

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PROGLYCEM®

diazoxide capsules

Read this carefully before you start taking **PROGLYCEM®** 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 **PROGLYCEM®**.

What is PROGLYCEM® used for?

PROGLYCEM® (diazoxide) is used to manage low blood sugar levels (hypoglycemia) in children and adults with certain conditions that can cause high levels of insulin (hyperinsulinism). These conditions include:

- Adults: cancerous or non-cancerous pancreas tumors that cannot be treated by surgery.
- Infants and Children:
 - Leucine sensitivity. This is an inherited condition.
 - Enlargement of islet cells (islet cell hyperplasia).
 - Too many cells in the pancreas that make insulin or too much growth of those cells (nesidioblastosis).
 - Cancerous or non-cancerous pancreas tumors, that cannot be treated by surgery.

PROGLYCEM® may be used before surgery as a temporary measure and after surgery if low blood sugar levels persists.

How does PROGLYCEM® work?

PROGLYCEM® (diazoxide) is a benzothiadiazine derivative. It works by blocking the release of insulin from your pancreas.

What are the ingredients in PROGLYCEM®:

Medicinal ingredients: Diazoxide

Non-medicinal ingredients: Lactose monohydrate, magnesium stearate

Capsule shell: gelatin, titanium dioxide (E171).

PROGLYCEM® comes in the following dosage forms:

Oral capsules: 100 mg

Do not use PROGLYCEM® if:

- you have reactive low blood sugar levels (functional hypoglycemia). This is a condition where blood sugar drops after a meal.
- you are allergic to diazoxide or other thiazides (a type of diuretic, used to treat fluid build-up/high blood pressure).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PROGLYCEM®. Talk about any health conditions or problems you may have, including if you:

- have increased levels of serum bilirubin, particularly in newborns,
- have low blood sugar levels,
- have increased heart rate and palpitations,
- have increased levels of uric acid in the blood or history of gout,
- have any kidney problems,
- have heart problems,
- are pregnant or a woman of child-bearing age,
- are breast-feeding. PROGLYCEM® may pass into your breast milk.

Other warnings you should know about:

- **Serious skin reactions**, such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), is possible with PROGLYCEM® treatment. This is a serious, life-threatening skin reaction that usually occurs within the first month of treatment. Monitor your skin, and notify your healthcare provider if you notice any signs and symptoms of DRESS.
- **Pericardial effusion** is possible with PROGLYCEM® treatment. This is when fluid builds up in the space around the heart. It is a serious condition that may lead to other heart problems. Should this happen to you, you may need a procedure to remove the fluid called pericardiocentesis. Your healthcare professional will monitor you for signs of pericardial effusion.
- **Salt and fluid retention** is possible with PROGLYCEM® treatment. This is when there is abnormal build-up of salt and fluid in the body. It is a serious condition that may lead to heart failure, especially if you have other heart problems. If you experience fluid and salt retention during treatment, your healthcare professional may reduce your dose of PROGLYCEM® and prescribe you diuretic medication.
- **Check-ups and testing:**
You will have regular visits with your healthcare professional during your treatment with PROGLYCEM®. They may:
 - Do blood or urine tests to monitor levels of blood cells, sugar, electrolyte and ketone bodies (acidic substances).
 - Check for signs and symptoms of certain side effects.

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

The following may interact with PROGLYCEM®:

- Medicines used to treat high blood pressure (antihypertensive agents)
- Chlorpromazine, a medicine used to treat certain mental or mood disorders
- Medicines used to prevent formation of blood clots (coumarin-based drugs)
- Diphenylhydantoin, a medicine used to treat seizures
- Medicines used to treat abnormal fluid build-up/high blood pressure (Diuretics)

How to take PROGLYCEM®:

- Always use this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Take PROGLYCEM® capsules by mouth.

Usual dose:

Your healthcare professional will decide the right dose for you depending on the severity of your condition.

- Adults and children: 3-8 mg/kg. This should be divided into 2 equal doses every 12 hours or 3 equal doses every 8 hours.
- Infants and newborns: 8-15 mg/kg. This should be divided into 2 equal doses every 12 hours or 3 equal doses every 8 hours.

Overdose:

Taking too much PROGLYCEM may cause you to have high blood sugar levels (hyperglycemia). When this happens, your healthcare professional may need to give you treatment to bring your blood sugar levels back to normal. They may also need to continue monitoring your blood sugar levels for up to 7 days after treatment.

