

PART III: CONSUMER INFORMATION

** Mylan-Acyclovir
Acyclovir tablets**

This leaflet is Part III of a three-part “Product Monograph” published when MYLAN-ACYCLOVIR (acyclovir) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MYLAN-ACYCLOVIR. 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:

MYLAN-ACYCLOVIR (acyclovir) is an antiviral medicine.

Treatment of shingles (herpes zoster)

MYLAN-ACYCLOVIR is used to treat shingles (herpes zoster) infections. Shingles is caused by the varicella-zoster virus. The virus multiplies in and eventually destroys affected skin cells. MYLAN-ACYCLOVIR stops the virus from multiplying and therefore from spreading to neighbouring healthy cells. It cannot replace a cell which has been damaged by the multiplying virus, but it will facilitate the process of healing.

Treatment of chickenpox (varicella)

MYLAN-ACYCLOVIR is used to treat chickenpox (varicella) which is caused by the varicella-zoster virus and is highly contagious. The disease is most contagious shortly before the rash appears, through the early stages of the rash and until all the blisters have dried. A patient is not contagious once all the blisters have become scabs.

Treatment and suppression of genital herpes

MYLAN-ACYCLOVIR is used to treat initial episodes of genital herpes.

Genital herpes is a sexually transmitted infection 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 fluid in these blisters contains the virus which causes the disease. It is a feature of all herpes viruses that once in the body, they stay there throughout life alternating between active (outbreak) and inactive states.

When taken on a daily basis, MYLAN-ACYCLOVIR can also be used to prevent the HSV infection from coming back. This type of treatment is called suppressive therapy.

When it should not be used:

You should not use MYLAN-ACYCLOVIR if you are allergic to or react badly to acyclovir or valacyclovir or any other components of the formulation of MYLAN-ACYCLOVIR (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:

MYLAN-ACYCLOVIR Tablets contain the active ingredient acyclovir.

What the non-medicinal ingredients are:

MYLAN-ACYCLOVIR 200 mg Tablets contain the non-medicinal ingredients: lactose, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, povidone, and FD&C blue No. 2 aluminum lake.

MYLAN-ACYCLOVIR 400 mg Tablets contain the non-medicinal ingredients: microcrystalline cellulose, sodium starch glycolate, magnesium stearate, povidone and Iron Oxide 30.

MYLAN-ACYCLOVIR 800 mg Tablets contain the non-medicinal ingredients: microcrystalline cellulose, sodium starch glycolate, magnesium stearate, povidone, and FD&C blue No. 2 aluminum lake.

What dosage forms it comes in:

MYLAN-ACYCLOVIR is available in tablets containing 200 mg, 400 mg or 800 mg of acyclovir.

WARNINGS AND PRECAUTIONS

Before using MYLAN-ACYCLOVIR, tell your doctor if:

- You have kidney problems or if you are 65 years of age or older. Your doctor may give you a lower dose of MYLAN-ACYCLOVIR and/or ask you to stay hydrated.
- You are severely immunocompromised (e.g. suffering a severe disease or have recently undergone an organ transplant, and are taking immunosuppressant drugs for either of these conditions).
- You are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed.

The safety and effectiveness in children less than 2 years of age are not known.

You must make sure you **drink plenty of liquids such as water** while you are being given MYLAN-ACYCLOVIR.

Feeling drowsy or sleepy may impair your ability to concentrate and react. Make sure you are not affected before you drive or operate machinery.

When using MYLAN-ACYCLOVIR for suppression of genital herpes, your doctor may periodically stop your drug therapy in order to reassess your need for continuous treatment. The effect of long-term use in humans has not been fully assessed. Prudence is therefore suggested when choosing continuous, long term therapy with MYLAN-ACYCLOVIR. Suppression of recurrent genital herpes is therefore, only recommended in those who are severely affected. Some patients experience increased severity of the first episode of genital herpes after stopping treatment.

Genital herpes is passed from one person to another through direct intimate contact. To reduce the risk of transmission, wash your hands immediately if you touch your skin sores, and do not touch other parts of your body until you have done so. Especially avoid intimate contact with others when the disease is visible. Herpes virus particles may also be released when you do not have blisters or sores. For this reason, it is safest to believe that you can spread the infection to your partner even when sores are not present.

