

Important Please Read

PART III: CONSUMER INFORMATION

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FINASTERIDE
Finasteride Tablets

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

ABOUT THIS MEDICATION

FINASTERIDE IS FOR USE BY MEN ONLY.

What the medication is used for:

FINASTERIDE is used to treat symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate. FINASTERIDE may also be used to reduce the risk of developing sudden inability to pass urine and the need for surgery.

FINASTERIDE is not approved for the prevention of prostate cancer.

What it does:

FINASTERIDE lowers levels of a key hormone called DHT (dihydrotestosterone), which is a major cause of prostate growth. Lowering DHT leads to shrinkage of the enlarged prostate gland in most men. This can lead to gradual improvement in urine flow and symptoms over the next several months. FINASTERIDE will help reduce the risk of developing a sudden inability to pass urine (acute urinary retention) and the need for surgery.

When it should not be used:

Do not take FINASTERIDE if you think you are allergic to any of its ingredients.

Women and children should not take FINASTERIDE. Women who are or may potentially be pregnant must not use FINASTERIDE (see WARNINGS AND PRECAUTIONS, Pregnancy).

What the medicinal ingredient is:

finasteride

What the important nonmedicinal ingredients are:

lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium lauryl sulfate, sodium starch glycolate and opadry blue (hypromellose, polyethylene glycol,

titanium dioxide, FD&C Blue #2 Indigo Carmine Aluminum Lake 11%-14%).

What dosage forms it comes in:

Each tablet of FINASTERIDE contains 5 mg of finasteride.

WARNINGS AND PRECAUTIONS

Pregnancy: Women who are or may potentially be pregnant must not use FINASTERIDE. They should also not handle crushed or broken tablets of FINASTERIDE. If the active ingredient in FINASTERIDE is absorbed after oral use or through the skin by a woman who is pregnant with a male baby, it may cause the male baby to be born with abnormalities of the sex organs.

FINASTERIDE tablets are coated and will prevent contact with the active ingredient during normal handling provided that the tablets are not broken or crushed. If a woman who is pregnant comes into contact with the active ingredient in FINASTERIDE, a physician should be consulted.

You must see your physician regularly while taking FINASTERIDE.

Follow your physician's advice about when to have these checkups.

About Prostate Specific Antigen (PSA). Your physician may have done a blood test called PSA for the screening of prostate cancer. FINASTERIDE can alter PSA values. You should tell your physician that you are taking FINASTERIDE. For more information, talk to your physician.

FINASTERIDE may increase the chance of a more serious form of prostate cancer.

INTERACTIONS WITH THIS MEDICATION

Tell your physician or pharmacist about all the medicines you take. This includes prescription and non-prescription medicines, and herbal supplements.

PROPER USE OF THIS MEDICATION

Take FINASTERIDE as your physician has prescribed.

Usual dose:

5 mg tablet once daily with or without food.

Missed dose:

If you miss a dose, do not take an extra one. Just take the next tablet as usual.

Important Please Read

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medicine, FINASTERIDE may cause side effects. Side effects due to FINASTERIDE may include:

- impotence (an inability to have an erection)
- less desire to have sex.
- problems with ejaculation, such as a decrease in the amount of semen released during sex.

In addition, some men may have breast swelling and/or tenderness.

Some men have also reported the following:

- allergic reactions such as rash, itching, hives, swelling of the lips, tongue, throat and face
- testicular pain
- an inability to have an erection that continued after stopping the medication
- muscle injury, muscle pain, muscle weakness, abnormal test results (CK elevation)
- problems with ejaculation that continued after stopping the medication
- male infertility and/or poor quality of semen. Improvement in the quality of semen has been reported after stopping the medication.
- depression
- decrease in sex drive that continued after stopping the medication.

In rare cases, male breast cancer has been reported.

You should promptly report to your physician any changes in your breasts such as lumps, pain or nipple discharge.

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

Symptoms / Effects	Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
	Only if severe	In all cases	
Rare	Allergic reactions including rash, hives, swelling of the lips, tongue, throat and face.		√

This is not a complete list of side effects. For any unexpected effects while taking FINASTERIDE, contact your physician or pharmacist.

HOW TO STORE IT

Store at temperature (15°C -30°C) and protect from light.

KEEP FINASTERIDE AND ALL MEDICINES OUT OF THE REACH OF CHILDREN.

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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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 of side effects. The Canada Vigilance Program does not provide medical advice.*

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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