If you think you, or a person you are caring for, have taken too much PROGLYCEM®, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

- If you miss a dose of PROGLYCEM®, take it as soon as possible. If it is almost time for your next scheduled dose, skip the missed dose.
- Take your next dose at the usual time. Do NOT take double the dose to make up for a dose you have missed.

What are possible side effects from using PROGLYCEM®?

These are not all the possible side effects you may have when taking PROGLYCEM®. If you experience any side effects not listed here, tell your healthcare professional.

- Excessive hair growth in women either on face, chest or back
- Digestive system problems, including: nausea, vomiting, stomach pain, decreased intestinal movement, diarrhea, temporary loss of taste
- High levels of uric acid in the blood which may cause joint pain, redness or swelling
- Skin rash or itching
- Headache
- Lightheaded, tiredness, or generally feeling ill
- Anxiety
- Trouble falling asleep or staying asleep

- Nerve inflammation, which may cause weakness, numbness, and pain
- Eye problems such as:
 - temporary cloudiness in the eye,
 - presence of blood in the eyes,
 - blind spot in your field of vision,
 - blurry or double vision; or
 - excess tear production
- Fungal or viral infection of the skin that causes inflammation, sores, or blisters
- Accelerated bone age in children that causes reduced final height
- Loss of scalp hair
- Fever
- Swelling of the lymph nodes
- Leaking of milk from the breasts unrelated to breastfeeding or enlargement of lump in breast

Serious side effects 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	
COMMON			
Sodium and fluid retention (abnormal build-up of salt and fluid in the body)		X	
Hyperglycemia or Glycosuria (high blood or urine sugar levels): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		X	
Tachycardia (fast heartbeat or palpitations): dizziness, light headedness, shortness of breath, racing heart			X
Thrombocytopenia (reduced blood platelets): increased chances of bleeding or bruising, fatigue and weakness			X
RARE			
Diabetic ketoacidosis (a complication of diabetes that results from increased levels of acid in the blood): excessive thirst, frequent urination, loss of appetite, nausea or vomiting and rapid weight loss			X
Hyperosmolar non-ketotic coma (coma resulting from very high blood glucose levels leading to			X

Serious side effects 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	
dehydration and state of altered consciousness)			
Pulmonary hypertension (high blood pressure in blood vessels in the lungs): Shortness of breath with everyday activities or at rest, irregular heartbeat, fast pulse, tiredness, dizziness, and fainting spells			X
Hypertension/Hypotension (changes in the levels of your blood pressure high or low): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations			X
Chest Pain			X
UNKNOWN FREQUENCY			
Changes in liver test results, including elevation in liver enzymes or bilirubin levels		X	
Changes in tests of kidney function, excessive protein loss in the urine, reduced urine volume, blood in the urine		X	
Reversible nephrotic syndrome: excess protein in urine, foamy urine, loss of appetite, weight gain from fluid retention, swelling		X	
Neutropenia/ Eosinophilia (changes to white blood cells – decreased neutrophils, increased eosinophils): infections, fatigue, fever, aches, pains and flu-like symptoms		X	
Drug reaction with eosinophilia and systemic symptoms (DRESS) (serious skin reaction that may affect one or more organs): fever, severe rash, peeling skin, swelling of the face, swollen lymph glands,			X

Serious side effects 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	
flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinating less often, less urine			
Anemia (decreased red blood cells/ anemia): fatigue, loss of energy, looking pale, shortness of breath, weakness		X	
Extrapyramidal signs (involuntary and uncontrollable movements like shaking of the hands, difficulty moving or rolling of the eyes)		X	
Acute pancreatitis/pancreatic necrosis (inflammation of the pancreas that can lead to permanent pancreatic cell damage): upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen			X
Pericardial effusion (build-up of fluid in the space around the heart): shortness of breath, trouble breathing when lying down, chest pressure or pain, lightheadedness, swelling of the abdomen or legs			X
Necrotizing enterocolitis (inflammation of the tissue of the intestine causing it to die): trouble digesting food, bloated or swollen abdomen, swelling, diarrhea, constipation			X

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

Reporting 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 (canada.ca/drug-device-reporting) 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.

Storage:

Store at room temperature (15°C to 30°C). Keep out of reach and sight of children.

If you want more information about PROGLYCEM®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.merck.ca, or by calling 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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