

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **MYLAN-VALACYCLOVIR**

Valacyclovir Tablets

Read this carefully before you start taking **Mylan-Valacyclovir** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Mylan-Valacyclovir**.

What is Mylan-Valacyclovir used for?

Mylan-Valacyclovir is an antiviral medicine. It is used for the following:

Treatment of shingles (herpes zoster)

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

Treatment or suppression of genital herpes

Mylan-Valacyclovir is 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. Mylan-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 Mylan-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.

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.

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

Reduction of transmission of genital herpes

Mylan-Valacyclovir taken every day and in combination with safer sex practices, including the use of condoms, 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.

Treatment of cold sores (herpes labialis)

Mylan-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.

Mylan-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.

How does Mylan-Valacyclovir work?

Mylan-Valacyclovir works by lowering the ability of herpes viruses to multiply in your body. Mylan-Valacyclovir does not cure herpes infections.

What are the ingredients in Mylan-Valacyclovir?

Medicinal ingredients: Mylan-Valacyclovir tablets contain valacyclovir 500 mg or 1000 mg as valacyclovir hydrochloride.

Non-medicinal ingredients:

Mylan-Valacyclovir 500 mg tablets contain FD&C blue #2 / indigo carmine aluminum lake, hydroxypropyl methylcellulose, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, n-butyl alcohol, polyethylene glycol, propylene glycol, shellac glaze, and titanium dioxide.

Mylan-Valacyclovir 1000 mg tablets contain ammonium hydroxide, hydroxypropyl methylcellulose, iron oxide black, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, n-butyl alcohol, polyethylene glycol, propylene glycol, shellac glaze, and titanium dioxide.

Mylan-Valacyclovir comes in the following dosage forms:

Tablets, 500 mg and 1000 mg.

Do not use Mylan-Valacyclovir if:

You should not use Mylan-Valacyclovir if you are allergic to or react badly to valacyclovir or acyclovir or any other components of the formulation of Mylan-Valacyclovir (see “**What are the ingredients in Mylan-Valacyclovir?**” section). Tell your healthcare professional if you have ever had an allergic reaction to any of these ingredients.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Mylan-Valacyclovir. Talk about any health conditions or problems you may have, including if you:

- have kidney problems or you are 65 years of age or older. Your healthcare professional may give you a lower dose of Mylan-Valacyclovir.
- have liver disease.
- have a weak immune system.
- are pregnant or planning to become pregnant. Your healthcare professional will consider the benefit to you and the risk to your baby of taking Mylan-Valacyclovir while you’re pregnant.

- are breastfeeding or planning to breastfeed. You must check with your healthcare professional before taking Mylan-Valacyclovir since the ingredients in this medication can pass into the breast milk.

Other warnings you should know about:

Driving and using machines

Be careful and see how you feel before driving or operating machinery while taking Mylan-Valacyclovir.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take Mylan-Valacyclovir:

You must take Mylan-Valacyclovir as prescribed by your healthcare professional. If you are not sure how many tablets to take, or how often to take them, ask your healthcare professional.

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

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

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

Usual dose:

Shingles (herpes zoster):

For the treatment of shingles, the usual dose of Mylan-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**

Episodic therapy involves taking Mylan-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 Mylan-Valacyclovir is started before the appearance of any sores, it may prevent sores from occurring.

For the treatment of an initial (first) episode of genital herpes, the usual dose of Mylan-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 Mylan-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 Mylan-Valacyclovir tablets 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 in Patients Infected with HIV**

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

- **Reduction of Transmission**

When taken every day, Mylan-Valacyclovir in combination with safer sex practices can also reduce the risk of transmitting genital herpes to your sexual partner.

For the reduction of transmission of genital herpes in patients with a history of 9 or fewer recurrences per year, the usual dose of Mylan-Valacyclovir is 500 mg once a day for the partner with the infection. Note that the efficacy of Mylan-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 Mylan-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 Mylan-Valacyclovir tablets as soon as you get the warning signs of an outbreak (i.e., tingling, itching or burning).

Overdose:

If you think you, or a person you are caring for, have taken too much Mylan-Valacyclovir, contact a 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 and then continue with the next dose at the proper time interval. However, if it is nearly time for your next dose, skip the missed dose. Do not double dose.

What are possible side effects from using Mylan-Valacyclovir?

These are not all the possible side effects you may have when taking Mylan-Valacyclovir. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Nausea
- Vomiting
- Diarrhea
- Stomach pain
- Mild headache

These side effects are generally mild and do not usually cause patients to stop taking Mylan-Valacyclovir.

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

Mylan-Valacyclovir can also:

- decrease the number of white blood cells (cells that help you fight infections). This is mainly reported in patients with low resistance to infection.
- alter liver function tests. This is a blood test that lets your healthcare professional know how well your liver is working.

If there are any significant changes due to Mylan-Valacyclovir, your healthcare professional will decide on the appropriate course of action.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Psychiatric and central nervous system effects: dizziness, confusion, agitation, hallucinations (seeing and hearing things that are not really there), decreased consciousness. This is usually seen in people with kidney problems, or in elderly.			✓
UNKNOWN			
Blood clotting disorder: bruising, bleeding (from gums), fever, fatigue, headache, confusion, numbness, paralysis			✓
Destruction of red blood cells creating anemia: bloody diarrhea, abdominal pain, fatigue, nausea, vomiting, confusion, swelling of hands and feet.			✓
Drug reaction with eosinophilia and systemic symptoms (DRESS) (serious skin reaction that may affect one or more organs): fever, severe rash, peeling skin, swelling of the face, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinating less often, less urine.			✓
Kidney pain (pain in the side between ribs and hip or kidney area of your back), kidney failure			✓
Psychiatric and central nervous system symptoms: tremor, loss of coordinated body movements, difficulty in speaking, severe mental health problems in which the person loses contact with reality and is unable to think and judge clearly, fits (seizures), altered brain function, loss of consciousness. This is usually seen in people with kidney problems, or in the			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
elderly.			
Rashes including increased sensitivity of the skin to sunlight		✓	
Severe allergic reactions: raised and itchy rashes; swelling, sometimes of the face or mouth, causing difficulty in breathing; collapse or loss of consciousness.			✓
Shortness of breath			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

Store Mylan-Valacyclovir tablets between 15° and 30°C. Protect from light.

Keep out of reach and sight of children.

Do not take any tablets 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 Mylan-Valacyclovir 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 Mylan-Valacyclovir reduces the risk of transmitting genital herpes to your partner.
- Talk to your healthcare professional 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 healthcare professional.

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

There are 2 different ways to manage genital herpes with Mylan-Valacyclovir.

Talk to your healthcare professional if you have questions about treatment with Mylan-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.

If you want more information about Mylan-Valacyclovir:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.mylan.ca or by calling 1-844-596-9526.

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