

FAMCICLOVIR MYLAN

for shingles

famciclovir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FAMCICLOVIR MYLAN.

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

The information in this leaflet was last updated on the date listed on the final page.

Some more recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking FAMCICLOVIR MYLAN against the benefits it can provide.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What FAMCICLOVIR MYLAN is used for

FAMCICLOVIR MYLAN 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 MYLAN 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.

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

This medicine is not recommended for use in children under 12 years of age.

Before taking FAMCICLOVIR MYLAN

When you must not take it

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

- famciclovir, the active ingredient
- penciclovir, a related antiviral medicine
- any of the other ingredients of FAMCICLOVIR MYLAN listed at the end of this leaflet (see 'Product Description')

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 FAMCICLOVIR MYLAN 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
- your kidneys
- your 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 breast feeding.

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

Tell your 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 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 MYLAN 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.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take FAMCICLOVIR MYLAN

Swallow the tablets whole with a full glass of water.

They may be taken with or without food.

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

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.

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 MYLAN 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

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.

Try to take the tablets at about the same time each day.

How long to take it

Continue taking FAMCICLOVIR MYLAN every day for the full course of treatment.

To help clear up your infection, you must take the full course of treatment, even if your symptoms begin to clear up after a few days.

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 timeframe 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 Australian Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much FAMCICLOVIR MYLAN. Show them the pack of FAMCICLOVIR MYLAN. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

Taking too much FAMCICLOVIR MYLAN 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 FAMCICLOVIR MYLAN

Things you must do

If you become pregnant while taking FAMCICLOVIR MYLAN, 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 MYLAN.

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

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 this medicine 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 breast-feeding, 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 MYLAN affects you.

This medicine can cause dizziness, sleepiness or confusion in some people.

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.
- 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FAMCICLOVIR MYLAN.

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 the below lists 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
- abdominal pain
- 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 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
- yellowing of the skin or eyes (signs of jaundice)
- palpitations (signs of abnormal heart beat)

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:

- 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)

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.

After taking FAMCICLOVIR MYLAN

Storage

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

Store it in a dry place where the temperature stays below 25°C.

Do not store FAMCICLOVIR MYLAN or any other 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 MYLAN 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 meters 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 you have left over.

Product description

What it looks like

FAMCICLOVIR MYLAN tablets are available in the following strengths for the treatment of shingles:

250mg - white, oval shape, biconvex, film coated, debossed with "FAM 250" on one side and "G" on other side in blister packs of 20, 21 and 56.

500mg - white, oval shape, biconvex, film coated, debossed with "FAM 500" on one side and "G" on other side in blister packs of 56.

Ingredients

The active ingredient in FAMCICLOVIR MYLAN is famciclovir.

Each FAMCICLOVIR MYLAN 250 tablet contains 250 mg of famciclovir.

Each FAMCICLOVIR MYLAN 500 tablet contains 500 mg of famciclovir.

The tablets also contain the following inactive ingredients:

- hypolose
- sodium starch glycollate
- microcrystalline cellulose
- silicon dioxide
- magnesium stearate
- Opadry II white OY-L-28900

This product contains lactose.

Supplier

FAMCICLOVIR MYLAN is supplied in Australia by:

Alphapharm Pty Ltd
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian registration numbers:

FAMCICLOVIR MYLAN 250 mg
- AUST R 157788

FAMCICLOVIR MYLAN 500 mg
- AUST R 157787

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