

FAVIC

Treatment of cold sores

famciclovir

Consumer Medicine Information (CMI)

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.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

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 recurrent outbreaks of cold sores in adults who have a normal immune system.

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

Cold sores usually begin on or around the lips, mouth, and nose as small red bumps that turn into fluid-filled blisters. Cold sores can be tender and painful. 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. Then a shallow ulcer and yellow crust form as the cold sore dries. The crust eventually falls off, exposing new pink-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.

Even after many years, some people may experience recurring cold sores due to viral reactivation.

Some common triggers to a cold sore may include:

- sun exposure
- stress
- fatigue
- menstrual periods
- fever
- illness
- dry chapped lips
- skin trauma
- a cold.

FAVIC does not cure the viral infection, however it helps to relieve the symptoms and shorten the duration of an outbreak.

The best results are obtained if the medicine is started as soon as possible after the first symptoms are noticed. These include tingling, itching or burning, or the appearance of redness or swelling. This is when the virus is reproducing rapidly.

There is no evidence that FAVIC is addictive.

FAVIC is not recommended for use in children or adolescents under 18 years of age.

Before you take it

When you must not take it

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

- Famciclovir, the active ingredient
- Penciclovir, a related antiviral medicine
- 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 it if the packaging is torn or shows signs of tampering.

Talk to your doctor or pharmacist if you are not sure whether you should start taking this medicine.

Before you start to take it

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

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

FAVIC should not be used during pregnancy unless necessary. Your doctor will discuss with you the

potential risks of taking FAVIC during pregnancy, and will also advise you if you should take FAVIC while breast-feeding, based on the benefits and risks of your personal situation.

Tell your doctor or pharmacist 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 them 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:

- 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.

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

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

How to take it

Swallow the tablets whole with a full glass of water.

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

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

If you do not understand the instructions on the box, ask them for help.

How much to take

The usual dose is three 500 mg tablets taken together as a single dose.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take FAVIC tablets as soon as possible after the first symptoms of a cold sore appear.

Symptoms include tingling, itching or burning or the appearance of redness and 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 FAVIC is all that is necessary for treating each episode of cold sores. The dose may be repeated if cold sores recur. Each pack of FAVIC for cold sores contains enough medicine for one dose.

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 it

Things you must do

If you become pregnant, make sure you tell your doctor or pharmacist before taking any further doses of FAVIC.

They can discuss with you the risks of taking it while you are pregnant.

Remind your doctor and pharmacist that you are taking FAVIC if you are about to be started on any new medicine.

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

Things you must not do

Do not take less than the recommended dose of 3 tablets, unless advised by your pharmacist.

If you stop your tablets suddenly, your condition may worsen or you may have unwanted side effects.

Do not take FAVIC to treat any other conditions unless your doctor or pharmacist 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.

Things that may help your condition

Cold sores are contagious and the virus 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 is visible, as the virus can be shed, making it easy to 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, or 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 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 or pharmacist if you notice any of the following 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

These side effects are usually mild.

Tell your doctor or pharmacist 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 (signs of jaundice)
- palpitations (signs of abnormal heart beat)

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:

- 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 or genitals (signs of a serious skin reaction)
- purple patches, itching, burning of the skin (signs of inflamed blood vessels)
- seizures or fits
- difficulty breathing or swallowing, wheezing or coughing, light-headedness, changes in alertness, skin reddening, facial/throat swelling, blue discoloration of the

lips, tongue or skin (signs of severe allergic reaction).

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 it

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 or pharmacist 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 500 are white to off-white, capsule-shaped tablets with 'FC 500' on one.

Each pack contains 30 or 56 tablets.

Ingredients

FAVIC 500 contains 500 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

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

Australian registration numbers:
FAVIC 500 - AUST R 159619

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