

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PRO-DAPAGLIFLOZIN

Dapagliflozin Tablets

Read this carefully before you start taking **PRO-DAPAGLIFLOZIN** 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 **PRO-DAPAGLIFLOZIN**.

Serious Warnings and Precautions

- **Diabetic ketoacidosis (DKA)** can happen while you are taking PRO-DAPAGLIFLOZIN. It is a serious and life-threatening condition, which may need urgent hospital care. Some cases of **DKA** have led to death. **DKA** can happen to diabetic patients with normal or high blood sugar levels. In **DKA** your body produces high levels of blood acids called ketones. It occurs because your body does not have enough insulin.
- **Seek medical help right away and stop taking PRO-DAPAGLIFLOZIN immediately** if you have any of the **DKA** symptoms. Do this even if your blood sugar levels are normal. The symptoms of **DKA** are: difficulty breathing, nausea, vomiting, stomach pain, and loss of appetite. Confusion, feeling thirsty, feeling unusually tired or sleepy, along with a sweet or metallic taste in the mouth or sweet smelling breath can be noticed. You may have a different odour to your urine or sweat.
- Do not use PRO-DAPAGLIFLOZIN if you have:
 - **DKA** or a history of **DKA**
 - Type 1 diabetes.

What is PRO-DAPAGLIFLOZIN used for?

- PRO-DAPAGLIFLOZIN is used along with diet and exercise to:
 - improve blood sugar levels in adults with type 2 diabetes. PRO-DAPAGLIFLOZIN can be used:
 - alone, if you cannot take metformin,
 - with metformin,
 - with a sulfonylurea,
 - with metformin and a sulfonylurea,
 - with sitagliptin (with or without metformin),
 - with insulin (with or without metformin).

- reduce the risk of hospitalization due to heart failure in adults:
 - with type 2 diabetes; and
 - that have or are at risk of developing cardiovascular disease (heart and blood vessel problems)
- PRO-DAPAGLIFLOZIN is used in adults along with other medicines to treat heart failure (when your heart cannot pump enough blood to your body). In these patients, PRO-DAPAGLIFLOZIN reduces the risk of:
 - death due to heart or blood vessel problems
 - hospitalization or urgent medical visits due to heart failure
- PRO-DAPAGLIFLOZIN is used in adults with chronic kidney disease to reduce their risk of:
 - further decline in kidney function
 - progression to end-stage kidney disease
 - death due to cardiovascular problems or kidney failure

How does PRO-DAPAGLIFLOZIN work?

PRO-DAPAGLIFLOZIN belongs to a class of medicines called Sodium-glucose co-transporter 2 (SGLT2) inhibitors. It removes excess sugar from the body through the urine. This reduces the amount of sugar in the blood. PRO-DAPAGLIFLOZIN also provides benefits to the heart and kidneys.

What are the ingredients in PRO-DAPAGLIFLOZIN?

Medicinal Ingredients: Dapagliflozin

Non-medicinal Ingredients: Anhydrous lactose, croscopovidone, ferric oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

PRO-DAPAGLIFLOZIN comes in the following dosage forms:

Tablets: 5 mg and 10 mg.

Do not use PRO-DAPAGLIFLOZIN if:

- you are allergic to dapagliflozin or to any of the other ingredients in PRO-DAPAGLIFLOZIN.
- you are on dialysis.

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

- have type 1 diabetes (your body does not produce any insulin). PRO-DAPAGLIFLOZIN should not be used in patients with type 1 diabetes.
- have an increased chance of developing diabetic ketoacidosis (DKA), including if you:
 - are dehydrated or suffer from excessive vomiting, diarrhea, or sweating
 - are on a very low carbohydrate diet
 - have been fasting for a while
 - are eating less, or there is a change in your diet
 - drink a lot of alcohol
 - have/have had problems with your pancreas, including pancreatitis or surgery on your pancreas
 - are hospitalized for major surgery, serious infection or serious medical illness. If you are going to have a surgery and after your surgery, or if you are hospitalized for a major surgery, a serious infection, or a serious medical illness, your healthcare professional may stop your treatment with PRO-DAPAGLIFLOZIN. Talk to your healthcare professional about when to stop taking PRO-DAPAGLIFLOZIN and when to start taking it again.
 - have a sudden reduction in your insulin dose
 - have a history of DKA.
- are older than 65 years of age
- have or have had any kidney problems
- have received immunosuppressive therapy (treatment that lowers the activity of your immune system) to treat your kidney problems.
- are on dialysis
- have or have had any cases of liver disease
- have low blood pressure
- have or have had heart disease or heart failure
- are taking a medicine to lower your blood pressure, including diuretics, known as water pills. If you take PRO-DAPAGLIFLOZIN with these medicines, it can increase the risk of dehydration.
- are taking medicines to lower your blood sugar. Tell your healthcare professional about all of the medicines you are taking to control your diabetes.
- have a history of yeast infection of the vagina or penis
- have a history of urinary tract infections
- have Anti-Neutrophil Cytoplasmic Antibody (ANCA)-associated vasculitis, which is an autoimmune disease affecting small blood vessels in the body
- have intolerance to some milk sugars. PRO-DAPAGLIFLOZIN tablets contain lactose.

