

PART III: CONSUMER INFORMATION**Pr PRO-METFORMIN
Metformin Hydrochloride Tablets, BP**

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

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

PRO-METFORMIN (metformin hydrochloride) is used to treat type 2 diabetes which cannot be controlled by proper diet, exercise and weight reduction.

What it does:

PRO-METFORMIN is used to treat type 2 diabetes. People with type 2 diabetes are not able to make enough insulin or respond normally to the insulin their bodies make. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems including kidney damage, amputations, and blindness. Diabetes is also closely linked to heart disease. The main goal of treating diabetes is to lower your blood sugar to a normal level.

High blood sugar can be lowered by diet and exercise, by a number of medicines taken by mouth, and by insulin shots. While you take your diabetes medicine, continue to exercise and follow the diet advised for your diabetes, by your doctor.

No matter what your recommended diabetes management plan is, studies have shown that maintaining good blood sugar control can prevent or delay complications of diabetes, such as blindness.

PRO-METFORMIN helps control your blood sugar. Although the mode of action is not fully understood, it is believed to help your body respond better to the insulin it makes naturally by:

- decreasing the amount of sugar your liver makes, and
- decreasing the amount of sugar your intestines absorb.

When it should not be used:

Do not take PRO-METFORMIN if you: have unstable and/or insulin-dependent (Type I) diabetes mellitus.

- have metabolic acidosis (including diabetic ketoacidosis, history of ketoacidosis or lactic acidosis – too much acid in the blood)
- drink a lot of alcohol
- have liver or kidney problems
- are going to have x-ray procedure with injection of dyes

- are stressed, have severe infections, are experiencing trauma, prior to surgery or during the recovery phase
- suffer from severe dehydration (have lost a lot of water from your body)
- are hypersensitive or allergic to metformin hydrochloride or any ingredient in the formulation or component of the container
- are breastfeeding
- are pregnant or planning to become pregnant
- have cardiovascular collapse (abrupt failure of blood circulation) or cardiorespiratory insufficiency

What the medicinal ingredient is:

Metformin hydrochloride.

What the non medicinal ingredients are:

PRO-METFORMIN tablets contain the following non medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and pregelatinized starch.

What dosage forms it comes in:

Tablets (film coated): 500 mg and 850 mg

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

- PRO-METFORMIN may rarely cause a serious, life-threatening condition called lactic acidosis (see section Lactic Acidosis below).
- You should not drink a lot of alcohol if you take PRO-METFORMIN (see section Lactic Acidosis below).

Lactic Acidosis

PRO-METFORMIN may rarely cause a serious, life-threatening condition called lactic acidosis.

You should not take PRO-METFORMIN due to greater risk for lactic acidosis if you:

- have kidney problems
- are 80 years or older and you have NOT had your kidney function tested
- are seriously dehydrated (have lost a lot of water from your body)
- have liver disease
- drink a lot of alcohol (regularly drink alcohol or sometimes drink a lot of alcohol, binge drinking)
- have an x-ray procedure with injection of dyes (contrast agents)
- prior to surgery or during recovery phase
- develop a serious medical condition, such as heart attack, severe infection, or a stroke

Due to greater risk for lactic acidosis, you should talk to your doctor if you take PRO-METFORMIN and if you:

- develop or experience a worsening of heart disease and particularly heart failure

Signs and symptoms of lactic acidosis include: discomfort, muscle pain, difficult or fast breathing, extreme tiredness, weakness, upset stomach, stomach pain, feeling cold, low blood pressure or slow heartbeat.

If any of the above side effects occur, consult your doctor immediately.

Tell your doctor if you are pregnant or plan to become pregnant. PRO-METFORMIN should not be used during pregnancy and insulin treatment is recommended during pregnancy. Talk with your doctor about your choices. You must not take PRO-METFORMIN if you are nursing a child.

Tell your doctor of any other medical condition including: vitamin B-12 deficiency or anemia, excessive alcohol use, allergies.

Do not start or stop any medicine without doctor or pharmacist approval.

