

**PART III: CONSUMER INFORMATION****Pr PRO-GLYBURIDE****Glyburide 5 mg Tablets**

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

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

PRO-GLYBURIDE (glyburide) is used to control high blood sugar in patients with stable, mild Type 2 diabetes (maturity-onset or adult type) which cannot be controlled by proper diet and exercise, or when insulin therapy is not appropriate.

**What it does:**

PRO-GLYBURIDE lowers blood sugar by stimulating the pancreas to secrete insulin. The pancreas must produce insulin for this medication to work.

In addition to taking PRO-GLYBURIDE, you should continue to exercise and follow the diet recommended for you by your doctor.

**When it should not be used:**

Do not take PRO-GLYBURIDE

- If you have Type 1 diabetes.
- If you have known hypersensitivity or allergy to glyburide, to any sulfonylurea or sulfonamides, or to any ingredient in the formulation or component of the container.
- If you have diabetic ketoacidosis (an emergency condition with high blood glucose levels, a lack of insulin and an accumulation of ketones (chemicals) in the blood and urine). This condition should be treated with insulin.
- In the presence of diabetic precoma or coma.
- If you have severe liver disease or frank jaundice (yellowing of the skin and/or eyes).
- If you have severe kidney disease.
- If you are taking bosentan.
- If you are pregnant or breastfeeding.

**What the medicinal ingredient is:**

Glyburide

**What the nonmedicinal ingredients are:**

Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, starch (corn starch, and pregelatinized corn starch) and talc.

**What dosage forms it comes in:**

Tablets. Each tablet contains 5 mg glyburide.

**WARNINGS AND PRECAUTIONS**

PRO-GLYBURIDE may cause low blood sugar (hypoglycaemia), especially if you miss a meal, exercise for a long time, drink alcohol or also take another antidiabetic medication.

You should ask your doctor, pharmacist or diabetes educator about symptoms of low blood sugar and what to do if you experience these symptoms. You should tell your friends, co-workers, or family members what they can do to help if you have a low blood sugar. You should also test your blood sugar as instructed by your doctor.

Before you use PRO-GLYBURIDE talk to your doctor or pharmacist if:

- You have or have had liver, kidney, or heart disease.
- You have low blood electrolyte (e.g., potassium, magnesium, or calcium) levels or conditions that could lead to low electrolyte levels (e.g., vomiting, diarrhea, dehydration).
- You are pregnant or planning to get pregnant.
- You are breastfeeding.
- You have a blood disease called G6PD-deficiency.
- You are over 60 years of age.
- You are taking clarithromycin (an antibiotic) or miconazole (an antifungal).

Lactose monohydrate is a non-medicinal ingredient in PRO-GLYBURIDE. Do not take PRO-GLYBURIDE if a doctor has told you that you have one of the following hereditary diseases: galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption.

Your blood sugar may get too high (hyperglycaemia) if you have fever, infection, surgery, or trauma (stress conditions). In such cases contact your doctor as your medication may need to be adjusted.

PRO-GLYBURIDE is not recommended for use in children under 18 years of age.

**Driving and Operating Machinery**

Alertness, reaction time and vision may be impaired due to low or high blood sugar (hypo- or hyperglycaemia), especially when beginning or after changing treatment or when PRO-GLYBURIDE is not taken regularly. This may affect your ability to drive or to operate machinery.

## INTERACTIONS WITH THIS MEDICATION

### Serious Drug Interactions

PRO-GLYBURIDE (glyburide) should not be taken if you are also taking bosentan. See “**When it should not be used**” section of this leaflet.

