

PART III: CONSUMER INFORMATION**PrDUTASTERIDE
Dutasteride Capsules**

This leaflet is part III of a three-part “Product Monograph” published when 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 DUTASTERIDE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

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

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.

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). DUTASTERIDE belongs to a group of medicines called 5 alpha-reductase enzyme inhibitors.

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.

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 DUTASTERIDE, however, it

may take up to 6 months to know if treatment with DUTASTERIDE will be beneficial.

When it should not be used:

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

What the medicinal ingredient is:

Dutasteride

What the important nonmedicinal ingredients are:

Butylated hydroxytoluene, gelatin, glycerine, mono- and di-glycerides of caprylic/capric acids, purified water, titanium dioxide and yellow ferric oxide, and red printing ink containing iron red oxide as the colourant.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

- **DUTASTERIDE is for use by men only**
- **Women who are pregnant, or who may become pregnant, should not handle DUTASTERIDE as it may pass through the skin. 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 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 DUTASTERIDE?

- **Do not donate blood while taking DUTASTERIDE and for at least 6 months after you have stopped taking DUTASTERIDE** in order to prevent giving 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,

IMPORTANT: PLEASE READ

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 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 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 DUTASTERIDE.

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 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 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).
- Ketoconazole (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 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 DUTASTERIDE. This drink is known to increase the blood levels of some drugs in the body.

PROPER USE OF THIS MEDICATION

Always take DUTASTERIDE exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Usual dose:

Monotherapy: One DUTASTERIDE 0.5 mg capsule once a day.

Combination therapy: One 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:

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, 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 dutasteride capsules, 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 dutasteride capsules with tamsulosin.

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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 capsules however, the relationship between long-term use of dutasteride capsules and breast cancer is not known.

**In a small number of people some of these events may continue after you stop taking dutasteride capsules.*

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 seek immediate and emergency medical attention
		Only if severe	In all cases	
Very Rare	<u>Allergic Reactions:</u>			
	Sudden wheeziness or chest tightness			✓
	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 dutasteride capsules, contact your doctor or pharmacist.

HOW TO STORE IT

- Store DUTASTERIDE capsules at room temperature 15°C - 30°C (59°F-86°F).
- 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 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

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting Sanis Health Inc. at: 1-866-236-4076, or by email: quality@sanis.com.

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