

PART III: CONSUMER INFORMATION**FAMVIR**[®] (famciclovir)

This leaflet is part III of a three-part "Product Monograph" published when **FAMVIR** (famciclovir) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about **FAMVIR** (famciclovir). Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATIONWhat the medication is used for:

FAMVIR is an antiviral medicine that is used to treat a number of viral infections described below. It stops the infecting virus from reproducing. Since the virus reproduces very early in the infection, the best results in the treatment are obtained if FAMVIR is started as soon as possible after the first symptoms appear.

Herpes zoster:

FAMVIR is used to treat herpes zoster (Shingles). Herpes zoster is an infection caused by a virus called varicella zoster (the same virus that causes chickenpox). FAMVIR stops the virus from spreading in the body so that healing can occur faster if taken within 72 hours of the first lesion, and reduces the blistering, pain, and rash.

Genital herpes:

FAMVIR is used to treat or prevent recurrence of the viral infections which cause genital herpes. Genital herpes is a viral infection caused by herpes simplex virus type 1 or 2, and is normally spread by sexual contact. It causes blisters and burning or itching around the genitals, which may be painful.

FAMVIR does not stop you from spreading herpes to another person. It is important to understand that the drug must be taken as early as possible as soon as you know that an attack is starting. Although FAMVIR does not cure the viral infection, it helps to shorten the duration of symptoms and allows the infections to heal faster.

What it does:

FAMVIR helps stop the virus from multiplying and shortens the time the virus is released and spread, which helps healing.

When it should not be used:Do not use FAMVIR if:

- you have a known hypersensitivity to FAMVIR (famciclovir), to penciclovir (a compound formed from famciclovir by your body and an ingredient of some other medicines) (See: What the important nonmedicinal ingredients are) or to any ingredient of the formulation or packaging

What the medicinal ingredient is:

Each FAMVIR tablet contains 125mg, 250 mg or 500 mg of famciclovir

What the important nonmedicinal ingredients are:

The tablets also contain some inactive ingredients to make up the bulk of each tablet: hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose, magnesium stearate, polyethylene glycols, sodium starch glycolate and titanium dioxide.

The tablets are gluten-free.

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

What Dosage Form it comes in:**HERPES ZOSTER**

FAMVIR tablets are white, oval, film-coated and biconvex tablet, marked FV on one side and 500 on the other side. Check with your doctor or pharmacist if your tablets look different from this.

GENITAL HERPES

125 mg tablet - round, white, film-coated and biconvex tablet with bevelled edges debossed and marked with FV on one side and 125 on the other side.

250 mg tablet - round, white, film-coated and biconvex tablet with bevelled edges debossed and marked with FV on one side and 250 on the other side.

Check with your doctor or pharmacist if the identifying markings or colour of your tablets are not the same as these.

WARNINGS AND PRECAUTIONS

Before you take FAMVIR, **talk to your doctor if:**

- You have an intolerance to some sugars, galactose intolerance, a severe lactase deficiency or glucose-galactose malabsorption, then you should not take FAMVIR, as this product contains lactose
- You have an allergy (including itching) or other unwanted (side) effects when previously taking FAMVIR
- You are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed
- You have a past history or current kidney disease
- You have severe liver problems
- You have other medical conditions

It is important to tell your doctor, dentist or pharmacist if you are taking other medication, as combining drugs can sometimes result in a change from the expected drug effects, or cause harmful effects.

INTERACTIONS WITH THIS MEDICATION

Always tell your doctor about other medical conditions you have or any medicines you are taking. This means medicines you bought for yourself as well as medicines on prescription. Your doctor or pharmacist will know if it is safe to take FAMVIR as well.

It is particularly important that you tell your doctor or pharmacist if you are taking any of the following medicines:

- Probenecid (used to treat high blood levels of uric acid associated with gout and to increase blood levels of penicillin-type antibiotics), or any other medicine that can affect your kidneys.
- Raloxifene (used to prevent and treat osteoporosis).

You can take FAMVIR with or without food.

PROPER USE OF THIS MEDICATION

How do I use FAMVIR?

