

PART III: CONSUMER INFORMATION**PRO-VALACYCLOVIR****Valacyclovir Hydrochloride Caplets, House Standard**

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

ABOUT THIS MEDICATION**What the medication is used for and what it does:**

PRO-VALACYCLOVIR is an antiviral medicine. It is used to lower the ability of herpes viruses to multiply in your body. PRO-VALACYCLOVIR does not cure herpes infections.

Treatment of shingles (herpes zoster)

PRO-VALACYCLOVIR is used to treat shingles (herpes zoster) infections. Shingles is caused by the varicella-zoster virus which damages nerves and skin. PRO-VALACYCLOVIR helps stop the virus from multiplying, therefore reducing the damage.

Treatment or suppression of genital herpes

PRO-VALACYCLOVIR 500 mg caplets are used to treat genital herpes which is caused by the herpes simplex virus (HSV).

HSV causes small, fluid-filled blisters in the genital area which break down into ulcers/sores which may be itchy or painful. The blisters contain many infectious HSV particles. PRO-VALACYCLOVIR helps stop HSV from multiplying which helps to shorten the time that the virus is shed from the skin and mucous membranes. It reduces the number of painful blisters and also helps them to heal more quickly.

If you start taking PRO-VALACYCLOVIR as soon as you feel an infection starting, you may actually prevent the blisters from developing. This type of treatment is called episodic therapy.

When taken every day, PRO-VALACYCLOVIR can also be used to prevent the HSV infection from coming back. This type of treatment is called suppressive therapy.

Reduction of transmission of genital herpes

PRO-VALACYCLOVIR taken every day and in combination with safer sex practices can reduce the risk of transmitting genital herpes to your sexual partner. This type of treatment is for reduction of transmission.

Sometimes the herpes simplex virus (HSV) may be released to the skin at levels too low to cause blisters – this is called viral shedding.

With no visible symptoms, viral shedding can occur anywhere in the "boxer short" area (from just below the waistline down to the upper thighs, including the buttocks). This means it is possible to transmit genital herpes through skin-to-skin contact with the "boxer short" area, even in the absence of blisters.

PRO-VALACYCLOVIR helps stop HSV from multiplying which helps to shorten the time that the virus is shed from the skin and mucous membranes.

Treatment of cold sores (herpes labialis)

PRO-VALACYCLOVIR is used to treat cold sores (herpes labialis) which are caused by the herpes simplex virus (HSV).

Cold sores are small, fluid-filled blisters that you get in or around your mouth. The blisters then break down into ulcers/sores which may be itchy or painful. The blisters contain many infectious HSV particles. Cold sores may be spread by kissing or other physical contact with the infected area of the skin.

PRO-VALACYCLOVIR helps stop HSV from multiplying which helps to shorten the time that the virus is released from the skin and mucous membranes. It reduces the number of painful blisters and also helps them to heal more quickly.

When it should not be used:

You should not use PRO-VALACYCLOVIR if you are allergic to or react badly to valacyclovir or acyclovir or any other components of the formulation of PRO-VALACYCLOVIR (see "What the non-medicinal ingredients are" section). Tell your doctor if you have ever had an allergic reaction to any of these ingredients.

What the medicinal ingredient is:

Valacyclovir hydrochloride

What the non-medicinal ingredients are:

Crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate, titanium dioxide. In addition to the above listed ingredients, PRO-VALACYCLOVIR 500 mg caplets also contain: FD&C blue #2 aluminum lake.

What dosage forms it comes in:

Caplets: 500 mg

WARNINGS AND PRECAUTIONS

Before using PRO-VALACYCLOVIR, tell your doctor if:

- You have kidney problems or you are 65 years of age or older. Your doctor may give you a lower dose of PRO-VALACYCLOVIR.
- You are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed. Your doctor may decide not to prescribe PRO-VALACYCLOVIR depending on your condition.

PROPER USE OF THIS MEDICATION

You must take PRO-VALACYCLOVIR as prescribed by your doctor. If you are not sure how many caplets to take, or how often to take them, consult your doctor or pharmacist.

You should not increase or decrease the prescribed dose or frequency unless advised by your doctor.

For shingles, genital herpes (initial and recurrent episodes) and cold sores, for best effect, start taking your PRO-VALACYCLOVIR caplets as soon as possible after your symptoms start.

Swallow the caplets with some water. It is important to drink enough water to prevent dehydration when you are taking PRO-VALACYCLOVIR. It does not matter if you take them with or without food.