Other warnings you should know about:

PRO-DAPAGLIFLOZIN can cause serious side effects, including:

- **Hypotension** (low blood pressure): This is common in patients with high blood sugar (glucose).
- **Hypoglycemia** (low blood sugar) **in patients with type 2 diabetes:** PRO-DAPAGLIFLOZIN can cause low blood sugar when used with other antidiabetic medications, including insulin. Your healthcare professional may adjust your dose of insulin or other antidiabetic medicines when taking PRO-DAPAGLIFLOZIN. This is to help you keep your blood sugar levels within the normal range during your treatment.
- **Yeast infection:** PRO-DAPAGLIFLOZIN increases your chance of getting a yeast infection of the vagina or penis, especially if you have had them in the past.
- **Urinary tract infection**
- **Urosepsis:** This is a severe infection that spreads from the urinary tract throughout the body. This condition is serious and may be life-threatening if left untreated. If you experience signs of this condition, **stop taking PRO-DAPAGLIFLOZIN right away and seek immediate medical help.**
- **Fournier's gangrene:** This is a serious infection affecting the soft tissue around the groin. Rare cases of Fournier's gangrene have been reported in patients with type 2 diabetes while taking SGLT2 inhibitors like PRO-DAPAGLIFLOZIN. This condition is serious and may be life threatening. If you experience signs of this condition, **stop taking PRO-DAPAGLIFLOZIN right away and seek immediate medical help.**
- **Kidney problems in patients with type 2 diabetes:** This may happen shortly after you start taking PRO-DAPAGLIFLOZIN.

See the Serious side effects and what to do about them table, below, for more information on these and other serious side effects.

Driving and using machines: Before doing tasks that require special attention, wait until you know how you respond to PRO-DAPAGLIFLOZIN. Dizziness, light-headedness, or fainting can occur, particularly when PRO-DAPAGLIFLOZIN is taken with insulin or other antidiabetic medicines.

Pregnancy: PRO-DAPAGLIFLOZIN should **not** be taken during pregnancy. It is not known if PRO-DAPAGLIFLOZIN will harm your unborn baby. If you discover that you are pregnant while taking PRO-DAPAGLIFLOZIN, **stop** the medication and contact your healthcare professional **as soon as possible.**

Breastfeeding: PRO-DAPAGLIFLOZIN should **not** be taken if you are breastfeeding. It is not known if dapagliflozin will pass into your breast milk and harm your baby. Talk to your

healthcare professional about ways to feed your baby if you are planning to breastfeed while taking PRO-DAPAGLIFLOZIN.

Children and adolescents: PRO-DAPAGLIFLOZIN is not to be used in children and adolescents under 18 years of age.

Check-ups and testing:

- Your healthcare professional may decide to perform tests before taking PRO-DAPAGLIFLOZIN and/or during treatment. These tests will check:
 - The amount of cholesterol (a type of fat) in your blood
 - The amount of red blood cells in your body
 - The amount of sugar (glucose) in your blood
 - That your kidneys are working properly
 - The volume of blood in your body
 - The level of electrolytes in your blood

Depending on your test results, your healthcare professional may adjust your dose, temporarily stop or discontinue your therapy with PRO-DAPAGLIFLOZIN.

- PRO-DAPAGLIFLOZIN will cause your urine to test positive for sugar (glucose).

