

PART III: CONSUMER INFORMATION**MYLAN-INDAPAMIDE**
(Indapamide Tablets, USP)

1.25 mg and 2.5 mg Tablets

This leaflet is part III of a three-part "Product Monograph" published when MYLAN-INDAPAMIDE was approved for sale in Canada and is designed specifically for Consumers. Read this carefully before you start taking MYLAN-INDAPAMIDE and each time you get a refill. This leaflet is a summary and will not tell you everything about MYLAN-INDAPAMIDE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

MYLAN-INDAPAMIDE is used to treat mild to moderate high blood pressure.

MYLAN-INDAPAMIDE can be used by itself or with other medicines to treat that condition.

What it does:

MYLAN-INDAPAMIDE is a diuretic often called a "water pill". It increases urination. This lowers blood pressure.

MYLAN-INDAPAMIDE affects the kidney's ability to reabsorb electrolytes.

This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking MYLAN-INDAPAMIDE regularly even if you feel fine.

When it should not be used:

Do not take MYLAN-INDAPAMIDE if you:

- Are allergic to indapamide or any other sulfonamide or to any non-medicinal ingredient in the formulation
- Have severe kidney disease
- Have severe liver disease or suffer from a condition called hepatic encephalopathy (a degenerative disease of the brain)
- Have low potassium levels in your blood
- Are taking drugs to treat heart rhythm disturbances (antiarrhythmics) that might cause severe cardiac arrhythmias
- Are breastfeeding. MYLAN-INDAPAMIDE passes into breast milk
- Are pregnant. MYLAN-INDAPAMIDE should not be used during pregnancy. If you become pregnant, discontinue use immediately and discuss with your doctor
- Have lactose intolerance or have hereditary galactose intolerance, glucose-galactose malabsorption or the Lapp lactase deficiency

because MYLAN-INDAPAMIDE contains lactose

What the medicinal ingredient is:

Indapamide

What the non-medicinal ingredients are:

Each MYLAN-INDAPAMIDE 1.25 mg tablets:

lactose, microcrystalline cellulose, povidone, starch, talc, sodium starch glycollate, magnesium stearate, hydroxypropyl methylcellulose, polydextrose, polyethylene glycol, titanium dioxide, triacetin, FD&C yellow #6, and D&C yellow #10.

Each MYLAN-INDAPAMIDE 2.5 mg tablets:

lactose, microcrystalline cellulose, povidone, starch, talc, sodium starch glycollate, magnesium stearate, FD&C red #40 Aluminum Lake, and FD&C blue #2 Aluminum Lake.

What dosage forms it comes in:

Tablets of 1.25 mg or 2.5 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use MYLAN-INDAPAMIDE talk to your doctor, nurse, or pharmacist if you:

- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating
- Have diabetes, liver or kidney disease
- Have any congenital or a family history of heart rhythm problems
- Suffer from hyperparathyroidism (dysfunctioning of the parathyroid gland)
- Have systemic lupus erythematosus (SLE)
- Are malnourished
- Are elderly
- Have coronary artery disease, heart disease or heart failure
- Had a surgery called a Sympathectomy
- Suffer from gout

MYLAN-INDAPAMIDE is not recommended for use in children.

You may become sensitive to the sun while taking MYLAN-INDAPAMIDE. Exposure to sunlight should be minimized.

Athletes should be aware that MYLAN-INDAPAMIDE contains an active ingredient, which may give a positive reaction in doping tests.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to MYLAN-INDAPAMIDE. Dizziness, lightheadedness, or fainting can especially

occur after the first dose or when another antihypertensive agent is added.

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-INDAPAMIDE:

- ACTH (e.g. tetracosactide) for treatment of arthritis or inflammatory bowel disease
- Alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications). They may cause low blood pressure and dizziness when you go from lying or sitting to standing up.
- Allopurinol (to treat gout)
- Antibiotics such as moxifloxacin, erythromycin IV
- Antifungal medications such as amphotericin B (IV)
- Antimicrobial medications such as pentamidine
- Baclofen, a skeletal muscle relaxant
- Calcium tablets or other calcium supplements
- Ciclosporin, tacrolimus or other medications to depress the immune system after organ transplantation
- Drugs to treat heart rhythm disturbances (e.g. digoxin, quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide)
- Drugs to treat high blood pressure, including angiotensin converting enzyme (ACE) inhibitors
- Drugs used to treat anxiety and schizophrenia (e.g. clozapine, risperidone, pimozide)
- Drugs used to treat depression, in particular selective serotonin reuptake inhibitors (SSRIs eg. paroxetine, sertraline, citalopram) and tricyclic antidepressants (imipramine)
- Iodinated contrast media
- Lithium used to treat bipolar disease
- Metformin, an oral medication for diabetes
- Nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, naproxen or celecoxib or high doses of acetylsalicylic acid (more than 3 g/day)
- Oral corticosteroids for treatment of asthma
- Potassium-sparing diuretics (e.g. amiloride, spironolactone, triamterene)
- Stimulant laxatives such as bisacodyl and senna

