

PART III: CONSUMER INFORMATION

Pr **GLUCOBAY™**

acarbose

This leaflet is Part 3 of a three-part "Product Monograph" published when GLUCOBAY was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about GLUCOBAY. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

GLUCOBAY (acarbose) is used alone or in combination with a sulfonylurea (such as tolbutamide, chlorpropamide, or DiaBeta®/glyburide), metformin, or insulin to lower blood glucose in adult patients with type 2 diabetes mellitus in addition to proper diet, exercise and weight reduction.

What it does:

GLUCOBAY will slow the absorption of glucose from your gut to reduce the high blood glucose levels that occur after each meal.

When it should not be used:

Do not take GLUCOBAY if you have or have had any of the following:

- Allergic reaction to acarbose or any of the other ingredients in GLUCOBAY
- Inflammation or ulceration of the bowel (eg, ulcerative colitis or Crohn's disease)
- Diabetic ketoacidosis
- Bowel obstruction
- Chronic intestinal diseases that affect digestion or absorption of food, or a large hernia

What the medicinal ingredient is:

Acarbose

What the important nonmedicinal ingredients are:

corn starch, magnesium stearate, microcrystalline cellulose, silicon dioxide

What dosage forms it comes in:

Tablets. Each tablet contains 50 mg or 100 mg acarbose.-

WARNINGS AND PRECAUTIONS

GLUCOBAY in combination with a sulfonylurea or insulin may cause low blood sugar (hypoglycemia). You should ask your doctor, pharmacist or diabetes educator about the symptoms of low blood sugar and what to do if you experience these symptoms. You should also test your blood sugar according to instructions given to you by your doctor, nurse, or pharmacist.

Before you use GLUCOBAY talk to your doctor or pharmacist if:

- you have or have had kidney or liver disease
- you are pregnant or planning to get pregnant
- you are breast-feeding

GLUCOBAY is not recommended for use in children under 18 years of age.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including the medicine you can buy without a prescription, and natural health products.

Drugs that interact with GLUCOBAY include digestive enzyme preparations, cholestyramine, diuretics (water pills), corticosteroids (such as prednisone), digoxin, thyroid medications, estrogen, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, and isoniazid.

Avoid drinking alcohol while taking GLUCOBAY.

PROPER USE OF THIS MEDICATION

Take the tablets as prescribed by your doctor. Tablets should be taken orally with the first bite of a main meal. Do not take GLUCOBAY between meals.

You should continue to monitor your blood glucose levels according to the instructions given to you by your healthcare professional.

Usual dose

The usual starting dose is 50 mg once daily. The usual maintenance dose is 50 mg or 100 mg three times daily. The maximum dose is 100 mg three times daily.

Overdose

If you take more GLUCOBAY tablets than you should, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose

If you miss a dose, take your next dose as usual. Do not double dose to make up for the missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

You may experience some side effects while taking GLUCOBAY. The most common are gastrointestinal in nature, such as flatulence (gas) and abdominal discomfort. It is also possible that you may pass softer stools or even experience diarrhea, particularly after a meal containing foods with sucrose (ordinary sugar). Normally, these symptoms will diminish with continued treatment. You should not take antacid preparations for treating these symptoms, as they are unlikely to have any beneficial effects. If your symptoms persist, or if you have any other undesirable effects, consult your doctor.

GLUCOBAY, when given alone, should not cause hypoglycemia (low blood sugar). However, since sulfonylureas (oral antidiabetic drugs) or insulin may cause hypoglycemia, the combination of a sulfonylurea or insulin and GLUCOBAY may also cause hypoglycemia. If you do experience hypoglycemia while you are taking GLUCOBAY, either alone or with a sulfonylurea, metformin or insulin, do not treat it with ordinary sugar (sucrose); instead, take glucose tablets (also known as dextrose).

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 call your doctor or pharmacist
	Only if severe	In all cases	
Uncommon			
Nausea, vomiting, abdominal pain	✓		
Rare			
Edema (swelling)	✓		
Jaundice (yellowing of the skin)			✓
Very Rare			
Allergic reactions: rash, skin inflammation		✓	

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

HOW TO STORE IT

It is best if you keep your tablets in their original carton. The tablets should be kept in a dry place at a temperature between 15°C and 25°C.

Keep out of the reach of children.

Do not use the tablets beyond the expiry date.

REPORTING SUSPECTED SIDE EFFECTS**Canada Vigilance Program**

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, 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.

NOTE: Should you require information related to the management of the side effect, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

Bayer Inc.

You can report any suspected adverse reactions associated with the use of health products to Bayer Inc. by:

- Toll-free telephone: 1-800-265-7382
- Email: canada.medinfo@bayer.com
- Regular Mail: Bayer Inc.
77 Belfield Road
Toronto, Ontario
M9W 1G6
Canada

NOTE: Should you require information related to the management of the side effect, please contact your health professional. Bayer Inc. does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

This document plus the full product monograph, prepared for health professionals can be found at: www.bayer.ca

or by contacting the sponsor at the above mentioned phone number and email address.

This leaflet was prepared by:

Bayer Inc.
77 Belfield Road
Toronto, Ontario
M9W 1G6
Canada

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