You should take FAMVIR only as directed by your doctor. Do not take more of it, do not take it more often and do not take it for a longer period of time than your doctor ordered.

Be sure to take FAMVIR regularly as prescribed. Try to take your tablets at the same time each day. You should continue to take your medicine even if you do not feel better, as it may take a few days for your medicine to work.

If your kidneys are not working very well, your doctor will probably have you take this medicine less often, check with your doctor if you have kidney problems.

FAMVIR will work whether or not you take it with food. You should swallow the tablets whole, with water. Do not chew them.

How long do I use FAMVIR?

The usual adult dose is one FAMVIR tablet three times a day for shingles. Follow your doctor's instructions about how and when to take your tablets. Start taking them as soon as you can for the best effect.

Most people take one tablet when they get up in the morning, one in the middle of the afternoon and one before going to bed at night.

Finish all the tablets you have been given even if you start to feel better. The treatment lasts for seven days.

Treating an outbreak of recurrent genital herpes:

If you have had herpes infections of the genitals before (called recurrent genital herpes), your doctor may decide to treat the outbreak. You will likely be told to take 125 mg twice a day for 5 days or if you are HIV-positive, 500 mg t twice a day for 7 days. Most people with recurrent genital herpes take one tablet when waking, and one tablet just before going to bed. FAMVIR should be taken as soon as possible after the early symptoms (pain, burning, blisters, itching, tingling) begin to appear.

Preventing outbreaks of recurrent genital herpes:

If you have had herpes infections of the genitals before (called recurrent genital herpes), then your doctor may decide to prevent future outbreaks. Your doctor will likely tell you that you should continually take 250 mg twice a day. Most people with recurrent genital herpes take one tablet when waking, and one tablet just before going to bed

Missed Dose:

If you miss taking a FAMVIR tablet, don't worry. Take it as soon as you remember. Take your next tablet at the normal time. However, do not take two doses within a time interval of less than 1 hour, in that case you should skip the missed dose. Carry on as normal until you have finished all the tablets. It is important that you finish all the tablets you have been given, unless your doctor tells you to stop taking them. Do not double-dose.

Overdose

In case of drug overdose, contact a healthcare practitioner (doctor), hospital emergency department or regional poison control centre, even if there are no symptoms. Bring your pack of tablets with you.

Taking too much of any type of medicine is risky.

Taking too much FAMVIR 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.

Important: Your doctor may give you different instructions better suited to your specific needs. If you need more information on how to take FAMVIR properly, double-check with your doctor or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Any medicine can cause side effects. With FAMVIR, some people may feel sick or get a headache, or experience confusion or dizziness. Other side effects include drowsiness (usually in older people), hallucinations (seeing or hearing things that are not really there), vomiting, yellowing of the skin and/or eyes, abnormal liver function test results, palpitations (signs of abnormal heart beat), skin rash, itching or blistering, diarrhea, tiredness and abdominal pain.

If you get these or any other problems while you are taking FAMVIR, tell your doctor or pharmacist.

Some effects could be serious:

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Signs of serious skin reaction: pruritus (e.g. itching, erythema multiforme, Steven Johnson syndrome, toxic epidermal necrolysis), severe blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals, angioedema (e.g. swelling of tissues such as face, mouth, eyes, throat, skin, hands and feet)			√
Serious allergic reaction with symptoms such as difficulty of breathing or swallowing, rash, itching, hives, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, hypotension, with or without generalized itching, skin reddening, facial/throat swelling, blue discoloration of the lips, tongue or skin			√
Seizures or fits			√
Signs of decrease in the number of blood platelets: Unexplained bruising, reddish or purplish patches on the skin or nosebleeds			√
Purple skin patches, itching, burning (signs of inflamed blood vessels)			√

Tell your doctor immediately or go to the emergency department at your nearest hospital if any of the following side effects occur:

If you experience anything unusual, while you are receiving treatment with FAMVIR, you should report it to your physician. A more complete listing of side effects reported to date, is contained in the Product Monograph supplied to your physician.

Driving and using machines

FAMVIR can cause dizziness, drowsiness or confusion in very rare cases. If you have any of these symptoms while taking FAMVIR, you should take special care when driving or using machines.

