

# Famciclovir AN Tablets

*Famciclovir*

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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 AN.

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

All medicines have risks and benefits. Your pharmacist or doctor have weighed the risks of you taking Famciclovir AN against the benefits it can provide.

If you have any concerns about this medicine, ask your pharmacist or doctor.

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

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### What Famciclovir AN is used for

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#### Shingles

FAMCICLOVIR AN is an antiviral medicine that is used to treat shingles in adults and adolescents.

Shingles is a condition that is caused by a herpes virus called varicella zoster, the same virus that causes chicken pox. The virus can become active again in the body, even after many years, resulting in shingles. The main symptom is a rash that can cause pain, burning and blisters.

Although FAMCICLOVIR AN 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.

#### Genital herpes

FAMCICLOVIR AN is used to treat outbreaks of genital herpes and also to suppress (prevent) recurrent outbreaks of the condition.

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 blisters that may be painful.

People who have frequent episodes of genital herpes can also take FAMCICLOVIR AN to help prevent the attacks.

Taking FAMCICLOVIR AN does not prevent you from spreading the herpes virus to another person.

#### Cold sores

FAMCICLOVIR AN 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 lips, mouth, and nose as small red bumps that turn in to 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 sores 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 AN for cold sores 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.

FAMCICLOVIR AN for treating shingles & genital herpes this medicine is not recommended for use in children under 12 years of age.

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

**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.

FAMCICLOVIR AN is only available with a doctor's prescription. It is not addictive.

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## Before you take Famciclovir AN

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### *When you must not take it*

Do not take FAMCICLOVIR AN if you have an allergy to:

- famciclovir, the active ingredient
- penciclovir, a related antiviral medicine
- any of the other 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.

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

In that case, return it to your pharmacist.

### *Before you start to take it*

#### **Tell your doctor if:**

- 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, intend to become pregnant or if you are breastfeeding.**

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

#### **Tell your doctor if you are lactose intolerant.**

FAMCICLOVIR AN tablets contain lactose.

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

Your doctor will want to know if you are prone to allergies.

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

### *Taking other medicines*

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

Some medicines and FAMCICLOVIR AN 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 pharmacist and doctor have more information.

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## How to take Famciclovir AN

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### **Swallow the tablets whole with a full glass of water.**

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

### **Follow all directions given to you by your doctor and pharmacist carefully.**

These instructions may differ from the information contained in this leaflet.

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

### *How much to take*

#### **For Shingles**

The usual dose is one 250 mg tablet three times each day for seven days, beginning no later than 72 hours after the rash appears.

#### **For Cold Sores**

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

### **For Genital Herpes**

Follow your doctor's instructions on how many Famciclovir AN tablets to take.

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.

**Follow your doctor's instructions on how many Famciclovir AN tablets to take.**

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

They will tell you exactly how much to take.

Follow the instructions that they give you.

### *When to take it*

#### **For Shingles:**

**Unless your doctor tells you otherwise, take one tablet when you get up in the morning, one in the afternoon and one just before going to bed at night.**

#### **For Genital Herpes:**

### **1. 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 three ways to take Famciclovir AN to treat an outbreak of genital herpes and your doctor will tell you which regimen is best for you:

- Two 500 mg Famciclovir AN tablets twice daily for one day  
**or**

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

- One 125 mg Famciclovir AN tablet every 12 hours for 5 days  
**Take the second dose (and subsequent doses, if applicable) 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.

### **2. 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 Famciclovir AN prescription filled.**

**Take one 250 mg Famciclovir AN tablet twice each day. Continue to take one 250 mg FLOVIR 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.

#### **For Cold Sores:**

**Take Famciclovir AN for cold sores tablets as soon as possible after the first symptoms (e.g. tingling, itching or burning) or signs (e.g. 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.

**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 long to take it*

**Continue taking Famciclovir AN every day for as long as your doctor tells you.**

To help clear up your infection, you must keep taking this medicine, even if your symptoms begin to clear up after a few days.

**To prevent recurrent episodes of genital herpes, you must take the tablets each day, even if you have no symptoms.**

It is important to keep taking your medicine even if you feel well.

