

PART III: CONSUMER INFORMATION

PROPECIA[®]
Finasteride tablets, USP

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

ABOUT THIS MEDICATION

PROPECIA[®] IS FOR USE BY MEN ONLY.

What the medication is used for:

PROPECIA[®] is used for the treatment of male pattern hair loss (also known as androgenetic alopecia).

What it does:

PROPECIA[®] 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 PROPECIA[®] if you think you are allergic to any of its ingredients.

Women and children should not take PROPECIA[®]. Do not take PROPECIA[®] if you are or may potentially be pregnant (see WARNINGS AND PRECAUTIONS, Pregnancy).

What the medicinal ingredient is:

finasteride

What the important nonmedicinal ingredients are:

docusate sodium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, methylhydroxypropylcellulose, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, talc, titanium dioxide, red ferric oxide and yellow ferric oxide.

What dosage form it comes in:

Each film-coated tablet of PROPECIA[®] contains 1 mg of finasteride.

WARNINGS AND PRECAUTIONS

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

PROSCAR[®] (finasteride at 5 times the dose of PROPECIA[®]) may increase the chance of a more serious form of prostate cancer.

Pregnancy

Women who are or may potentially be pregnant must not use PROPECIA[®]. They should also not handle crushed or broken tablets of PROPECIA[®]. If the active ingredient in PROPECIA[®] 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. PROPECIA[®] 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 PROPECIA[®], a physician should be consulted.

INTERACTIONS WITH THIS MEDICATION

PROPECIA[®] 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.

PROPECIA[®] 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 PROPECIA[®].

PROPER USE OF THIS MEDICATION

Take PROPECIA[®] as your physician has prescribed.

Usual dose: Take one tablet of PROPECIA[®] 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 PROPECIA[®]?

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 PROPECIA[®]?

PROPECIA[®] can only work over the long term if you continue taking it.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medicine, PROPECIA® 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 PROPECIA® 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.

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

Symptom/effect		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, and swelling of the lips, tongue, throat and face			✓

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

HOW TO STORE IT

Store PROPECIA® in a dry place at room temperature (15 °C-30 °C) and protect from moisture. Keep blister in the outer carton until all tablets are used.

KEEP PROPECIA® AND ALL MEDICINES OUT OF THE REACH OF CHILDREN.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect.ca;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.ca.

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 PROPECIA®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information (or Consumer Information)* by visiting the [Health Canada website](http://HealthCanada.ca) or Merck Canada website www.merck.ca or by calling Merck Canada at 1-800-567-2594

To report an adverse event related to PROPECIA®, please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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