PROPER USE OF THIS MEDICATION

Take MYLAN-INDAPAMIDE exactly as prescribed. It is recommended to take your dose at about the same time every day in the morning. MYLAN-INDAPAMIDE is for oral use: swallow the tablet whole with water.

Usual Adult dose:

1.25 mg tablet a day.

Maximum dose:

2.5 mg a day

Your doctor may increase the dose to a maximum of 2.5 mg daily depending on your response to treatment after 4 to 8 weeks.

Recommended dose for the elderly: 1.25 mg tablet a day.

This dose may be adjusted depending on your kidney function.

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 have forgotten to take your dose during the day, carry on with the next one at the usual time. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- **Headache**
- **Pains in the stomach, back, chest**
- **Dizziness**
- **Fatigue, weakness**
- **Burning or prickling feeling in hands, arms, legs or feet**
- **Muscle cramps**
- **Vertigo**
- **Constipation, diarrhea, nausea, vomiting**
- **Cough, dry mouth**
- **Swelling**
- **Rash, itching**

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

MYLAN-INDAPAMIDE 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 with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Electrolyte disturbances (low levels of sodium, potassium and/or chloride): muscle weakness, pain or cramps, irregular heartbeat, weakness, generally feeling unwell.		✓	
	Changes in heart rate: faster, slower or irregular heart beat		✓	
	Hyperuricaemia: high uric acid levels in the blood, which may cause gout: pain, swelling and redness in the joints		✓	
	Increased Blood sugar: frequent urination, thirst, hunger.		✓	

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Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Uncommon	Low blood pressure: dizziness, fainting, lightheadedness. May occur when you move from lying down or sitting to standing up.		✓	
Unknown	Decreased White Blood Cells: infections, fatigue, fever, aches, pains and flu-like symptoms.		✓	
	Eye Disorders: Acute Myopia: sudden near sightedness or blurred vision. Visual impairment			✓
Unknown	Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine.			✓

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Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
Decreased Platelets: Bruising or unusual bleeding from the skin or other areas, fatigue, weakness.		✓	
Decreased Red Blood Cells (anemia): fatigue, shortness of breath, irregular heart rate, dizziness, headache, pale skin.		✓	
Liver disorder yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		✓	
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 with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
Inflammation of the pancreas: severe upper stomach pain that gets worse when you lie down, often with nausea and vomiting.			✓
Allergic Reaction/Angioedema (swelling of the face, lips, mouth, tongue or throat) which may cause difficulty in swallowing or breathing.			✓
Hypercalcaemia: high calcium levels in the blood, may cause loss of appetite, nausea, vomiting, constipation, stomach pain.			✓

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 seek immediate emergency medical attention
		Only if severe	In all cases	
Unknown	Torsade de pointes: lifethreatening irregular heart beat Record of the electrical activity of the heart (electrocardiogram (ECG)) showing a prolonged QT interval			✓
	Possible worsening of preexisting lupus: a disease affecting the skin, joints and kidneys			✓
	Hepatitis a liver disease which may cause nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light colored bowel motions, dark coloured urine			✓

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 seek immediate emergency medical attention
		Only if severe	In all cases	
	Severe skin reactions: Stevens Johnson Syndrome, Toxic epidermic necrolysis: skin rash, redness of the skin, blistering of the lips, eyes or mouth, skin peeling, accompanied by fever, chills, headache, cough, body aches and generally feeling unwell			✓

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

HOW TO STORE IT

Keep out of reach and sight of children.
 Store MYLAN-INDAPAMIDE between 15°C to 30°C.
 Do not use after the expiry date stated on the carton or blister.

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;
- 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.

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 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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