

Treatment of genital herpes

contains the active ingredient famciclovir

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about FAVIC.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking FAVIC against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What FAVIC is used for

FAVIC is an antiviral medicine that is used to treat outbreaks and prevent recurrent outbreaks of genital herpes in adults and adolescents.

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 the appearance of blisters which may be painful.

People can also take FAVIC to help prevent frequent episodes of genital herpes.

Although FAVIC 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 FAVIC does not prevent you from spreading the herpes virus to another person.

Your doctor may have prescribed FAVIC for another reason. Ask your doctor if you have any questions about why FAVIC has been prescribed for you.

FAVIC is available only with a doctor's prescription.

There is no evidence that FAVIC is addictive.

FAVIC is not recommended for use in children under 12 years of age, as the safety and efficacy of famciclovir in this age group has not been established.

Before you take FAVIC

When you must not take it

Do not take FAVIC if you are allergic to medicines containing:

- 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
- skin rash, itching or hives
- swelling of the face, lips, tongue or any parts of the body.

Do not take FAVIC if the expiry date (Exp.) printed on the pack has passed.

Do not take FAVIC if the packaging is torn or shows signs of tampering.

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 are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

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

- problems with your immune system (which helps fight off infections)
- kidney disease
- liver disease.

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell him/her before you start taking FAVIC.

Taking other medicines

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

Some medicines and FAVIC may interfere with each other. These include:

- medicines that affect kidney function
- probenecid, a medicine used to treat gout.

Your doctor can tell you what to do if you are taking any of these medicines.

These medicines may be affected by FAVIC or may affect how well it works. You may need different amounts of your medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking FAVIC.

How to take FAVIC

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

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

How much to take

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 two ways to take FAVIC to treat an outbreak of genital herpes and your doctor will tell you which regimen is best for you:

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

Or

- One 125 mg FAVIC 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 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 so follow their instructions carefully.

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 FAVIC prescription filled.

Take one 250 mg FAVIC tablet twice each day.

Continue to take one 250 mg FAVIC 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 to take FAVIC

Swallow the tablets whole with a full glass of water.

How long to take FAVIC for

Continue taking your medicine for the full course of treatment or for as long as your doctor tells you to.

To help clear up your infection, you must take the full course of treatment, even if you feel your condition has improved after a few days.

If you forget to take it

Take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

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 FAVIC. Do this even if there are no signs of discomfort or poisoning. You may need medical attention.

While you are taking FAVIC

Things you must do

If you become pregnant while taking FAVIC, tell your doctor.

Your doctor can discuss with you the risks of taking FAVIC while you are pregnant.

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

Tell any other doctor, dentist or pharmacist who treats you that you are taking FAVIC.

Things you must not do

Do not stop taking FAVIC, or lower the dose without checking with your doctor.

Do not take FAVIC to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how FAVIC affects you.

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

Avoid sexual intercourse when symptoms are present, even if you have starting taking FAVIC, because the risk of infecting your partner is increased.

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 FAVIC.

All medicines can have side effects. Sometimes they are serious, most

of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list 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

These 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.

You may need medical attention if you have the above side effects.

Tell your doctor immediately, or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- 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 are 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.

These are serious but very rare side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After taking FAVIC

Storage

Keep FAVIC 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.

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

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store FAVIC or any other medicine in the bathroom or near a sink.

Do not leave FAVIC in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking FAVIC, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

FAVIC comes in two strengths of tablet for the treatment of genital herpes:

- FAVIC 125 – white to off-white, round tablet with 'FC' over '125' on one side. Each pack contains 40 tablets.
- FAVIC 250 – white to off-white, round tablet with 'FC' over '250'

on one side. Each pack contains 20 or 56 tablets.

Ingredients

The active ingredient in FAVIC is famciclovir:

- each FAVIC 125 tablet contains 125 mg of famciclovir
- each FAVIC 250 tablet contains 250 mg of famciclovir.

The tablets also contain:

- sodium starch glycolate
- microcrystalline cellulose
- hydroxypropylcellulose
- magnesium stearate
- Opadry II 85F18378 White (ARTG No 12135).

The tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Manufacturer

Sigma Pharmaceuticals (Australia)
Pty Ltd
96 Merrindale Drive
Croydon Vic 3136
Tel: 03 - 9839 2800

Australian registration numbers:

FAVIC 125 - AUST R 159602

FAVIC 250 - AUST R 159611

This leaflet was prepared in May 2010.