Usual adult dose:**Shingles (herpes zoster):**

For the treatment of shingles, the usual dose of PRO-VALACYCLOVIR is 1000 mg orally three times a day for 7 days. Most people take one dose when they get up in the morning, one dose mid-afternoon and one dose before they go to bed at night. Spreading the doses evenly throughout the day will help to shorten your rash and discomfort.

Genital herpes:

- **Episodic Therapy**

For the treatment of an initial (first) episode of genital herpes, the usual dose of PRO-VALACYCLOVIR is 1000 mg orally two times a day. The treatment is usually taken for 10 days.

For the treatment of recurrent episodes of genital herpes, the usual dose of PRO-VALACYCLOVIR is 500 mg orally two times a day for 3 days. Take one dose in the morning and one in the evening. Take your PRO-VALACYCLOVIR caplets as soon as you get the warning signs of an outbreak (i.e., itching, burning, swelling or pain in your genital area). This may actually prevent the blisters from developing.

- **Suppressive Therapy**

For the suppression of genital herpes, the usual dose of PRO-VALACYCLOVIR is 1000 mg orally once a day. If you have a history of 9 or fewer recurrences per year, your doctor may prescribe an alternative dose of 500 mg orally once a day. You should continue to take this medicine every day and follow your doctor's instruction.

For the suppression of genital herpes in HIV-infected patients with CD4 cell count > 100 cells/mm³, the recommended dosage of PRO-VALACYCLOVIR is 500 mg orally two times a day.

- **Reduction of Transmission**

For the reduction of transmission of genital herpes in patients with a history of 9 or fewer recurrences per year, the usual dose of PRO-VALACYCLOVIR is 500 mg once a day for the

partner with the infection. Note that the efficacy of PRO-VALACYCLOVIR for reducing transmission of genital herpes has not been established in individuals with multiple partners, non-heterosexual couples, and couples not counselled to use safer sex practices.

Cold sores (herpes labialis):

For the treatment of cold sores, the usual dose of PRO-VALACYCLOVIR is 2000 mg orally two times a day for 1 day (24-hour period). The second dose should be taken around 12 hours after the first dose, but not less than 6 hours after the first dose. Do not exceed 1 day of treatment. Take your PRO-VALACYCLOVIR caplets as soon as you get the warning signs of an outbreak (i.e., tingling, itching or burning).

Overdose:

If you think you have taken too much PRO-VALACYCLOVIR, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you forget to take a dose, take it as soon as you remember. Then continue with the next dose at the proper time interval. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

PRO-VALACYCLOVIR does not often have side effects. Some people may feel sick (nausea, vomiting, diarrhea and stomach pain) or have a mild headache. These side effects are generally mild and do not usually cause patients to stop taking PRO-VALACYCLOVIR.

If you experience any of the following side effects, contact your doctor as soon as possible:

- Skin rash (which may also occur after exposure to UV light e.g., sunbathing or using a sun bed)
- Pain in the side (between ribs and hip) or kidney area of your back

Tell your pharmacist or doctor if you notice any other side effects from your medicine which are not mentioned here. A complete listing of adverse events that have been reported is contained in the Product Monograph supplied to your doctor and pharmacist.

If you feel worse, or if you have taken all the caplets and do not feel better, tell your doctor as soon as possible.

PRO-VALACYCLOVIR can alter liver function tests. This is a blood test that lets your doctor know how well your liver is working. If there are any significant changes due to PRO-VALACYCLOVIR, your doctor will decide on the appropriate course of action.

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

Frequency	Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Unknown	Blood clotting disorder with symptoms such as bruising, bleeding (from gums), fever, fatigue, headache, confusion, numbness, paralysis.		✓	✓
Unknown	Destruction of red blood cells creating anemia with symptoms such as bloody diarrhea, abdominal pain, fatigue, nausea, vomiting, confusion, swelling of hands and feet.		✓	✓
Rare	Central nervous system effects with symptoms such as dizziness, confusion, agitation, hallucinations, particularly in those with kidney problems.		✓	✓

This is not a complete list of side effects. For any unexpected effects while taking PRO-VALACYCLOVIR, contact your doctor or pharmacist.

HOW TO STORE IT

Store PRO-VALACYCLOVIR caplets between 15°C and 30°C. Keep the caplets away from direct heat and sunlight.

Keep your PRO-VALACYCLOVIR caplets in a safe place where children cannot reach or see them.

Do not take any caplets after the expiry date.

MORE FACTS ABOUT GENITAL HERPES

What is genital herpes?

