

**PART III: CONSUMER INFORMATION**

**Pr REPAGLINIDE**

Repaglinide

0.5 mg, 1 mg and 2 mg tablets

Oral Antidiabetic Agent

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.

**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 controlled by diet and exercise alone (monotherapy).
- in combination with metformin to lower blood sugar in patients whose blood sugar levels cannot be controlled by diet and exercise only plus metformin only.

What it does:

REPAGLINIDE is an oral antidiabetic agent used for the treatment of diabetes mellitus. It helps your body release more insulin when your blood sugar is high. This helps improve your blood sugar control.

When it 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)
- If you are taking clopidogrel (a medicine used to prevent blood clots)

What the medicinal ingredient is:

Repaglinide

What the important nonmedicinal ingredients are:

calcium hydrogen phosphate, anhydrous  
cellulose, microcrystalline  
ferric oxide red (2 mg only)  
ferric oxide yellow (1 mg only)

glycerol  
hydroxypropylcellulose  
magnesium stearate  
maize starch  
meglumine  
polacrillin potassium  
poloxamer type 188  
silica, colloidal anhydrous

What dosage forms it comes in:

REPAGLINIDE is available in three strengths in bottles of 100 tablets:

- 0.5 mg (white tablets)
- 1 mg (yellow, slightly dotted tablets)
- 2 mg (pale red, slightly dotted tablets)

**WARNINGS AND PRECAUTIONS**

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take REPAGLINIDE.

Talk about any health conditions or problems you may have, including 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

Other warnings you should know about:

REPAGLINIDE is not recommended for use in children and adolescents less than 18 years of age.

The treatment with insulin secretagogues (drugs that stimulate insulin secretion from the pancreas) in general has been associated with more heart-related deaths as compared to treatment with diet alone or diet plus insulin.

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

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 warning 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.

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

**Driving and Operating Machinery:**

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

**INTERACTIONS WITH THIS MEDICATION**

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**Serious Drug Interactions**

Do not use of repaglinide with gemfibrozil (used to treat high blood fats).

Do not use repaglinide with clopidogrel (a medicine used to prevent blood clots).

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:

- Other anti-diabetic agents (used to lower blood sugar)
- Monoamine oxidase inhibitors (used to treat depression)
- 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 levels 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 (used to suppress the immune system)
- Deferasirox (used to reduce chronic iron overload)
- Non-prescription and over the counter drugs such as drugs for appetite control, asthma, colds, cough, hay fever or sinus problems

Alcohol may increase the effect of REPAGLINIDE on lowering your blood sugar and therefore impair your ability to concentrate. Avoid drinking alcohol while you are taking REPAGLINIDE.

Grapefruit juice may increase the effect of REPAGLINIDE.

**PROPER USE OF THIS MEDICATION**

How to take REPAGLINIDE:

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

Usual dose:

REPAGLINIDE tablets should be taken with meals, usually 15 minutes before 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 heartbeat, nervousness, shakiness, nausea and sweating.

Discuss with your healthcare professional about how to treat low blood sugar.

If you think you have taken too much REPAGLINIDE, 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 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**

These are not all the possible side effects you may feel when taking REPAGLINIDE. If you experience any side effects not listed here, contact your healthcare professional. Please also see WARNINGS AND PRECAUTIONS.

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

**Common**

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

**Uncommon**

- liver dysfunction
- itching
- redness
- vomiting
- rash
- hives
- abnormal blood test results

**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	
Very Common	Low blood sugar (hypoglycemia)  Symptoms include: cold sweat, cool pale skin, headache, rapid heartbeat, feeling sick and/or difficulty in concentrating.		√	
Common	High blood sugar (hyperglycemia)  Symptoms include: increased urination, feeling thirsty, dry skin and dry mouth.		√	

**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
Sudden severe headache or worsening of headache, dizziness, tremors, fatigue or increased sweating			√
Diarrhea, constipation, gas, upset stomach, nausea or abdominal pain		√	
Sudden partial or complete loss of vision			√
Uncommon	Chest pain or pressure, and/or shortness of breath		√
	Allergy Symptoms include: swelling, difficulty breathing, rapid heartbeat, feeling dizzy and sweating		√

*If you have troublesome symptom or side effects that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.*

**HOW TO STORE IT**

Keep out of reach and sight of children.

REPAGLINIDE should be stored between 15°C - 25°C, which is generally room temperature. 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 on the package. 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 protect the environment.

**REPORTING SUSPECTED SIDE EFFECTS**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report:**

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Consumer Side Effect Reporting Form and send it by:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to:  
Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
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: 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**

If you want more information about REPAGLINIDE:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professional and includes this Patient Medication Information by visiting Health Canada website at <http://www.hc-sc.gc.ca> ; or by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

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Last revised: December 15, 2016