

PART III: CONSUMER INFORMATION

Pr REPAGLINIDE

Repaglinide Tablets, House Standard

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

What the medicinal ingredient is:

Repaglinide

What the nonmedicinal ingredients are:

amberlite (polacrillin potassium), calcium hydrogen phosphate anhydrous, colloidal silicon dioxide, glycerol, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, poloxamer 407, povidone (polyvidone), yellow iron oxide (1 mg), or red iron oxide (2 mg).

What dosage forms it comes in:

Tablets: 0.5 mg, 1 mg and 2 mg

ABOUT THIS MEDICATION

What the medication is used for:

REPAGLINIDE is used:

- to lower blood sugar in patients with type 2 diabetes mellitus whose blood sugar levels cannot be satisfactorily controlled by diet and exercise alone (monotherapy).
- in combination therapy with metformin to lower blood sugar in patients whose blood sugar levels cannot be controlled by diet and exercise only plus metformin monotherapy.
- in combination with rosiglitazone in patients who cannot take metformin and whose blood sugar levels cannot be controlled by diet and exercise plus ps-REPAGLINIDE or rosiglitazone monotherapy.

What it does:

REPAGLINIDE is an oral antidiabetic agent used for the treatment of diabetes mellitus that works by stimulating release of insulin from the pancreas and thereby reducing levels of sugar in the blood and urine.

When REPAGLINIDE should not be used:

Do not take REPAGLINIDE:

- If you have known hypersensitivity to repaglinide tablets or any of the other ingredients in REPAGLINIDE
- If you have diabetic ketoacidosis (accumulation of ketones in the blood and urine)
- If you have type 1 diabetes
- If you have severe liver disease
- If you are taking gemfibrozil (a medicine used to lower increased fat levels in the blood)

WARNINGS AND PRECAUTIONS

The treatment with insulin secretagogues (drugs that stimulate insulin secretion from the pancreas) in general has been reported to be associated with increased cardiovascular mortality (death) as compared to treatment with diet alone or diet plus insulin.

REPAGLINIDE may cause low blood sugar (hypoglycemia).

You should ask your doctor or pharmacist or diabetes educator about symptoms of low blood sugar and what to do if you experience these symptoms. You should also test your blood sugar as instructed by your doctor.

The warnings signs of hypoglycemia may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heart beat; feeling sick; difficulty in concentrating.

Severe hypoglycemia can cause loss of consciousness, seizure, brain damage and even death. Before you use REPAGLINIDE talk to your doctor or pharmacist if you:

- have a history of allergy or intolerance to any medications or other substances
- have a history of liver or kidney problems
- are or think you may be pregnant
- are breastfeeding
- are over 75 years of age

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.

Alcohol may increase the effect of REPAGLINIDE on lowering your blood sugar and therefore impair

your ability to concentrate. In this case, do not drive or operate machinery.

INTERACTIONS WITH THIS MEDICATION

Serious Drug Interactions

Use of REPAGLINIDE (repaglinide) with gemfibrozil (used to treat high blood fats) is contraindicated.

Many medicines affect the way glucose works in your body and this may influence your REPAGLINIDE dose. Listed below are the most common medicines which may affect your treatment with REPAGLINIDE:

- Monoamine oxidase inhibitors
- Beta blocking agents (used to treat high blood pressure and certain heart conditions)
- Angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure and certain heart conditions)
- Salicylates (e.g. acetylsalicylic acid)
- Octreotide
- Non steroidal anti-inflammatory agents (NSAIDS) (a type of painkillers)
- Anabolic steroids and corticosteroids (used for anemia or to treat inflammation)
- Oral contraceptives (used for birth control)
- Thiazides (diuretics or 'water pills')
- Danazol (used to treat breast cysts and endometriosis)
- Thyroid hormones (used to treat patients with low production of thyroid hormones)
- Sympathomimetics (used to treat asthma)
- Clarithromycin, trimethoprim, rifampicin (antibiotics)
- Itraconazole, ketoconazole (anti-fungal drug)
- Phenytoin, carbamazepine, phenobarbital (used to treat epilepsy/seizures).
- Cyclosporine
- Non-prescription and over the counter drugs such as drugs for appetite control, asthma, colds, cough, hay fever or sinus problems
- Alcohol

Grapefruit juice may increase the effect of REPAGLINIDE.

Tell your doctor if you have recently taken any of these medicines, or any medicines obtained without a prescription.

PROPER USE OF THIS MEDICATION

How to use REPAGLINIDE

Your doctor will prescribe REPAGLINIDE according to your needs. Take REPAGLINIDE exactly as prescribed by your doctor.

REPAGLINIDE tablets should be taken with meals, usually within 15 minutes of the meal. However, REPAGLINIDE tablets may be taken 30 minutes before a meal or right before a meal.

Overdose:

If you take more REPAGLINIDE than you should your blood sugar may become too low leading to a hypoglycemic event. The symptoms of such an event include: headache, dizziness, tiredness, rapid heart beat, nervousness, shakiness, nausea and sweating.

If you experience any of these symptoms, you should take glucose tablets or sugar or have a sugary drink and then rest.

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 miss a dose of REPAGLINIDE, do not take the missed dose. Wait and take your usual dose before your next meal.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The following side effects may occur during your treatment with REPAGLINIDE:

Very common

- hypoglycemia (low blood sugar)

If your blood sugar is low or you experience any of the symptoms of hypoglycemia such as cold sweat, cool pale skin, headache, rapid heart beat, feeling sick and/or difficulty in concentrating eat a glucose tablet or a high sugar drink or snack, then rest.

Common

- hyperglycemia (high blood sugar).

If your blood sugar is high or you experience any of the symptoms of hyperglycemia such as increased urination; feeling thirsty; dry skin and dry mouth talk to your doctor

- visual disturbance
- abdominal pain
- nausea
- vomiting
- constipation

Uncommon

- liver dysfunction
- allergy
- itching

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
		Only if severe	In all cases	
Common	Low blood sugar		✓	
	High blood sugar		✓	
	Sudden severe headache or worsening of headache, dizziness, fatigue or increased sweating			✓
	Diarrhea , constipation, gas nausea or abdominal pain		✓	
Uncommon	Sudden partial or complete loss of vision			✓
	Chest pain or pressure, and/or shortness of breath			✓

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

HOW TO STORE IT

How to store REPAGLINIDE

REPAGLINIDE should be stored between 15°C and 30°C. Protect from light and moisture. Do not store REPAGLINIDE in moist areas, like the bathroom medication cabinet or other damp places. Always store it in the bottle it came in, with the lid on tight.

Do not use REPAGLINIDE after the expiry date printed on the package.

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 0701E
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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