

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PROSCAR®

Finasteride tablets

Read this carefully before you start taking **PROSCAR®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PROSCAR**.

What is PROSCAR used for?

PROSCAR is used in adults to:

- treat and control symptoms of Benign Prostatic Hyperplasia (BPH). BPH is a condition in men in which the prostate gland is enlarged. PROSCAR can also be taken with doxazosin (an alpha blocker) to reduce symptoms related to BPH.
- reduce the risk of urinary system problems, such as:
 - a sudden inability to pass urine
 - the need for surgery (the removal of part or all of the prostate gland).

PROSCAR is not approved for the prevention of prostate cancer.

How does PROSCAR work?

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 other symptoms related to BPH.

What are the ingredients in PROSCAR?

Medicinal ingredient: finasteride

Non-medicinal ingredients: 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.

PROSCAR comes in the following dosage forms:

Tablet 5 mg

Do not use PROSCAR if:

- you are allergic to finasteride, any ingredient in PROSCAR or component of its container.
- are a woman or child. Women who are or may potentially be pregnant must not use PROSCAR.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PROSCAR. Talk about any health conditions or problems you may have.

Other warnings you should know about

Monitoring and testing

- PROSCAR may increase your chance of a more serious form of prostate cancer. You may undergo a blood test called Prostate-Specific Antigen (PSA) test. The PSA test is for the screening of prostate cancer. PROSCAR can alter PSA values. If you have a PSA test done, you should tell the healthcare professional administering the test that you are taking PROSCAR.
- Your healthcare professional will check your PSA levels at least six months after you begin treatment and periodically after.
- You should monitor your breasts regularly. Speak to your healthcare provider immediately if you notice any changes. This may include lumps, pain or nipple discharge, breast enlargement, and tenderness.

Pregnancy

- Women who are or may be pregnant must not use PROSCAR.
- They should also not handle crushed or broken tablets of PROSCAR. A male baby may be harmed if a pregnant woman is exposed to the medicinal ingredient in PROSCAR. It may cause the male baby to be born with abnormalities of the sex organs. A pregnant woman may be exposed if absorbed through the skin. PROSCAR tablets are coated to prevent contact with the medicinal ingredient during normal handling (i.e. tablets are not broken or crushed).
- Speak to a healthcare professional if a pregnant woman comes into contact with the active ingredient in PROSCAR.

Behaviour and mood changes

- There have been reports that PROSCAR may cause changes in mood including extreme sadness (depression), injuries from hurting yourself on purpose (self-harm injury), and thoughts of suicide (suicidal ideation). These mental health problems may continue even after you stop treatment.
- Tell your healthcare professional if you have had these behaviour and mood changes before. They should check your mental health before, during and after your treatment with PROSCAR.
- If you feel sad, want to hurt yourself, or end your own life or if others around you notice changes in your behaviour, get medical help right away.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

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

How to take PROSCAR:

- Take PROSCAR exactly as your healthcare professional has prescribed.
- Take by mouth with or without food.

Usual dose:

Take one 5 mg tablet once a day.

Overdose:

If you think you, or a person you are caring for, have taken too much PROSCAR, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you missed a dose of this medication, you do not need to make up the missed dose. Skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

What are possible side effects from using PROSCAR?

These are not all the possible side effects you may have when taking PROSCAR. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- blood in semen;
- breast swelling and/or tenderness;
- impotence (an inability to have an erection);
- less desire to have sex;
- male infertility;
- muscle injury, muscle pain, muscle weakness, abnormal test results (CK elevation);
- problems with ejaculation that continued after stopping the medication;
- problems with ejaculation, such as a decrease in the amount of semen released during sex;
- testicular pain.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Behaviour and mood changes: a sad mood that gets worse or doesn't go away, extreme sadness (depression)		✓	
Self-harm behaviours: injuries from deliberately hurting oneself (self-harm), thought of ending one's life (suicidal ideation)			✓
RARE			
Allergic reactions: hives, itching, rash, and swelling of the lips, tongue, throat and face			✓
Male breast changes: lumps, pain or nipple discharge		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.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.

Storage:

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

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 Patient Medication Information by visiting the Health Canada website <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.organon.ca, or by calling 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

Last Revised NOV 24, 2023

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