

## PART III: CONSUMER INFORMATION

### **APO-GLYBURIDE** **Glyburide Tablets** **Apotex Standard**

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

#### ABOUT THIS MEDICATION

##### What the medication is used for:

APO-GLYBURIDE (glyburide) is used as an adjunct to proper diet, exercise and weight reduction to lower blood glucose in adult patients with type 2 diabetes mellitus.

##### What it does:

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

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 and by doing so can prevent long term complications.

In addition to taking APO-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 APO-GLYBURIDE

- If you have Type 1 diabetes.
- If you have known hypersensitivity or allergy to this drug, 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.

- Diabetic precoma or coma.
- During stress conditions such as severe infections, trauma or surgery.
- In the presence of liver disease or frank jaundice; or kidney disease.
- If you are being treated with bosentan.
- If you are pregnant or breastfeeding.

##### What the medicinal ingredient is:

The medicinal ingredient for APO-GLYBURIDE is glyburide.

##### What the important nonmedicinal ingredients are:

APO-GLYBURIDE tablets contain the following non-medicinal ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

##### What dosage forms it comes in:

Tablets. Each tablet contains 2.5 mg or 5.0 mg glyburide.

#### WARNINGS AND PRECAUTIONS

Proper diet, exercise and weight reduction are important to help you control your diabetes.

Your blood glucose may change in some situations, for example if you are stressed or suffering from other illnesses (e.g. infections). At such times, your doctor may need to modify your dose.

APO-GLYBURIDE may cause low blood sugar (hypoglycemia), especially if you miss a meal, exercise for a long time, drink alcohol or use another antidiabetic medication with APO-GLYBURIDE.

Elderly patients may be more likely to experience low blood sugar with APO-GLYBURIDE.

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 doesn't go away. Signs of severe hypoglycemia can include disorientation, loss of consciousness, and seizures.

You should ask your doctor, pharmacist or diabetes educator about symptoms of low blood sugar and what to do if you experience these

symptoms. Teach your friends, co-workers, or family members what they can do to help you if you have low blood sugar.

You should also test your blood sugar as instructed by your doctor.

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

- You have or have had liver, kidney, or heart disease;
- You are pregnant or planning to get pregnant;
- You are breast-feeding.
- You have a blood disease called G6PD-deficiency anemia
- You have a heart disease.

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

**Driving and Operating Machinery:**

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

**INTERACTIONS WITH THIS MEDICATION**

Ask your doctor or pharmacist before taking any other medicine, including over-the-counter products.

Drugs that can interact with APO-GLYBURIDE include: diuretics (water pills), corticosteroids (such as prednisone), ACE inhibitors (a drug used to treat high blood pressure (hypertension)), birth control pills, and some kinds of cold and allergy drugs.

Avoid drinking alcohol while you are taking APO-GLYBURIDE.

**PROPER USE OF THIS MEDICATION**

**Usual dose:**

Take APO-GLYBURIDE exactly as prescribed by your doctor.

The usual dose is 2.5 to 10 mg daily. 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 hypoglycemia.

**In case of drug overdose, contact a health professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no**

**Missed Dose:**

If you forget to take APO-GLYBURIDE tablets, do not take a double dose to make up for forgotten individual doses.

Discuss with your healthcare for dealing with such mistakes (in particular forgetting a dose or skipping a meal) or in the event a dose cannot be taken at the prescribed time.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

**Side effects:**

As with any type of medication, APO-GLYBURIDE is associated with some side effects.

The most common side effect of APO-GLYBURIDE is low blood sugar (hypoglycemia). Please see the **WARNINGS and PRECAUTIONS** section above.

The following side effects have been observed with APO-GLYBURIDE use: nausea, heartburn, feeling "full", vomiting, diarrhea, abdominal pain and weight gain.

Allergic skin reactions (itchiness, rash, eruption) have been reported in a number of patients. An increased sensibility to light has been associated with the use of oral antidiabetic drugs.

Transient visual disturbances may occur at the beginning of the treatment due to variations in level of blood sugar.

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

Symptom/ Effect		Talk with your doctor or pharmacist		Stop taking APO-GLYBURIDE and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Low blood sugar (hypoglycemia)	✓		
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 (difficult breathing, hives, decreased blood pressure)			✓
	Allergic inflammation of blood vessels (vasculitis)			✓
	Serious Skin Reactions [bullous reactions (Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis), drug rash with eosinophilia and systemic symptoms (DRESS), exfoliative dermatitis and erythema multiforme]: any combination of red itchy rash with blisters and peeling of the skin and/or of the lips, eyes, mouth, nasal passages or genitals. It often goes with			✓

Symptom/ Effect		Talk with your doctor or pharmacist		Stop taking APO-GLYBURIDE and call your doctor or pharmacist
		Only if severe	In all cases	
	fever, chills, headache, cough, body aches or joint pain. You may have less or dark urine, yellow skin or eyes			

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

#### HOW TO STORE IT

APO-GLYBURIDE should be stored at controlled room temperature 15°C to 30°C.

#### 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 1908C  
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](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

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISepdia, Apotex's Drug Information Service at:

1-800-667-4708

This leaflet can also be found at:

<http://www.apotex.ca/products>.

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