

PART III: CONSUMER INFORMATION

Pr Mylan-Cilazapril

Cilazapril Monohydrate Tablets

1 mg, 2.5 mg, 5 mg

This leaflet is part III of a three-part "Product Monograph" published when Mylan-Cilazapril 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-Cilazapril. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Mylan-Cilazapril is used to treat the following:

- Mild to moderate essential high blood pressure (hypertension). The cause of essential high blood pressure is unknown.
- Heart failure. This is a condition where the heart cannot pump adequate amounts of blood to satisfy the needs of the body.

What it does:

Mylan-Cilazapril is an angiotensin-converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in '-PRIL'.

It works by making your blood vessels relax and widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood around your body if you have chronic heart failure.

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking Mylan-Cilazapril regularly even if you feel fine.

When it should not be used:

Do not take Mylan-Cilazapril if you:

- Are allergic to cilazapril or to any non-medicinal ingredient in the formulation.
- Are allergic (hypersensitive) to other ACE inhibitor medicines. These include captopril, enalapril, lisinopril and ramipril.
- Have experienced an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing, to any ACE inhibitor or without a known cause. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.

- Have been diagnosed with hereditary angioedema: an increased risk of getting an allergic reaction that is passed down through families. This can be triggered by different factors, such as surgery, flu, or dental procedures.
- Are pregnant or intend to become pregnant. Taking Mylan-Cilazapril during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. Mylan-Cilazapril passes into breast milk.
- Have a build up of fluid in your abdomen (ascites).
- Are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril/valsartan), as the risk of angioedema is increased. Do not take Mylan-Cilazapril for at least 36 hours before or after you take sacubitril/valsartan, a medicine used to treat heart failure. Are already taking a blood pressure-lowering medicine that contains aliskiren (such as RASILEZ) and you have diabetes or kidney disease.
- Are lactose intolerant or have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
 as lactose is a non-medicinal ingredient in Mylan-Cilazapril.

What the medicinal ingredient is:

Cilazapril monohydrate

What the nonmedicinal ingredients are:

colloidal silicon dioxide, D&C Yellow No. 10 (5 mg strength only), FD&C Blue No. 2 (5 mg strength only), FD&C Red No. 40 (5 mg strength only), FD&C Yellow No. 6 (5 mg strength only), hydroxypropyl methylcellulose (1 mg and 2.5 mg strengths only), lactose anhydrous, polydextrose (1 mg and 2.5 mg strengths only), polyethylene glycol, pregelatinized starch, red iron oxide (2.5 mg strength only), sodium bicarbonate, sodium stearyl fumarate, titanium dioxide, triacetin (1 mg and 2.5 mg strengths only) and yellow iron oxide (1 mg and 2.5 mg strengths only).

Mylan-Cilazapril contains lactose, which is a type of sugar. If you have an intolerance to lactose, talk to your doctor or pharmacist before taking this medicine.

What dosage forms it comes in:

Tablets; 1 mg, 2.5 mg and 5 mg

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy
Mylan-Cilazapril should not be used during pregnancy. If you discover that you are pregnant while taking Mylan-Cilazapril, stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.

BEFORE you use Mylan-Cilazapril talk to your doctor, nurse or pharmacist if you:

- Are allergic to any drug used to lower blood pressure.
- Have narrowing of an artery or a heart valve.
- Have/had a heart attack or a stroke.
- Have heart failure.
- Have diabetes, liver or kidney disease.
- Are on dialysis.
- Are on LDL apheresis (a treatment to lower the LDL cholesterol in the blood).
- Are dehydrated or recently suffered from excessive vomiting, diarrhea or sweating.
- Are on a low salt diet.
- Are receiving gold (sodium aurothiomalate) injections.
- Have recently received or are planning to have allergy shots for bee or wasp stings.
- Have a collagen disease (skin disease) such as lupus (systemic lupus erythematosus) or scleroderma (a skin condition leading to hardening or thickening of the skin).
- Are less than 18 years old. Mylan-Cilazapril is not recommended for use in children.
- Are taking a medicine that contains aliskiren, such as RASILEZ, used to lower high blood pressure. The combination with Mylan-Cilazapril is not recommended.
- Are taking any of the following medicines, the risk of angioedema may be increased:
 - o Medicines used to prevent organ transplant rejection and for cancer (e.g. temsirolimus, sirolimus, everolimus).
 - o DPP-IV inhibitors (e.g. alogliptin, linagliptin, saxagliptin and sitagliptin, medicines used to treat diabetes). Are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”) or other drugs that may increase serum potassium (e.g., trimethoprim-containing products).
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Mylan-Cilazapril.

You may become sensitive to the sun while taking Mylan-Cilazapril. Exposure to sunlight should be minimized until you know how you respond.

If you are going to have surgery and will be given an anesthetic, be sure to tell your doctor or dentist that you are taking Mylan-Cilazapril.