This is not a complete list of side effects. If you have any unexpected effects after receiving FAMVIR, contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

- Keep FAMVIR in the bottle or package provided by the pharmacist.
- Store at room temperature (15-25°C).
- FAMVIR must be kept out of the reach and sight of children.
- Don't take your tablets if they are past their expiry date.
- Never let anyone else take your tablets, even if they have shingles as well.
- Finish all the tablets in the way you have been told.

More information about shingles.

What is shingles like?

- At first you might feel burning and tingly where the rash is coming. You may get pain for a few days before you see the rash.
- Most people with shingles get a blistering rash down one side of their body or face. This can be painful.
- New blisters will keep coming for about five days. After this, the blisters will dry to form scabs.
- You may feel weak and tired.
- The rash usually lasts for two to three weeks. Afterwards, people can have pain where the rash was, sometimes for

several months.

Who gets shingles?

People of any age can get shingles. Most people who get it are middle-aged or older.

You can only get shingles if you have had chickenpox.

50% of people have had shingles by the age of 85.

What causes shingles?

- Shingles is caused by the same virus that causes chickenpox.
- After you have had chickenpox, the inactive virus stays in your body.
- Many years later the virus can start to work again. This may happen when you are run down or tired.

How is shingles treated?

Tablets for shingles, such as FAMVIR, stop the virus spreading. They cut down blistering and pain of the rash. They help you get better quicker if you take them early in your illness.

What else can you do?

- To stop the rash itching, have cool baths - do not use perfumed soap or bath oils. You can also put ice cubes wrapped in a washcloth on the rash, or cover it with a soothing lotion like calamine for the first three days.
- Keep the rash clean and dry.
- Wear loose clothes.
- Do not scratch the rash. It could get infected and take longer to get better.
- Rest when you feel tired.
- Try to eat well and drink plenty of fluids.
- Tell your doctor right away if you start to have trouble with your eyes. Shingles can sometimes cause eye problems which can be treated.

Can other people catch your shingles?

Shingles is caused by the same virus that causes chickenpox. Most doctors agree that people do not catch shingles from each other. When you have shingles, you can give chickenpox to someone who has never had chickenpox before - but this is unlikely.

What is Genital Herpes?

Genital Herpes is a viral infection of the genital (sex organ) area which is caused by the Herpes Simplex Virus. You might suspect the onset of this infection if you see the appearance of sores or blisters or feel a burning sensation in your genital region.

Type II herpes simplex virus is the main cause of the sores and blisters that develop in your genital area, but you can also catch genital herpes from herpes simplex Type I which can be the cause of cold sores which occur around your mouth.

Genital Herpes can occur as a first-episode attack or recurrent infection. Unlike many other viruses, recovery from the first attack does not leave you with lifelong protection from re-infection. The virus is able to remain hidden in the nerves after the initial infection and stays there until reactivated.

Since your body still carries the highly infectious virus, you can easily infect someone else, even if you feel fine and you have no symptoms of genital herpes. This explains why genital herpes is one of the most common sexually transmitted diseases (STD).

The risk is higher for people who are more sexually active and have more sexual partners. It is therefore recommended that you avoid sexual activity if you or your partner have any symptoms of herpes, even if you have started your treatment.

If you are taking FAMVIR to treat or to suppress genital herpes, or you have had genital herpes in the past, you should still practise “safer sex”, including the use of condoms. This is important to prevent you passing the infection on to others.

While taking this medication:

- remember that your infection is contagious.
- tell any other doctor, pharmacist or dentist you see, that you are taking FAMVIR.
- contact your doctor if you develop any unusual discomfort.
- you should not take FAMVIR when pregnant or breast-feeding unless your doctor tells you to.
- do not give FAMVIR to others because it may not be suitable for them.
- store your tablets in a dry place at room temperature in the original container provided by the pharmacy.
- keep this medication out of reach of children.
- read your prescription label carefully; consult your doctor or pharmacist if you have any questions or require further information.

MORE INFORMATION

This document plus the product monograph, prepared for health professionals can be found at: <http://www.novartis.ca> or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc. at: 1-800-363-8883.

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