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

*If you forget to take it*

**Take a dose as soon as you remember. Take your next tablet at the usual time, and then go back to taking it as you would normally.**

**Do not take two doses within a time frame of less than one hour. In that case, skip the missed dose.**

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

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when 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 number 13 11 26), or go to Accident and Emergency) at your nearest hospital if you think that) you or anyone else may have taken too much Famciclovir AN. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.**

Taking too much Famciclovir AN 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 AN

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*Things you must do*

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

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 Famciclovir AN.**

**Tell any other doctor, dentist or pharmacist who treats you that you are taking Famciclovir AN.**

*Things you must not do*

**Do not give this medicine to anyone else even if their condition seems to be the same as yours.**

**Do not use it to treat any other complaints unless your doctor tells you to.**

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

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

*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 AN affects you.**

This medicine can cause dizziness, sleepiness or confusion.

**Practice "safer sex", including the use of condoms, when symptoms are present, even if you have started taking Famciclovir AN for genital herpes.**

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

*Things that may help your condition*

**For Shingles**

**Take the following precautions to avoid spreading the virus:**

- Keep the areas affected by the virus as clean and dry as possible.
- Wear loose-fitting clothing to avoid irritating the rash.

- Avoid touching or scratching the sore area as you may spread the virus on your fingers.

**For Genital Herpes**

**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.

**For Cold Sores**

**Take the following precautions to avoid spreading the virus:**

- 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.

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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 AN.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by these lists of possible side effects.**

You may not experience any of them.

**Tell your doctor if you notice any of the following side effects and they worry you:**

- headache
- dizziness
- nausea (feeling sick) or vomiting
- diarrhoea

- itching or an itchy rash (urticaria)
- abnormal liver function test results.

The above 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.

The above side effects may need medical attention.

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following side effects happen to you:**

- swelling below the surface of the skin (e.g. swelling around the face, eye, eyelid or throat)
- 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.

The above side effects are very rare.

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

Other side effects not listed here or not yet known may happen in some people.

**Ask your doctor or pharmacist to answer any questions you may have.**

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## After taking Famciclovir AN

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### Storage

**Keep your medicine in the original container until it is time to take it.**

**Store your Famciclovir AN tablets in a dry place where the temperature stays below 25°C. Do not store your medicines in the bathroom or near a sink.**

**Do not leave the tablets in the car or on window sills.**

Heat and dampness can destroy some medicines. Famciclovir AN tablets will keep best if they are stored cool and dry.

**Keep the medicine 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 you have left over.**

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## Product description

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### What Famciclovir AN looks like

Famciclovir AN is available as tablets containing 125, 250 & 500 mg of famciclovir.

Famciclovir AN 125 mg tablets are supplied in blister packs containing 10, 40 & 56 tablets.

Famciclovir AN 250 mg tablets are supplied in blister packs containing 20, 21, 30 & 56 tablets.

Famciclovir AN 500 mg tablets are supplied in blister packs containing 20, 30 & 56 tablets.

- **Famciclovir AN 125 mg (AUST R 195175)**

White to pale yellow colored, round film-coated, biconvex tablets with beveled edges, debossed with 'X' on one side and '48' on the other side.

- **Famciclovir AN 250 mg (AUST R 195181)**

White to pale yellow colored, round film-coated, biconvex tablets with beveled edges, debossed with 'X' on one side and '49' on the other side.

- **Famciclovir AN 500 mg (AUST R 195174)**

White to pale yellow colored, oval film-coated, biconvex tablets, debossed with 'X' on one side and '34' on the other side.

### Ingredients

#### Active ingredient:

Famciclovir

#### Inactive ingredients:

- sodium starch glycollate
- lactose anhydrous
- hydroxypropylcellulose
- magnesium stearate
- hypromellose
- macrogol 400
- titanium dioxide

### Name and Address of the Sponsor

**Amneal Pharma Australia Pty Ltd**  
12 River St,  
South Yarra, VIC 3141  
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### Date of Preparation

July 2014