Driving and using machines

You may feel dizzy while taking Mylan-Cilazapril. This is more likely to happen when you first start treatment or when the dose is increased. If you feel dizzy, do not drive or use any tools or machines.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with Mylan-Cilazapril:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, potassium-sparing diuretics (a specific kind of “water pill,” e.g. spironolactone, triamterene, amiloride, eplerenone) or other drugs that may increase serum potassium (e.g. trimethoprim-containing products and cotrimoxazole for infections caused by bacteria; cyclosporine, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots).
- Allopurinol used to treat gout.
- Anesthetics and narcotics (for pain relief)
- Antipsychotics (for treatment of schizophrenia or bipolar disorder)
- Anti-diabetic drugs including insulin and oral medicines (e.g. metformin, gliptins, sulfonylureas).
- Digoxin, a heart medication
- Gold salts (for the treatment of rheumatoid arthritis).
- Lithium (used to treat bipolar disorder).
- Non-steroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include aspirin, indometacin, naproxen, ibuprofen and celecoxib.

IMPORTANT: PLEASE READ

- Other blood pressure lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. RASILEZ), angiotensin receptor blockers (ARBs) or other ACE inhibitors (in addition to Mylan-Cilazapril).
- Steroid medicines (such as hydrocortisone, prednisolone and dexamethasone) or other medications which suppress the immune system.
- Tricyclic antidepressants (e.g. amitriptyline, clomipramine, imipramine)
- mTOR inhibitors (e.g. sirolimus, everolimus)
- DPP-IV inhibitors (e.g. alogliptin, linagliptin, saxagliptin, and sitagliptin)

Taking Mylan-Cilazapril with food and drink

Tell your doctor or pharmacist if you are taking food supplements that contain potassium.

PROPER USE OF THIS MEDICATION

Take Mylan-Cilazapril exactly as prescribed. It is recommended to take your dose at about the same time every day.

Usual Adult Dose:

Follow your doctor’s instructions about how much medicine you should take. If you have any questions, you should consult your doctor or pharmacist.

Overdose:

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

If you take more Mylan-Cilazapril than you should, the following effects may happen: feeling dizzy or light-headed, shallow breathing, cold clammy skin, being unable to move or speak and a slow heart beat.

Missed Dose:

If you forget to take a dose, skip the missed dose. Then take the next dose when it is due.

Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Dizziness, headache, trouble sleeping
- Drowsiness, feeling tired, weakness
- Runny or blocked nose, sneezing
- Rash, itching
- Abdominal pain, upset stomach, decreased appetite
- Diarrhea, constipation, nausea, vomiting
- Muscle cramps and/or joint pain, pins and needles sensation
- Sweating more than usual, flushing

If any of these affects you severely, tell your doctor, nurse or pharmacist.

Mylan-Cilazapril can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

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

Symptom / effect		Talk to your healthcare professional		Stop taking drug and seek immediate emergency medical help
		Only if severe	In all cases	
Common (affects less than 1 in 10 people)	Low Blood Pressure: Dizziness, fainting, lightheadedness. May occur when you go from sitting to standing up.		√	√ (if actual fainting occurs)
	Increased levels of potassium in the blood: irregular heartbeat, muscle weakness and generally feeling unwell		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and seek immediate emergency medical help
		Only if severe	In all cases	
Uncommon (affects less than 1 in 100 people)	Angioedema and Severe Allergic Reactions (anaphylaxis): Swelling of the face, eyes, lips, tongue or throat, difficulty swallowing or breathing, rash (including skin rash which may be severe), hives, itching, fever, abdominal cramps, chest discomfort or tightness.			√
	Electrolyte Imbalance: Weakness, drowsiness, muscle pain or cramps, irregular heartbeat		√	
	Increased heart rate		√	
	Chest pain (Angina)			√
	Breathing problems, including shortness of breath and tightness in the chest			√
Rare (affects less than 1 in 1,000 people)	Decreased platelets: Bruising, bleeding, fatigue and weakness.		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and seek immediate emergency medical help
		Only if severe	In all cases	
	Decreased white blood cells: Infections (e.g., sore throat, fever), fatigue, aches, pains, and flu-like symptoms.		√	
	Stroke: Weakness, blurred vision slurred speech, trouble speaking, face drooping, dizziness, headache.			√
	Heart attack: chest pain and pressure (can be radiating from the left arm), heart palpitations, nausea, vomiting, trouble breathing, sweating, anxiety.		√	
	Irregular heartbeat		√	
	Lupus-like Syndrome: Fever, fatigue, joint and muscle pain, generally feeling unwell.		√	

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

Symptom / effect	Talk to your healthcare professional		Stop taking drug and seek immediate emergency medical help
	Only if severe	In all cases	
Liver Disorder: Yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		√	
Inflammation of the Pancreas: Abdominal pain that lasts and gets worse when you lie down, nausea, vomiting.		√	
Kidney Disorder: Change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue.		√	

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

Symptom / effect	Talk to your healthcare professional		Stop taking drug and seek immediate emergency medical help
	Only if severe	In all cases	
Serious skin reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis): Any combination of itchy skin rash, redness, blistering and severe peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands, joint pain, yellowing of the skin or eyes, dark urine.			√

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

If you have any further questions, ask your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15°C to 30°C). Keep container tightly closed.

Keep out of reach and sight of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of

medicines no longer required. These measures will help to protect the environment.

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 1908C
Ottawa, Ontario
K1A 0K9

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: 1-844-596-9526.

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