

PART III: CONSUMER INFORMATION

Pr **PRO-DUTASTERIDE**
Dutasteride Capsules

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

ABOUT THIS MEDICATION

What the medication is used for:

PRO-DUTASTERIDE is used alone (monotherapy) in the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with enlarged prostates.

PRO-DUTASTERIDE is also used in combination with the alpha blocker, tamsulosin, in the treatment of moderate to severe symptomatic BPH in men with enlarged prostates. Combination therapy was also shown to be better than tamsulosin, but not dutasteride at reducing the risk of acute urinary retention (or where patient suddenly cannot urinate at all) and/or the need for BPH related surgery.

PRO-DUTASTERIDE is not approved for use in the prevention of prostate cancer.

What it does:

Prostate growth is caused by a hormone in the blood called dihydrotestosterone (DHT). PRO-DUTASTERIDE belongs to a group of medicines called 5 alpha-reductase enzyme inhibitors. PRO-DUTASTERIDE lowers DHT production in the body, leading to a shrinkage of the enlarged prostate in most men, which leads to improvements in BPH symptoms and improved urinary flow, reduced risk of acute urinary retention (or where patient suddenly cannot urinate at all), and reduced risk of the need for BPH related surgery.

PRO-DUTASTERIDE is also used with another medicine called tamsulosin, an alpha blocker, which acts by relaxing smooth muscle in the prostate and bladder neck at the site of obstruction, resulting in improvements in BPH symptoms and improved urinary flow.

Symptoms of BPH may be seen to improve after 3 months of treatment with PRO-DUTASTERIDE, however, it may take up to 6 months to know if treatment with PRO-DUTASTERIDE will be beneficial.

When it should not be used:

- Women and children should never take PRO-DUTASTERIDE.
- Do not take PRO-DUTASTERIDE if you are allergic to dutasteride or other alpha-reductase inhibitors or any of the other ingredients of PRO-DUTASTERIDE.

What the medicinal ingredient is:
dutasteride

Pro Doc

What the nonmedicinal ingredients are:

Nonmedicinal ingredients in your medicine include butyl hydroxytoluene (BHT), gelatin, glycerol, glycerol monocaprylocaprate, lecithin (soya), triglycerides (medium chain), purified water, titanium dioxide and yellow iron oxide.

What dosage forms it comes in:

Soft gelatin capsules. Each capsule contains 0.5 mg of dutasteride.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- **PRO-DUTASTERIDE is for use by men only.**
- **Women who are pregnant, or who may become pregnant, should not handle PRO-DUTASTERIDE as it may pass through the skin. PRO-DUTASTERIDE may affect the normal development of the external genital organs in a male baby.**

Heart failure (the heart does not pump blood as well as it should) was reported more often in patients taking dutasteride and an alpha-blocker, tamsulosin, in clinical studies than in patients taking dutasteride. It is not known if taking dutasteride and an alpha-blocker caused heart failure.

BEFORE you use PRO-DUTASTERIDE talk to your doctor or pharmacist if:

- You have or have had liver problems
- You have or have had prostate cancer or urinary tract disease

What are the special precautions about PRO-DUTASTERIDE?

- **Do not donate blood while taking PRO-DUTASTERIDE and for at least 6 months after you have stopped taking PRO-DUTASTERIDE** in order to prevent giving PRO-DUTASTERIDE to a pregnant woman through blood transfusion.
- In a clinical study of men aged 50 to 75 years with a recent negative biopsy for prostate cancer and an increased prostate specific antigen (PSA) blood test, men taking dutasteride had a serious form of prostate cancer more often than men who did not take dutasteride.

You must see your doctor regularly. While taking PRO-DUTASTERIDE you must have regular checkups, including digital rectal examination and PSA examination. Follow your doctor's advice about when to have these checkups.

Checking for prostate cancer

A man can have BPH and prostate cancer at the same time. Prior to treatment with PRO-DUTASTERIDE, you should have a thorough urological evaluation to determine the severity of your

condition, and to rule out the need for immediate surgery or the possibility of prostate cancer.

