

## Treatment of cold sores

*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 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.

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 or adolescents under 18 years of age.

#### 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.

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## How to take FAVIC

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**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*

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

Your doctor may prescribe a different dose.

### *How to take FAVIC*

Swallow the tablets whole with a full glass of water.

### *When to take FAVIC*

**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 FAVIC 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.

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## While you are taking FAVIC

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### *Things you must do*

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

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 FAVIC.**

**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 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.

### *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.

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## Side effects

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**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 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 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.**

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## After taking FAVIC

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### *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.**

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## Product description

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### *What it looks like*

FAVIC 500 are white to off-white, capsule-shaped tablet with 'FC 500' on one.

Each pack contains 3 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*

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

Australian registration numbers:  
FAVIC 500 - AUST R 159619

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