Other drugs that may interact with PRO-GLYBURIDE include:

- other oral antidiabetic drugs and insulin
- antibiotics (sulphonamides/sulfa drugs, clarithromycin, rifampin, quinolones, tetracyclines)
- anti-tuberculosis drugs (e.g. isoniazid)
- anti-fungal drugs (miconazole, fluconazole)
- cyclosporine (an immunosuppressant drug)
- non-steroidal anti-inflammatory drugs (NSAIDs) including phenylbutazone (used to treat inflammation and pain)
- corticosteroids (used to treat inflammation)
- salicylates (e.g. acetylsalicylic acid)
- angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure and certain heart conditions)
- coumarin derivatives (blood thinners such as warfarin)
- beta blockers (used to treat high blood pressure and certain heart conditions)
- calcium channel blockers (used to treat high blood pressure)
- diuretics (thiazides, furosemide) (used to treat high blood pressure and certain heart conditions)
- fibrates (clofibrate), nicotinic acid (used to treat high levels of fats in the blood)
- nicorandil (used to treat angina)
- H<sub>2</sub>-receptor antagonists (used to treat acid reflux/heartburn)
- monoamine oxidase inhibitors (used to treat depression)
- fluoxetine (used to treat depression)
- probenecid (used to treat high levels of uric acid in the blood and gout)
- barbiturates (sedatives, anti-seizure medications)
- phenytoin (anti-seizure medication)
- estrogen and progestogen
- anabolic steroids and androgens (male hormones)
- danazol (used to treat breast cysts and endometriosis)
- thyroid products
- laxatives
- alcohol. Avoid drinking alcoholic beverages and taking medicines containing alcohol while you are taking PRO-GLYBURIDE as this can lead to a drop in blood sugar (hypoglycaemia).

This is not a complete list of possible drug interactions. Tell your doctor if you have recently taken any of the medicines listed above or any other medicines, including those obtained without a prescription. Do not take other medicines unless prescribed or approved by your doctor. Tell any health care professionals that you see that you are taking PRO-GLYBURIDE.

## PROPER USE OF THIS MEDICATION

Take PRO-GLYBURIDE exactly as prescribed by your doctor. Never exceed the prescribed dose.

### Usual dose:

The usual dose is 2.5 to 10 mg daily. The maximum daily dose is 20 mg. A dose of more than 10 mg should be taken in two divided doses.

Tablets should be taken during or immediately after meals.

### Overdose:

Overdosage with this medication may result in hypoglycaemia.

If you take more than the recommended number of tablets, 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-GLYBURIDE tablets, take your missed dose as soon as possible, unless it is almost time for your next dose. Do not take a double dose to make up for the forgotten dose.

Discuss with your health care practitioner how you should address missed doses or skipped meals, or in the event a dose cannot be taken at the prescribed time.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effect:

- low blood sugar. If your blood sugar gets too low, you may feel shaky, weak, drowsy, confused, or very hungry. You may sweat or have blurred vision, abnormal heartbeats, trouble concentrating, or a headache that does not go away. Signs of severe hypoglycaemia can include disorientation, loss of consciousness, and seizures.

Other side effects:

- nausea, heartburn, feeling “full”, vomiting, diarrhea and abdominal pain
- allergic skin reactions (itchiness, rash, eruption), sensitivity to light
- temporary problems with the eye sight (transient visual disturbances).

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking PRO-GLYBURIDE and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Low blood sugar (hypoglycaemia)		√	
Uncommon	Skin reactions (itchiness, rash, eruption)		√	
Rare	Blood disorders (unusual bruising or bleeding)		√	
Very rare	Liver problem (yellowing of the eyes or skin)			√
	Allergic reaction (difficulty breathing, decreased blood pressure)			√

If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations, fainting, or seizures, you should seek immediate medical attention.

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

**HOW TO STORE IT**

PRO-GLYBURIDE should be stored between 15-30°C, and not beyond the expiry date indicated on the package.

**Keep out of reach of children and pets.**

Medicines should not be disposed of down the drain or in household garbage. 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](http://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](http://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 found by contacting Pro Doc Ltée at 1-800-361-8559, <http://www.prodoc.qc.ca> or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

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