About Prostate Specific Antigen (PSA)

If a doctor asks you to have a Prostate Specific Antigen (PSA) test which is used for screening prostate cancer, you should tell your doctor that you are taking PRO-DUTASTERIDE. PRO-DUTASTERIDE can lower the PSA test result. A low PSA level may give you a false sense of security about your risk for prostate cancer. Your doctor is aware of this effect and can still use PSA to see if you might have prostate cancer. Increases in your PSA levels while on treatment with PRO-DUTASTERIDE (even if the PSA levels are in the normal range) should be evaluated by your doctor.

INTERACTIONS WITH THIS MEDICATION

Interactions with other medicines

Some medicines can react with PRO-DUTASTERIDE and may make it more likely that you will have side effects. Some of these medicines may include:

- Verapamil or diltiazem (for high blood pressure)
- Ritonavir (for HIV)
- Ketaconazole (for fungal infections)
- Ciprofloxacin or troleandomycin (for bacterial infections)
- Cimetidine (for heart burn)
- Certain herbal medicines such as St. John’s Wort or Milk Thistle

Make sure your doctor knows if you are taking any of these, or other medicines. Your dose of PRO-DUTASTERIDE may need to be reduced. Remember to include all medicines, herbal remedies or dietary supplements, such as vitamins, iron or calcium, which you have bought yourself without a prescription.

Do not eat grapefruit or drink grapefruit juice while taking PRO-DUTASTERIDE. This drink is known to increase the blood levels of some drugs in the body.

PROPER USE OF THIS MEDICATION

Always take PRO-DUTASTERIDE exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Usual dose:

Monotherapy: One PRO-DUTASTERIDE 0.5 mg capsule once a day.

Combination therapy: One PRO-DUTASTERIDE 0.5 mg capsule once a day with one tamsulosin 0.4 mg once a day.

- Swallow the capsule whole. DO NOT chew or open the capsules. Contact with the contents of the capsules may make your mouth or throat sore.
- The capsules can be taken with or without food.

Do not share your medication with others.

Overdose:

If you think you, or a person you are caring for, have taken too much PRO-DUTASTERIDE, 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, you can just take the next scheduled dose. Don’t take any extra capsules to make up for doses you forgot to take.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects of PRO-DUTASTERIDE, taken alone or in combination with tamsulosin, are not being able to achieve or maintain an erection* (impotence), decrease in libido* (decreased desire to have sex or a reduced sex drive), changes or problems with ejaculations* (including a decrease in amount of semen released during sex) and breast swelling or tenderness.

If breasts swelling or tenderness becomes troublesome, or if you notice breast lumps or nipple discharge, you should talk to your doctor about these changes. Additionally, some people may experience dizziness when taking PRO-DUTASTERIDE with tamsulosin.

Rare side effects (may affect up to 1 in 1,000 people) of hair loss (usually from the body) or abnormal hair growth have been reported.

Very rare side effects (1 in 10,000 people) of allergic reactions, depressed mood, and pain and swelling in the testicles have been reported.

Breast cancer has been reported in patients taking dutasteride however, the relationship between long-term use of dutasteride and breast cancer is not known.

**In a small number of people some of these events may continue after you stop taking PRO-DUTASTERIDE.*

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

Symptom / effect	Talk to your doctor or pharmacist		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Very Rare	Allergic Reactions: Sudden wheeziness or chest tightness		√

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

Symptom / effect		Talk to your doctor or pharmacist		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
	Swelling of eyelids, face or lips			√
	Lumpy skin rash or “hives” anywhere on the body			√

If you notice these side effects and any other side effects not mentioned in this leaflet, tell your doctor or pharmacist.

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

HOW TO STORE IT

- Store PRO-DUTASTERIDE between 15°C and 30°C in the original container to protect from moisture.
- Keep out of the reach and sight of children.
- Return any cracked or leaking capsules to your pharmacist for replacement.
- Return any unused capsules to a pharmacist

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.

MORE INFORMATION

If you want more information about PRO-DUTASTERIDE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer 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 Pto Doc Ltee : 1 800 361-8559, medinfo@prodoc.qc.ca, www.prodoc.qc.ca.

This leaflet was prepared by Pro Doc Ltee, Quebec, Canada.

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