

Important: Please Read

PART III: CONSUMER INFORMATION

 **Glucosoft®**
0.5 mg, 1 mg and 2 mg
Repaglinide Tablets
Oral anti-diabetic agent

Read this carefully before you start taking Glucosoft® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Glucosoft®.

ABOUT THIS MEDICATION

What is Glucosoft® used for?

- 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 alone.
- In combination with rosiglitazone in patients who cannot take metformin and whose blood sugar levels cannot be controlled by diet and exercise plus Glucosoft® or rosiglitazone alone.

How does Glucosoft® work?

Glucosoft® is an oral anti-diabetic 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.

What are the ingredients in Glucosoft®?

Medicinal ingredient: Repaglinide

Nonmedicinal ingredients: Amberlite (polacrillin potassium), calcium hydrogen phosphate, glycerol, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, poloxamer (0.5 mg), povidone (polyvidone), red iron oxide (2 mg), yellow iron oxide (1 mg).

Glucosoft® comes in the following dosage forms

Glucosoft® is available as tablets (in blister pack of 90 tablets) in three strengths:

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

Do not use Glucosoft® if you:

- Have a known hypersensitivity to repaglinide tablets or any of the other ingredients in Glucosoft®.
- Have diabetic ketoacidosis (accumulation of ketones in the blood and urine).
- Have type 1 diabetes.
- Have severe liver disease.
- Are taking gemfibrozil (a medicine used to lower increased fat levels in the blood).
- Are taking clopidogrel (a medicine used to prevent blood clots).

WARNINGS AND PRECAUTIONS

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

GlucoNorm® 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.

GlucoNorm® 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 GlucoNorm®.

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 heartbeat
- 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 GlucoNorm® 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 GlucoNorm® (repaglinide) with gemfibrozil (used to treat high blood fats).

Do not use GlucoNorm® (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 GlucoNorm® dose.

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

- 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 GlucoNorm® on lowering your blood sugar and therefore impair your ability to concentrate. Avoid drinking alcohol while you are taking GlucoNorm®.

Grapefruit juice may increase the effect of GlucoNorm®.

PROPER USE OF THIS MEDICATION

How to take GlucoNorm®:

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

Usual dose:

GlucoNorm® tablets should be taken with meals, usually 15 minutes before 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 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 GlucoNorm®, 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 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

What are the possible side effects from using GlucoNorm®?

These are not all the possible side effects you may feel when taking GlucoNorm®. 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 GlucoNorm®:

Common

- Visual disturbance
- Abdominal pain
- Nausea
- 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.		✓	
	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			✓

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	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.

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 \(http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php\)](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) 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.

HOW TO STORE IT

Storage:

Keep out of reach and sight of children.

GlucNorm® should be stored between 15°C - 25°C, which is generally room temperature. Do not store GlucNorm® in moist areas, like the bathroom medication cabinet or other damp places. Always store it in the original package to protect from moisture.

Do not use GlucNorm® 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.

MORE INFORMATION

If you want more information about GlucoNorm®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professional and includes this Patient Medication Information by visiting the Health Canada website at <http://www.hc-sc.gc.ca>; or by calling Novo Nordisk Canada Inc. at 1-800-465-4334.

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