Genital herpes, one of the most common sexually transmitted infections, is caused by the herpes simplex virus (HSV), the same family of viruses that causes cold sores or fever blisters. You can get genital herpes by having sex (skin-to-skin contact including genital, anal, and/or oral contact) with a person who has herpes. Genital herpes does not always occur on the genitals. It may occur anywhere in the “boxer short” area for both men and women (from just below the waistline down to the upper thighs, including the buttocks).

Are there any warning signs of a genital herpes outbreak?

Many people have genital herpes and don’t even know it. Here are some of the signs and symptoms that may signal a genital herpes outbreak:

- Swelling, pain, itching, or burning in your genital area
- Redness, tiny blisters, or sores
- Burning feeling when urinating
- Genital discharge
- Muscle aches, tiredness, or headaches

There is no cure for genital herpes. Once the herpes virus enters the body, it is present throughout life, alternating between active (outbreak or viral shedding) and inactive states.

Why outbreaks recur is still unknown. Some people know what triggers their genital herpes infection to become active again, while others do not. Some factors that may trigger the virus into activity are lack of sleep, poor diet, stress and menstruation.

Try to notice if these factors cause your infection to return, as you may be able to avoid some of them. Taking your PRO-VALACYCLOVIR caplets as soon as you get the warning signs may actually prevent the blisters from developing.

How did I get genital herpes?

Genital herpes is passed from one person to another through direct intimate contact. It can be transmitted sexually, by direct contact with blisters or sores, which contain many infectious virus particles. It can also be transmitted through skin-to-skin contact with the “boxer short” area even in the absence of blisters, because the virus can be active on the skin without causing symptoms.

Small cuts or scratches in the skin or mucous membranes allow the virus to gain entry into the body more easily. These may not be visible to the naked eye.

Genital herpes cannot be transmitted via handshakes, toilet seats, swimming pools, saunas, hot tubs or blood transfusions.

Can I transmit genital herpes to other people?

Yes. It is important to remember that the herpes virus can be shed from your skin even when you do not have any signs or symptoms. For this reason, you can transmit the infection to your partner through skin-to-skin contact with the “boxer short” area even in the absence of blisters or sores. In 70% of cases, genital herpes is transmitted when there are no signs or symptoms.

How can I reduce the risk of transmitting genital herpes to other parts of my body or to other people?

You do not have to stop having sex if you have genital herpes. However, here are some things you should consider in order to reduce the risk of transmission:

- Avoid sexual contact with your partner when you have an outbreak of genital herpes, or think you are about to have an outbreak.
- Use latex or polyurethane condoms each time you engage in sexual intercourse even when there are no signs of infection.
- Avoid touching or breaking the blisters or sores and do not pick the scabs when they form.
- Always wash your hands if you touch the blisters, sores, or scabs.
- If you or your partner has an active genital herpes infection (or even the warning signs), avoid contact with the blisters or sores.
- When combined with safer sex practices, including condoms, daily therapy with PRO-VALACYCLOVIR reduces the risk of transmitting genital herpes to your partner.
- Talk to your doctor about the best options for you and your partner.

What about genital herpes and pregnancy?

There is no evidence that having genital herpes affects fertility in men or women and is unlikely to complicate a pregnancy. The measures described above will also help to reduce the risk of transmitting genital herpes during pregnancy. Special precautions should be taken during pregnancy to avoid transmission to a pregnant woman if her partner has genital herpes. Care is needed at the time of birth if there is an active infection present. Discuss the options available with your doctor.

How can you treat (or manage) your genital herpes?

There are 3 different ways to manage genital herpes with PRO-VALACYCLOVIR :

Episodic therapy: Episodic therapy involves taking PRO-VALACYCLOVIR for a specific number of days during an outbreak to help speed the healing of blisters, shorten the duration of pain and discomfort, and reduce viral shedding (the stage during which herpes virus is secreted). If treatment with PRO-VALACYCLOVIR is started before the appearance of any sores, it may prevent sores from occurring.

Suppressive therapy: PRO-VALACYCLOVIR can also be used to help prevent outbreaks of genital herpes. PRO-VALACYCLOVIR will not cure genital herpes, but, if taken

every day, it may prevent genital herpes outbreaks before they start. Suppressive therapy can significantly reduce the frequency of outbreaks, although results will vary from person to person. Many people can remain recurrence-free while on suppressive treatment.

Reduction of Transmission: When taken every day, PRO-VALACYCLOVIR in combination with safer sex practices can also reduce the risk of transmitting genital herpes to your sexual partner.

Talk to your doctor if you have questions about treatment with PRO-VALACYCLOVIR and if you are concerned about transmitting genital herpes to your partner. Your physician will help you decide which type of therapy is best for you.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
 - By calling 1-866-234-2345 (toll-free);
 - By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9
- Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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