

Important: Please Read

PART III: CONSUMER INFORMATION

GlucNorm® 0.5 mg, 1 mg and 2 mg
Repaglinide Tablets

Oral anti-diabetic agent

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

ABOUT THIS MEDICATION

What the medication is used for:

GlucNorm® 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 GlucNorm® or rosiglitazone monotherapy.

What it does:

GlucNorm® 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 GlucNorm® should not be used:

Do not take GlucNorm®:

- If you have known hypersensitivity to repaglinide tablets or any of the other ingredients in GlucNorm®
- 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)

What the medicinal ingredient is:

Repaglinide

What the nonmedicinal ingredients are:

Microcrystalline cellulose
Calcium hydrogen phosphate
Maize starch
Amberlite (polacrillin potassium)

Povidone (polyvidone)
Glycerol
Magnesium stearate
Meglumine
Poloxamer (0.5 mg)
Yellow iron oxide (1 mg)
Red iron oxide (2 mg)

What dosage forms it comes in:

GlucNorm[®] is available in three strengths in bottles of 100 tablets:

- 0.5 mg (white tablets)
- 1 mg (yellow tablets)
- 2 mg (peach-coloured tablets)

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.

GlucNorm[®] 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 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.

Before you use GlucNorm[®] 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 GlucNorm[®] 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 GlucNorm[®] (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 GlucNorm[®] dose.

Listed below are the most common medicines which may affect your treatment with GlucoNorm®:

- 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 GlucoNorm®.

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 GlucoNorm®

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

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

Overdose:

If you take more GlucoNorm® 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.

If you take more GlucoNorm® than you should, contact your doctor, or poison control centre, or the nearest hospital emergency department immediately.

Missed Dose:

If you miss a dose of GlucoNorm®, 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 GlucoNorm®:

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 or pharmacist |
| | | 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 | | | ✓ |

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 | |
| | Chest pain or pressure, and/or shortness of breath | | | ✓ |

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

HOW TO STORE IT

How to store GlucoNorm®

Keep out of reach and sight of children. GlucoNorm® should be stored between 15°C - 25°C, which is generally room temperature. Do not store GlucoNorm® 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 GlucoNorm® 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 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 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 the sponsor, Novo Nordisk Canada Inc., at: 1-800-465-4334

The leaflet was prepared by Novo Nordisk Canada Inc.

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