INTERACTIONS WITH THIS MEDICATION

Some drugs may interact with PRO-METFORMIN. Careful monitoring is advised. Tell your doctor if you are taking:

- other diabetes drugs such as glyburide
- furosemide
- nifedipine
- cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, and vancomycin)
- other drugs tend to produce hyperglycemia (high blood sugar) and may lead to a loss of blood sugar control. Some example of drugs that can increase the blood sugar include:
 - Thiazide and other diuretics (water pills)
 - Corticosteroids
 - Phenothiazines
 - Thyroid products
 - Estrogens or estrogens plus progestogen
 - Oral contraceptives
 - Phenytoin
 - Nicotinic Acid
 - Sympathomimetics
 - Calcium channel blocking drugs
 - Isoniazid
 - Beta-2-agonists
- ACE inhibitors drugs may lower blood glucose and the combination with PRO-METFORMIN should be carefully monitored.

Before using any drugs or herbal products, check with your doctor or your pharmacist.

PROPER USE OF THIS MEDICATION

Usual dose:

Your doctor will tell you how much medicine to take and when to take it. Follow the directions provided by your doctor for using this medicine. Taking this medicine with food will decrease symptoms such as nausea and vomiting.

Overdose:

In general, an overdose may lead to increased symptoms as described under “SIDE EFFECTS AND WHAT TO DO ABOUT THEM” including stomach discomfort, nausea, vomiting, diarrhea, drowsiness, weakness, dizziness, malaise and headache.

A serious, life-threatening condition called lactic acidosis may also occur (see **WARNINGS and PRECAUTIONS**, Lactic Acidosis).

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 PRO-METFORMIN tablets, do not take a double dose to make up for forgotten individual doses. Take the next dose at the usual time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Common side effects of PRO-METFORMIN include:

- diarrhea
- nausea
- upset stomach
- abdominal bloating
- gas
- loss of appetite

These side effects generally go away after you take the medicine for a while. Taking your medicine with meals can help reduce these side effects. Tell your doctor if the side effects bother you a lot, last for more than a few weeks, come back after they've gone away, or start later in therapy. You may need a lower dose or need to stop taking the medicine for a short period or for good.

PRO-METFORMIN rarely cause hypoglycemia (low blood sugar) by themselves. However, hypoglycemia can happen if you do not eat enough, if you drink alcohol, or if you take other medicines to lower blood sugar.

Lactic Acidosis. In rare cases, PRO-METFORMIN can cause a serious side effect called lactic acidosis. This is caused by a buildup of lactic acid in your blood. This build-up can cause serious damage. Lactic acidosis caused by PRO-METFORMIN is rare and has occurred mostly in people whose kidneys were not working normally. Although rare, if lactic acidosis does occur, it can be fatal in up to half the people who develop it.

It is also important for your liver to be working normally when you take PRO-METFORMIN. Your liver helps remove lactic acid from your blood.

Make sure you tell your doctor before you use PRO-METFORMIN if you have kidney or liver problems.

You should also **stop using PRO-METFORMIN and call your doctor right away if you have signs of lactic acidosis. Lactic acidosis is a medical emergency that must be treated in a hospital.**

If your medical condition suddenly changes, stop taking PRO-METFORMIN and call your doctor right away. This may be a sign of lactic acidosis or another serious side effect.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM	
Symptom / effect	Stop taking drug and call your doctor or pharmacist
Uncommon	
Feeling very weak, tired or uncomfortable	✓
Unusual muscle pain	✓
Trouble breathing	✓
Unusual or unexpected stomach discomfort	✓
Feeling cold	✓
Feeling dizzy or Lightheaded	✓
Suddenly developing a slow or irregular heartbeat	✓
Rare	
Lactic acidosis and symptoms which may be	✓
<ul style="list-style-type: none"> • Feeling very weak, tired, or uncomfortable • Unusual muscle pain • Trouble breathing • Unusual or unexpected stomach discomfort • Feeling cold • Feeling dizzy or • Lightheaded • Suddenly developing a slow or irregular heartbeat 	

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

HOW TO STORE IT

Store at room temperature (15°C to 30°C). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication. Keep out of reach of children.

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 0701D
Ottawa, Ontario
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 side effects, contact your health professional. 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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