

FAVIC FOR COLD SORES

Treatment of cold sores

famciclovir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FAVIC FOR COLD SORES.

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

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

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

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

What FAVIC FOR COLD SORES is used for

FAVIC FOR COLD SORES is an antiviral medicine that is used to treat recurrent outbreaks of cold sores in adults who have a normal immune system (the body system which fights against harmful bacteria, viruses and fungi).

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 FOR COLD SORES 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 or signs of a cold sore 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 FOR COLD SORES is addictive.

FAVIC FOR COLD SORES 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 FOR COLD SORES 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 FOR COLD SORES if you have a problem with your body's immune system, which helps to fight infections.

Your pharmacist will refer you to your doctor in that case.

Do not take FAVIC FOR COLD SORES 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 pharmacist or doctor if you are not sure whether you should start taking this medicine.

Before you start to take it

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

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

They can discuss with you the risks and benefits involved. FAVIC FOR COLD SORES should only be used by pregnant or breast feeding women under medical supervision.

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

- liver disease
- signs and symptoms of an infection other than your cold sore.

Tell your pharmacist if you have a problem with your kidneys. Those who have the following conditions may be at risk of having problems with their kidneys. **Tell you pharmacist if you:**

- have diabetes
- are over 50 years of age
- have high blood pressure, heart problems or cardiovascular problems

- have any other medical condition

Your pharmacist or doctor may want to take extra precautions 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 FOR COLD SORES.

Taking other medicines

Tell your pharmacist or doctor 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 FOR COLD SORES may interfere with each other. These include:

- medicines that affect kidney function
- probenecid, a medicine used to treat gout
- medicines that can affect your immune system
- raloxifene, a medicine used to treat osteoporosis.

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

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

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

How to take it

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

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 FOR COLD SORES tablets as soon as possible after the first signs or symptoms of a cold sore appear.

These 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 FOR COLD SORES is all that is necessary for treating each episode of cold sores. Each pack of FAVIC FOR COLD SORES contains enough medicine for one dose. A repeat dose during this episode is not recommended. If another episode of cold sores recurs, another dose may be taken. However, treatment should not be repeated within 7 days.

If you take too much (overdose)

Immediately telephone your pharmacist or 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 FOR COLD SORES. Do this even if there are no signs of discomfort or poisoning.

You may need medical attention.

Taking too much FAVIC FOR COLD SORES 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 it

Things you must do

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

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

Remind your pharmacist or doctor that you are taking FAVIC FOR COLD SORES 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 FOR COLD SORES.

Things you must not do

Do not repeat treatment within seven days.

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

Do not take FAVIC FOR COLD SORES to treat any other conditions unless your pharmacist or doctor tells you to.

Do not give FAVIC FOR COLD SORES 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 FOR COLD SORES 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 pharmacist or doctor as soon as possible if you do not feel well while you are taking FAVIC FOR COLD SORES.

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 pharmacist or doctor to answer any questions you may have.

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

- headache
- dizziness
- nausea (feeling sick) or vomiting
- diarrhoea
- stomach pain
- itching or an itchy rash (urticarial).

These side effects are usually mild.

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

- a rash that is separate from the shingles rash
- 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 pharmacist or 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 pharmacist or doctor if you notice anything that is making you feel unwell.

After taking it

Storage

Keep FAVIC FOR COLD SORES 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 FOR COLD SORES or any other medicine in the bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

Disposal

If your pharmacist or doctor tells you to stop taking FAVIC FOR COLD SORES, 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 FOR COLD SORES are white to off-white, capsule-shaped tablets with 'FC 500' on one.

Each pack contains 3 tablets.

Ingredients

FAVIC FOR COLD SORES contains 500 mg of famciclovir.

The tablets also contain:

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

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

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street
Cremorne Victoria 3121

Australian registration numbers:

FAVIC FOR COLD SORES - AUST R 212115

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