

# FAMCICLOVIR GENERICHEALTH

## For cold sores

(famciclovir) film-coated tablets

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### Consumer Medicine Information

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#### What is in this leaflet

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This leaflet answers some common questions about Famciclovir generichealth. 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 Famciclovir generichealth 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.

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#### What Famciclovir generichealth is used for

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Famciclovir generichealth is an antiviral medicine 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.

Although Famciclovir generichealth does not cure the viral infection, 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 onset of symptoms of a cold sore, such as

tingling, itching or burning, or the appearance of the first signs, such as redness or swelling. This is when the virus is reproducing rapidly.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Famciclovir generichealth for cold sores is not recommended for use in infants, children or adolescents under 18 years of age.

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#### Before you take Famciclovir generichealth

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*When you must not take it*

**Do not take Famciclovir generichealth if you have an allergy to:**

- any medicine containing famciclovir (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;
- swelling of the face, lips, tongue or other parts of the body;

- rash, itching or hives on the skin.

**If you experience an allergic reaction, stop using the medicine and inform your doctor or pharmacist immediately.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**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 have allergies to any other medicines, foods, preservatives or dyes.**

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

- you have a problem with your body's immune system, which helps to fight off infections.
- you have a problem with your kidneys or 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 breastfeeding.**

Famciclovir generichealth should not be used during pregnancy unless necessary. Your doctor will discuss with you the potential risks of taking Famciclovir generichealth during pregnancy, and will also advise you if you should take Famciclovir generichealth while breastfeeding, based on the benefits and risks of your particular situation.

**If you have not told your doctor about any of the above, tell them before you start taking Famciclovir generichealth.**

*Taking other medicines*

**Tell your doctor or pharmacist 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 generichealth 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;
- medicines that can affect your immune system.

These medicines may be affected by Famciclovir generichealth or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

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## How to take Famciclovir generichealth

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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; or

- a dose of 750 mg (one 250 mg tablet + one 500 mg tablet), given twice per day.

Your doctor may have prescribed a different dose.

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 reduced kidney function, the dose may be reduced.

**Ask your pharmacist or doctor if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

*How to take it*

Swallow the tablets whole with a full glass of water.

They may be taken with or without food.

Do not change the dose yourself, without your doctor's advice, regardless of how well you may feel.

*When to take it*

**Take Famciclovir generichealth (for cold sores) tablets as soon as possible after the first symptoms (eg. tingling, itching or burning) or signs (eg. redness or swelling) of a cold sore appear.**

**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*

A single dose of Famciclovir generichealth may be all that is necessary for treating each episode of cold sores. The dose may be repeated if cold sores recur.

Each pack of Famciclovir generichealth 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 Famciclovir generichealth. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.**

You may need urgent medical attention.

Taking too much Famciclovir generichealth 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.

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## While you are taking Famciclovir generichealth

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### *Things you must do*

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

**Tell any other doctors, dentists and pharmacists who treat you that you are taking Famciclovir generichealth.**

**If you become pregnant while taking Famciclovir generichealth, tell your doctor.**

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

**Tell your pharmacist or doctor if your symptoms do not improve within a few days, or if they become worse.**

### *Things you must not do*

**Do not take Famciclovir generichealth to treat any other complaints unless your doctor tells you to.**

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

**Do not stop taking your tablets or change the dosage without checking with your doctor first.**

### *Things to be careful of*

**If you are pregnant or breastfeeding, 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 generichealth affects you.**

This medicine can cause dizziness, sleepiness or confusion.

### *Things that may help your condition*

**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 (eg. drinking glasses, eating utensils, or towels).
- Avoid direct skin-to-skin contact of the area with other people (eg. kissing) until the cold sore has healed.

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

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.

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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 Famciclovir generichealth.**

This medicine helps most people with cold sores, but it may have unwanted side effects in a few people. 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 the following lists of 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;
- tiredness, sleepiness
- nausea (feeling sick) or vomiting;
- diarrhoea;
- stomach pain;
- itching or an itchy rash (urticaria);
- abnormal liver function test results.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- a rash elsewhere on the 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;
- palpitations (signs of abnormal heart beat).

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

- swelling below the surface of the skin (eg. swelling around the face, eye, eyelid or throat);
- bruising or bleeding more easily than usual (may indicate that the number of platelets (a type of blood cell responsible for blood clotting) in your blood is reduced);
- widespread red, raised areas, blisters or sores 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);
- persistent pain in the upper right abdomen, yellowing of the skin and/or eyes, dark urine or pale bowel motions (signs of a possible liver problem);
- 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).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people

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## After taking FAMCICLOVIR GENERICHEALTH

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### *Storage*

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

If you take the 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 Famciclovir generichealth or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**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.**

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## Product description

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### *What it looks like*

Famciclovir generichealth 125 mg tablets are white, round film coated tablets with "FM" on one side and "125" on the other side.

Famciclovir generichealth 250 mg tablets are white, round film coated tablets, marked with "FM" on one side and "250" on the other side.

Famciclovir generichealth 500 mg tablets are white, oval, film coated tablets with "FM" on one side and "500" on the other side.

### *Ingredients*

#### **Active ingredient**

Famciclovir generichealth 125 contain 125 mg famciclovir per tablet.

Famciclovir generichealth 250 contain 250 mg famciclovir per tablet.

Famciclovir generichealth 500 contain 500 mg famciclovir per tablet.

#### **Other ingredients**

- microcrystalline cellulose;
- crospovidone;
- colloidal anhydrous silica;
- copovidone;
- sodium stearyl fumarate;
- Opadry White YS-22-18096.

### *Australian Registration Numbers*

Famciclovir generichealth 125 mg:  
AUST R 177010

Famciclovir generichealth 250 mg:  
AUST R 177012

Famciclovir generichealth 500 mg:  
AUST R 177014

### *Distributor*

Famciclovir generichealth is distributed in Australia by:

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