Although decreased sperm counts were observed in animals treated with high doses, these effects did not occur in humans.

PROPER USE OF THIS MEDICATION

Medication should not be shared with others. The prescribed dosage should not be exceeded.

Usual dose for shingles:

For the treatment of shingles (herpes zoster), the usual dose of MYLAN-ACYCLOVIR is 800 mg every 4 hours, 5 times daily for 7 to 10 days. MYLAN-ACYCLOVIR must be taken as early as possible within 72 hours of the onset of lesions.

Usual dose for chickenpox:

For the treatment of chickenpox (varicella), the usual dose of MYLAN-ACYCLOVIR is 20 mg/kg (not to exceed 800 mg) 4 times daily for 5 days. MYLAN-ACYCLOVIR must be taken as early as possible within 24 hours of the appearance of rash.

Usual dose for genital herpes:

For the treatment of an initial episode of genital herpes, the usual dose of MYLAN-ACYCLOVIR is 200 mg every 4 hours, 5 times daily (maximum 1 g daily) for 10 days. MYLAN-ACYCLOVIR must be taken as early as possible following onset of signs and symptoms.

For the suppression of genital herpes, the usual dose of MYLAN-ACYCLOVIR is 200 mg 3 to 5 times daily or 400 mg twice daily. You should follow dosing instructions carefully. The objective is to keep enough of the drug in the body at all times to prevent the herpes virus from multiplying. Your doctor will try to prescribe the minimum dose required to do this in your case and may therefore increase or decrease your dose during the first few weeks. Follow your doctor’s instruction carefully to ensure that you get the best possible response to treatment.

For the treatment of recurrent episodes of genital herpes, the usual dose of MYLAN-ACYCLOVIR is 200 mg every 4 hours 5 times daily for 5 days. MYLAN-ACYCLOVIR must be taken at the earliest sign or symptom (prodrome) of recurrence.

Overdose:

In case of drug overdose, contact a health care practitioner, 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

As with any widely prescribed medication, adverse events in association with the use of MYLAN-ACYCLOVIR are reported from time to time.

Common side effects may affect up to 1 in 10 people:

- Headache
- Nausea, diarrhea, upset stomach, vomiting
- Feeling unwell
- Weakness, lack of energy
- Skin tingling, itching

Other side effects include: dizziness; high temperature (fever); itchy, bumpy rash; skin reaction after exposure to light (photosensitivity); hair loss; unusual bruising or bleeding; shortness of breath; effects on blood and urine tests; swelling of the face, lips, mouth, tongue or throat; increases in the enzymes that work in the liver; feeling agitated or confused; feeling shaky, unsteady and a lack of co-ordination; difficulty speaking or hoarseness; seeing or hearing things that are not really there; feeling drowsy or sleepy; inability to think or judge clearly or concentrate; disturbances of behaviour, speech and eye movements; unconsciousness; yellowing of the skin and whites of the eyes, inflammation of the liver; and changes to blood test results (reduced numbers of red blood cells, white blood cells, or blood platelets).

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 call your doctor or pharmacist
		Only if severe	In all cases	
Unknown	Severe allergic reaction: itchy, bumpy rash; swelling, sometimes of the face or mouth causing difficulty in breathing; collapse			✓
	Kidney failure: pain in the side (between ribs and hip) or kidney area of your back			✓
	Blood disorders: unusual bruising or bleeding			✓

HOW TO STORE IT

Store MYLAN-ACYCLOVIR Tablets at room temperature (15° to 30°C). MYLAN-ACYCLOVIR Tablets should be stored in a dry place and protected from light.

Keep your MYLAN-ACYCLOVIR Tablets in a safe place where children cannot reach them.

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, ON 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 the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

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

MORE INFORMATION

This document can be found at: www.mylan.ca.

The full Product Monograph prepared for health professionals can be obtained by contacting the sponsor, Mylan Pharmaceuticals ULC at: 1-800-575-1379.

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