

PART III: CONSUMER INFORMATION**Pr PRO-PIOGLITAZONE
(Pioglitazone Hydrochloride)**

This leaflet is part III of a three-part Product Monograph for PRO-PIOGLITAZONE that is designed specifically for Consumers. This leaflet summarizes medical information from the Product Monograph in commonly used terms. Not all scientific information is included. Contact your doctor or pharmacist if you have any questions about PRO-PIOGLITAZONE.

ABOUT THIS MEDICATION**What PRO-PIOGLITAZONE is used for:**

Your doctor has prescribed PRO-PIOGLITAZONE to treat type 2 diabetes, as an addition to diet and exercise, in order to improve your blood sugar control.

What Is Type 2 Diabetes?

Insulin is a hormone that the body makes to help use food for energy. There are two types of diabetes: in type 1 diabetes, the body stops producing insulin. In type 2 diabetes, the body does not respond to insulin as well as it should, and/or cannot make enough insulin on its own. When this happens, glucose (sugar) builds up in the blood. This can lead to serious medical problems, including kidney damage, eye damage, nerve damage, heart disease, or stroke. The main goal of diabetes treatment is to lower blood sugar to a normal level.

How Is Type 2 Diabetes Usually Controlled?

Treatment of type 2 diabetes must always include proper diet, exercise and weight control under the guidance of your physician.

What PRO-PIOGLITAZONE does:

PRO-PIOGLITAZONE is a member of a class of drugs that are insulin-sensitizing agents. PRO-PIOGLITAZONE helps your body respond better to its own insulin, thereby reducing blood sugar levels in the body. Because PRO-PIOGLITAZONE does not cause your body to produce more insulin, it rarely causes hypoglycemia (low blood sugar) when used alone. Even if you are taking PRO-PIOGLITAZONE, you should still exercise and follow the recommended nutritional plan for your diabetes.

When PRO-PIOGLITAZONE should not be used:

PRO-PIOGLITAZONE should not be used by patients who:

- have or have had heart problems or heart failure
- have serious liver damage
- are pregnant
- are allergic to pioglitazone hydrochloride or any other ingredients of PRO-PIOGLITAZONE.
- have or have had bladder cancer
- have blood or a red colour in their urine

What the medicinal ingredient is:

Pioglitazone hydrochloride

What the nonmedicinal ingredients are:

Carboxymethyl cellulose calcium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate.

What dosage forms it comes in:

Tablets: 15 mg, 30 mg and 45 mg.

WARNINGS AND PRECAUTIONS

Because PRO-PIOGLITAZONE works only in the presence of insulin, it should not be used if you have type 1 diabetes (when the pancreas does not produce insulin).

Serious side effects with PRO-PIOGLITAZONE include:

- Heart failure. Symptoms of heart failure include shortness of breath, weakness, tiredness, swelling (edema), or unusual weight gain
- Liver problems. Symptoms of liver problems include tiredness, lack of appetite, dark urine, yellowing of the skin or the white part of the eye
- Bladder cancer. Symptoms of bladder cancer include blood or a red colour in your urine, an increased need to urinate, or pain while you urinate

PRO-PIOGLITAZONE is not approved for use with metformin and a sulfonylurea, therefore PRO-PIOGLITAZONE should not be taken with metformin and a sulfonylurea.

PRO-PIOGLITAZONE is not approved for use with insulin therapy, therefore PRO-PIOGLITAZONE should not be taken with insulin.

Consult your doctor promptly during periods of stress, such as fever, trauma, infection or surgery, since your medication requirements may change during these times.

Fractures, usually in the hand, upper arm or foot, have been seen with PRO-PIOGLITAZONE use in women. Talk to your doctor about the risk of fracture.

Before or while taking PRO-PIOGLITAZONE, talk to your doctor or pharmacist if you:

- *have liver disease.* PRO-PIOGLITAZONE is not recommended in patients with liver disease.
- *are planning to become pregnant.* Only insulin should be used during pregnancy to maintain blood glucose levels as close to normal as possible.
- *are breastfeeding*
- *are a woman who has not reached menopause but have no menstrual periods.* You may become pregnant unless you use an effective method of birth control. PRO-PIOGLITAZONE, like other drugs in this class, may cause

- women with insulin resistance to ovulate again.
- *have edema (water retention)*

PRO-PIOGLITAZONE should not be used in children under 18 years of age.

INTERACTIONS WITH THIS MEDICATION

Drugs that interact with PRO-PIOGLITAZONE include:

Oral Contraception: Women using oral birth control pills should check with their doctor about the possible need to adjust the dose or use alternative methods of contraception when taking PRO-PIOGLITAZONE. Women should also inform their doctors of any changes in their monthly cycle.

PRO-PIOGLITAZONE may also interact with some other drugs such as gemfibrozil, rifampicin, nifedipine and atorvastatin calcium. Tell your doctor if you are taking these medicines.

PROPER USE OF THIS MEDICATION

Usual dose:

PRO-PIOGLITAZONE should be taken once daily without regard to meals. The initial dose is 15 or 30 mg once daily. Do not exceed 45 mg once daily.

Take your PRO-PIOGLITAZONE each day, as instructed by your doctor or pharmacist. PRO-PIOGLITAZONE can help you control your blood glucose levels only if you take it regularly. PRO-PIOGLITAZONE should generally be taken at the same time each day at whatever time you find most convenient to remember.

