

PART III: CONSUMER INFORMATION

Pr MAR-ACARBOSE

Acarbose Tablets 50 mg and 100 mg

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

ABOUT THIS MEDICATION

What the medication is used for:

MAR-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:

MAR-ACARBOSE 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 MAR-ACARBOSE if you have or have had any of the following:

- Allergic reaction to acarbose or any of the other ingredients in MAR-ACARBOSE
- 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:

Maize starch, magnesium stearate, microcrystalline cellulose, Silica colloidal anhydrous

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

MAR-ACARBOSE 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 MAR-ACARBOSE 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

MAR-ACARBOSE 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 MAR-ACARBOSE 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 MAR-ACARBOSE.

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 MAR-ACARBOSE 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 think you have taken too much MAR-ACARBOSE, contact your healthcare professional, 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 MAR-ACARBOSE. 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.

MAR-ACARBOSE, 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 MAR-ACARBOSE may also cause hypoglycemia. If you do experience hypoglycemia while you are taking MAR-ACARBOSE, 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 to your healthcare professional		Stop taking drug and get immediate medical help
	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 MAR-ACARBOSE, contact your doctor or pharmacist.

HOW TO STORE IT

Storage should be between 15°C and 25°C. Keep the tablets in dry place. Keep out of reach and sight of children.

At storage conditions up to 25°C and below 60% relative humidity, the unpacked tablets can be stored for up to two weeks. At higher temperatures and/or relative humidity, discoloration can occur in tablets that are not in the pack. The tablets should therefore not be removed from the foil until immediately before use.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

For more information, please contact your healthcare professionals or pharmacist first, or Marcan Pharmaceuticals Inc. at: 1-855-627-2261 or visit the website at www.marcanpharma.com

The information in this document is current as of the last revision date shown below.
For the most current information please visit our website or contact us directly.

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