

PART III: CONSUMER INFORMATION**PrFINASTERIDE**

Finasteride Tablets, House Standard

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 for the treatment of male pattern hair loss (also known as androgenetic alopecia).

What it does

FINASTERIDE blocks an important enzyme (Type II 5-alpha-reductase) involved in the regulation of the hair follicle and lowers the levels of dihydrotestosterone (DHT) in the scalp, a major cause of male pattern hair loss.

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. Do not take FINASTERIDE if you are or may potentially be pregnant (see WARNINGS AND PRECAUTIONS, Pregnancy).

What the medicinal ingredient is

Finasteride

What the non-medicinal ingredients are

Docusate sodium, Hydroxypropyl Cellulose, Hypromellose, Iron Oxide Red, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch, Sodium Starch Glycolate, Talc, Titanium Dioxide and Yellow Iron Oxide.

What dosage form it comes in

Tablets (film-coated): 1 mg

WARNINGS AND PRECAUTIONS

BEFORE you use FINASTERIDE talk to your physician or pharmacist about any medical problems you have or have had, especially liver disease, and about any allergies.

Finasteride 5 mg (5 times the dose of FINASTERIDE for treatment

of male pattern hair loss) may increase the chance of a more serious form of prostate cancer.

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.

INTERACTIONS WITH THIS MEDICATION

FINASTERIDE usually does not interfere with other medicines. However, you should always tell your physician about all medicines you are taking or plan to take, including those obtained without prescription.

FINASTERIDE can affect a blood test called PSA (prostate-specific antigen) used for the screening of prostate cancer. If you have a PSA test done, you should tell your physician that you are taking FINASTERIDE.

PROPER USE OF THIS MEDICATION

Take FINASTERIDE as your physician has prescribed.

Usual dose

Take one tablet of FINASTERIDE every day, with or without food.

Missed Dose

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

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.

When can I expect to see results from using FINASTERIDE?

Male pattern hair loss is a condition that develops over a long period of time. On average, healthy hair grows only about 1 cm each month. Therefore, it will take time to see any effect. In general, daily use for three months or more may be necessary before you notice that hair growth is increased, or further hair loss is prevented.

How long do I need to use FINASTERIDE?

FINASTERIDE can only work over the long-term if you continue taking it.

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medicine, FINASTERIDE may cause side effects.

Common side effects:

- less desire to have sex;
- difficulty in achieving an erection;
- problems with ejaculation, such as a decrease in the amount of semen released during sex (this does not appear to interfere with normal sexual function).

In clinical studies, these side effects disappeared in men who stopped taking FINASTERIDE and in most men who continued treatment.

In general use, the following have been reported infrequently:

- breast enlargement (swelling) and/or tenderness;
- depression;
- decrease in sex drive that continued after stopping the medication;
- allergic reactions including rash, itching, hives, and swelling of the lips, tongue, throat and face;
- muscle injury, muscle pain, muscle weakness, abnormal test results (CK elevation);
- problems with ejaculation that continued after stopping the medication;
- testicular pain;
- blood in semen
- difficulty in achieving an erection 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;
- male breast cancer.

Talk to your doctor about any changes in your breast such as lumps, pain or nipple discharge. Tell your physician or pharmacist promptly about these or any other unusual symptoms.

HOW TO STORE IT

Store between 15°C and 30°C and protect from light. Keep blister in the outer carton until all tablets are used.

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 (<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

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor, Sanis Health Inc., at:

1-866-236-4076
or quality@sanis.com

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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 call your doctor or pharmacist
		Only if severe	In all cases	
Rare	Allergic reactions including rash, hives, and swelling of the lips, tongue, throat and face			✓

PART III: CONSUMER INFORMATION**Pr FINASTERIDE
Finasteride Tablets, USP**

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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 a sudden inability to pass urine and the need for surgery. Your physician may prescribe FINASTERIDE along with another medicine, called doxazosin (an alpha-blocker), to help you better control your BPH symptoms.

If your physician has prescribed doxazosin as well, please read the patient information provided for this product too.

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 non-medicinal ingredients are

Docusate sodium, FD& C Blue #2 Aluminum Lake, Hydroxypropyl Cellulose, Hypromellose, Lactose Monohydrate,

Magnesium Stearate, Microcrystalline Cellulose; Pregelatinized Starch, Sodium Starch Glycolate, Talc, Titanium Dioxide, and Yellow Iron Oxide.

What dosage forms it comes in

Tablets (film-coated): 5 mg.

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.

Combination therapy of FINASTERIDE and doxazosin may increase the chances of dizziness, postural hypotension (dizziness upon standing), weakness, impotence and abnormal ejaculation.

PROPER USE OF THIS MEDICATION

Take FINASTERIDE as your physician has prescribed.

Usual dose

5 mg tablet once daily by mouth with or without food.

Missed dose

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

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;
- blood in semen;
- 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 doctor or pharmacist		Stop taking drug and call your doctor 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 between 15°C and 30°C. Protect from light to prevent discoloration.

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 (<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

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