Your doctor has prescribed PRO-PIOGLITAZONE specifically for you. Do not give your medicine to anyone else, even if they have a similar condition.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose of PRO-PIOGLITAZONE, do not take a double dose to make up for the missed dose. Take your dose at the regular time on the following day.

Monitoring:

- *Fasting blood glucose:* Test your blood sugar levels with your personal glucose meter as often as your doctor recommends.
- *Glycosylated hemoglobin (HbA1c):* This blood test is done periodically to determine the average control of your blood sugar levels.
- *Liver Enzymes:* Your doctor may recommend a blood test to monitor your liver function before you start PRO-PIOGLITAZONE and may repeat this test occasionally while you take PRO-PIOGLITAZONE.

- *Eye:* should be checked regularly. Rarely, some patients have experienced vision changes due to swelling in the back of the eye while taking PRO-PIOGLITAZONE

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The following side effects have been commonly reported with pioglitazone hydrochloride (could affect up to 1 in 10 patients):

- Edema (fluid retention or swelling) which could lead to heart failure. If you notice swelling in extremities (arms and legs, hands and feet), unusually rapid increase in weight, tiredness, trouble breathing or shortness of breath, call your doctor. These symptoms, although not specific, may signal heart problems or heart failure.
- Low blood sugar (hypoglycemia): Dizziness, lack of energy, drowsiness, headache, trembling, sweating, or hunger may mean that your blood sugar is too low. This can happen if you skip meals, drink alcohol, use another medicine that lowers blood sugar, exercise (particularly hard or long), or if you have certain medical problems. Call your doctor if you feel that your symptoms of low blood sugar are uncomfortable. If you are using PRO-PIOGLITAZONE by itself, there is less risk of having low blood sugar.
- Increased weight. Tell your doctor if you gain a lot of weight in a short period of time.

The following side effects have been reported rarely with pioglitazone hydrochloride (could affect up to 1 in 1000 patients):

- Liver problems. If you experience nausea, vomiting, stomach pain, lack of appetite, tiredness, dark urine, or yellowing of the skin, stop taking PRO-PIOGLITAZONE and call your doctor right away.
- Breakthrough bleeding (unexpected vaginal bleeding or spotting) while using oral contraceptives, or generally, if you experience any symptoms that persist or become troublesome, these should be discussed with your doctor.
- Blurred vision due to swelling (or fluid) in the back of the eye.
- Fractures, usually in the hand, upper arm or foot, have been seen with PRO-PIOGLITAZONE use in women. Talk to your doctor about the risk of fracture.
- Bladder cancer. If you experience blood or a red colour in your urine, an increased need to urinate, or pain while you urinate, stop taking PRO-PIOGLITAZONE and call your doctor right away.

The following side effects have been reported very rarely with pioglitazone hydrochloride (could affect up to 1 in 10,000 patients):

- Heart failure or pulmonary edema (fluid accumulation in the lungs). Symptoms of heart failure include shortness of breath, getting tired easily after light physical activity such as walking, waking up short of breath at night and swollen ankles or feet. Symptoms of fluid in the lungs are breathlessness, which may be very severe and usually

worsens on lying down. Stop taking PRO-PIOGLITAZONE and call your doctor right away if you experience these symptoms.

- Anemia (low red blood cell count) which may make you feel very weak or tired.
- Swelling of the face, lips, mouth, tongue or throat (which may cause difficulty in swallowing or breathing); hives or rash (which may be itchy). Stop taking PRO-PIOGLITAZONE and call your doctor right away if you experience these symptoms.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor		Stop taking PRO-PIOGLITAZONE and call your doctor immediately
		Only if severe	In all cases	
Common	Fluid retention or swelling in extremities (arms and legs, hands and feet)		√	
Common (when taken with other antidiabetic medicines)	Low blood sugar (hypoglycemia): Dizziness, lack of energy, drowsiness, headache, trembling sweating, hunger	√		
Rare	Liver problems: nausea, vomiting, stomach pain, lack of appetite, tiredness, dark urine, or yellowing of the skin			√
	Blurred vision or decreased vision [which may be due to swelling (or fluid) in the back of the eye]			√
	Fractures, usually in the hand, upper arm or foot, in women		√	
	Bladder cancer: blood or red colour in urine, increased need to urinate, pain while you urinate			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor		Stop taking PRO-PIOGLITAZONE and call your doctor immediately
	Only if severe	In all cases	
Very rare			√
Heart failure or fluid in the lungs (pulmonary edema): trouble breathing or shortness of breath, getting tired easily after light physical activity, unusual tiredness, waking up short of breath at night, swollen ankles or feet, unusually rapid increase in weight			
Allergic reactions: swelling of the face, lips, mouth, tongue or throat (may cause difficulty in swallowing or breathing), hives or rash			√

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

HOW TO STORE IT

Store PRO-PIOGLITAZONE tablets between 15°C and 30°C. Keep container tightly closed. Protect from moisture.

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 0701E
Ottawa, Ontario
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 Pro Doc Ltée at 1-800-361-8559,

<http://www.prodoc.qc.ca> or info@prodoc.qc.ca .

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