

PART III: CONSUMER INFORMATION


PROSCAR[®]
 Finasteride tablets, USP

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

ABOUT THIS MEDICATION

PROSCAR[®] IS FOR USE BY MEN ONLY.

What the medication is used for:

PROSCAR[®] is used to treat symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate. PROSCAR[®] 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 PROSCAR[®] 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.

PROSCAR[®] is not approved for the prevention of prostate cancer.

What it does:

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

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

What the medicinal ingredient is:

finasteride

What the important nonmedicinal ingredients are:

cellulose and cellulose derivatives, coloring agents (FD&C blue 2 aluminum lake, titanium dioxide, yellow ferric oxide), corn starch, docusate sodium, lactose, magnesium stearate, sodium starch glycolate and talc.

What dosage forms it comes in:

Each film coated tablet of PROSCAR[®] contains 5 mg of finasteride.

WARNINGS AND PRECAUTIONS

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

You must see your physician regularly while taking PROSCAR[®]. 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. PROSCAR[®] can alter PSA values. You should tell your physician that you are taking PROSCAR[®]. For more information, talk to your physician.

PROSCAR[®] 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 PROSCAR[®] and doxazosin may increase the chances of dizziness, postural hypotension (dizziness upon standing), weakness, impotence and abnormal ejaculation.

PROPER USE OF THIS MEDICATION

Take PROSCAR[®] 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, PROSCAR® may cause side effects. Side effects due to PROSCAR® 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;
- changes in mood, which can include suicidal thoughts.

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 PROSCAR®, contact your physician or pharmacist.

HOW TO STORE IT

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

KEEP PROSCAR® 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](#);
- 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](#).

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 PROSCAR®:

- 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](#) or Organon Canada website www.organon.ca or by calling Organon Canada at 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

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