoz 250mg is available in blister packs of 20, 21 and 56 tablets.

Famciclovir Sandoz 500mg is available in blister packs of 30 and 56 tablets.

Ingredients

Active ingredients:

- Famciclovir Sandoz 250mg - contain 250mg famciclovir per tablet
- Famciclovir Sandoz 500mg - contain 500mg famciclovir per tablet.

Inactive ingredients:

Famciclovir Sandoz 250 mg film-coated tablets contain:

- hypromellose (E 464)
- hydroxypropylcellulose (E 463)
- lactose
- macrogol
- magnesium stearate (E 572)
- sodium starch glycollate
- titanium dioxide (E171).

Famciclovir Sandoz 250 mg tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

Famciclovir Sandoz 500 mg tablets contain:

- hypromellose (E 464)
- hydroxypropylcellulose (E 463)
- macrogol
- magnesium stearate (E 572)
- sodium starch glycollate
- titanium dioxide (E171).

Famciclovir Sandoz 500 mg tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

More information

For more information about genital herpes, visit www.herples.com.au.

Supplier

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