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 PRO-DAPAGLIFLOZIN:

- medicines you take for diabetes to lower your blood sugar levels. This includes sulfonylurea medication such as glyburide, gliclazide or glimepiride, or insulin. If you take PRO-DAPAGLIFLOZIN with any of these medicines, it can increase the risk of low blood sugar. Your healthcare professional will tell you how much of each medicine to take.
- medicines used to lower your blood pressure, including diuretics, known as water pills. If you take PRO-DAPAGLIFLOZIN with these medicines, it can increase the risk of dehydration.
- Lithium. If you take PRO-DAPAGLIFLOZIN with lithium, it can lower the amount of lithium in your blood. Your doctor will tell you if your dose of lithium needs to be changed.

How to take PRO-DAPAGLIFLOZIN:

Take PRO-DAPAGLIFLOZIN:

- as directed by your healthcare professional
- once a day
- at any time of the day
- by mouth
- with or without food

Swallow tablet whole. Do not cut or divide PRO-DAPAGLIFLOZIN tablets.

Usual dose:

The dose of PRO-DAPAGLIFLOZIN prescribed to you will depend on your condition and your response to treatment.

Patients with type 2 diabetes

To control your blood sugar: the usual adult starting dose is one 5 mg tablet a day. Your healthcare professional may increase your dose to one 10 mg tablet a day, if needed.

To reduce your risk of hospitalization due to heart failure: the usual adult dose is one 10 mg tablet a day.

Patients with Heart Failure or Chronic Kidney Disease

The usual adult dose is one 10 mg tablet a day.

Overdose:

If you think you, or a person you are caring for, have taken too much PRO-DAPAGLIFLOZIN, contact a 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 PRO-DAPAGLIFLOZIN, take it as soon as you remember. If you do not remember until it is almost time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose.

What are possible side effects from using PRO-DAPAGLIFLOZIN?

These are not all the possible side effects you may feel when taking PRO-DAPAGLIFLOZIN. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- sore throat
- flu (fever, tiredness, body aches)
- stuffy or runny nose
- constipation
- diarrhea
- nausea

- back pain
- pain in the arms, legs, hands or feet
- headache
- rash
- joint pain

If any of these affects you severely, tell your healthcare professional.

PRO-DAPAGLIFLOZIN can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests. They will tell you if your test results are abnormal and if you need treatment to correct these side effects.

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			
Urinary tract infection: Pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine		✓	
Yeast infection of vagina: severe itching, burning, soreness, irritation, and a whitish or whitish-gray cottage cheese-like discharge	✓		
Yeast infection of penis: red, swollen, itchy head of penis, thick, lumpy discharge under foreskin, unpleasant odour, difficulty retracting foreskin, pain passing urine or during sex	✓		
UNCOMMON			
Volume depletion (loss of needed fluids from the body; dehydration): dry or sticky mouth, headache, dizziness or urinating less often than normal, thirst		✓	
Hypotension (low blood pressure): dizziness, fainting, light-headedness; may occur when you go from lying to sitting to standing up		✓	

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	
Hypoglycemia (low blood sugar) in patients with type 2 diabetes: shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood		✓	
RARE			
Diabetic ketoacidosis (DKA) in patients with type 2 diabetes: difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, feeling very thirsty, feeling unusual tiredness, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat			✓
Kidney problems in patients with type 2 diabetes: any change in the amount, frequency or colour (pale or dark) of urine		✓	
Fournier's gangrene (a serious infection affecting soft tissue around the groin): pain or tenderness, redness of the skin, or swelling in the genital or perineal area, with or without fever or feeling very weak, tired, or uncomfortable			✓
VERY RARE			
Acute kidney infection: painful, urgent or frequent urination, lower back (flank) pain, fever or chills, cloudy or foul smelling urine, blood in your urine			✓
Urosepsis (severe infection that spreads from urinary tract throughout body): fever or low body temperature, chills, rapid breathing, rapid heartbeat, pain with urination, difficulty urinating, frequent urination			✓
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen		✓	

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) 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 PRO-DAPAGLIFLOZIN out of reach and sight of children.

If you want more information about PRO-DAPAGLIFLOZIN:

- 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>); Or by contacting Pro Doc Ltée : 1-800-361-8559, www.prodoc.qc.ca, medinfo@prodoc.qc.ca.

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