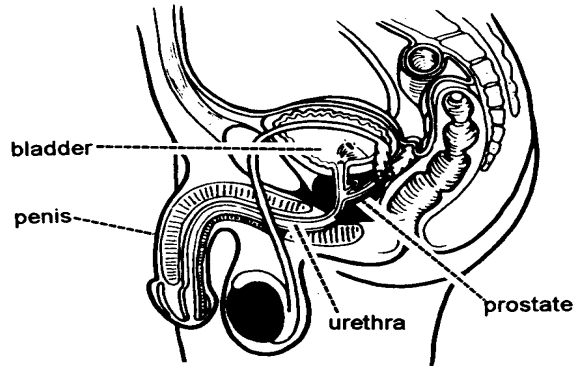


# PROSCAR<sup>®</sup> TABLET

Finasteride (5 mg)

## What is in this leaflet

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2. How Proscar works
3. Before you take Proscar
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## What Proscar is taken for

Why your doctor prescribed Proscar?

Your doctor has prescribed Proscar because you have a benign prostatic hyperplasia or BPH. Your prostate gland, which is near your bladder, has become bigger and is making it more difficult for you to pass urine.

### What is the prostate?

The prostate is a walnut-sized gland found only in men. It is located below the bladder and it surrounds the urethra, a tube that carries urine from the bladder out through the tip of the penis (see diagram). The prostate's main function is to produce fluid for semen, the fluid that carries sperm.

## How Proscar works

Proscar is a 5-alpha reductase inhibitor. It shrinks the enlarged prostate gland and relieves urinary symptoms. Proscar will help reduce the risk of developing a sudden inability to pass urine (acute urinary retention) and the need for surgery.

## Before you take Proscar

### What is BPH?

BPH is a benign enlargement of the prostate gland which is common in men over 50 years old. Because the prostate is close to the bladder and surrounds part of the urethra, its enlargement may affect your ability to urinate. You may experience symptoms such as a need to urinate often, especially at night, a feeling that you must urinate right away, difficulty in starting to urinate, a weak or interrupted urinary stream, or a feeling that you cannot empty your bladder completely.

In some men, BPH can lead to serious problems, including urinary tract infections, a sudden inability to pass urine, as well as the need for surgery. For this reason, a man with symptoms of BPH should see his physician.

### - When you must not take it

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

The condition for which Proscar is prescribed occurs only in men. Women and children should not take Proscar.

### - Before you start to take it

BPH develops over a long period of time. Some people show early improvement in symptoms, but you may need to take Proscar for at least six months to see if it improves your symptoms. Whether or not you notice any improvement or change in symptoms, therapy with Proscar may reduce your risk for a sudden inability to pass urine and the need for surgery. You must visit your doctor regularly for periodic checkups and evaluation of your progress.

Although BPH is not cancer and does not lead to cancer, the two conditions can exist at the same time. Only a doctor can evaluate your symptoms and their possible causes.

Proscar can affect a blood test called Prostate-Specific Antigen (PSA). If you have a PSA test done, tell your doctor that you are taking Proscar.

Tell your doctor before taking Proscar about any medical problems you have or have had, about any allergies or any such conditions:

- severely decreased urine flow
- liver problems

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## - Taking other medicines

Proscar usually does not interfere with other medicines. However, you must tell your doctor about all medicines you are taking or plan to take, including those obtained without prescription.

## **How to take Proscar**

### - How much to take

Take one tablet of Proscar every day, with or without food. Follow your doctor's advice.

Your doctor may prescribe Proscar along with another medicine, called doxazosin, to help you better control your BPH.

### - When to take it

Take as directed by your doctor or pharmacist

### - How long to take it

Remember that it took many years for your prostate to grow large enough to cause your symptoms. Proscar can treat your symptoms and control the disease only if you continue to take it over the long term.

### - If you forget to take it

Try to take Proscar as your doctor has prescribed. However, if you miss a dose, do not take an extra one. Just take the next tablet as usual.

### - If you take too much (overdose)

If you take too many tablets, contact your doctor immediately.

## **While you are taking Proscar**

### - Things you must do

Go to your doctor for regular checkups, including a physical

check for prostate cancer if you are over 50.

### - Things you must not do

Do not give Proscar to anyone else, even if they have the same condition as you.

### - Things to be careful of

Proscar is for the treatment of BPH in men only. Women who are or may potentially be pregnant must not take 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. If a woman who is pregnant comes into contact with the active ingredient in Proscar, a doctor should be consulted. Proscar tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets are not broken or crushed. It is not known whether Proscar is excreted in human milk.

If you have questions, ask your doctor.

## **Side effects**

Like any medicine, Proscar may have unintended or undesirable effects, so-called side effects. Side effects due to Proscar may include impotence (an inability to have an erection) or less desire to have sex. Some men may have changes or problems with ejaculation, such as a decrease in the amount of semen released during sex. If symptoms persisted, they usually resolved on discontinuing Proscar.

Some men have also reported the following:

- allergic reactions such as rash, itching, hives and swelling of the lips, tongue, throat and face
- testicular pain
- an inability to have an erection that continued after stopping the medication
- 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

You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement or nipple discharge as these may be signs of a serious condition, such as breast cancer. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI)

How can I learn more about Proscar and BPH?

Not all the information about your medicine is printed here.

If after reading this leaflet you have any questions or are not sure about anything, ask your doctor or pharmacist, who have more detailed information about this product and BPH.

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## Storage and Disposal of Proscar

### - Storage

Proscar should be stored below 30°C (86°F) and protected from light. Keep Proscar in the original container and keep the container closed tightly.

Keep Proscar and all medicines out of the reach of children.

How long can I keep my medicine? Do not take this medicine after the month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

### - Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist how to dispose it.

## Product Description

### - What it looks like

Proscar is a blue, apple shaped film-coated tablet. Proscar is available as 5 mg tablets with MSD 72 on one side and Proscar on the other.

### - Ingredients

Active ingredient:

It contains 5 mg of finasteride as the active ingredient.

Inactive ingredients:

- lactose (Hydrous)
- pregelatinised starch (maize)
- sodium starch glycollate
- yellow ferric oxide / E172
- docusate sodium
- microcrystalline cellulose
- magnesium stearate
- methylhydroxypropylcellulose (hydroxypropyl

methylcellulose, hypromellose)

- hydroxypropyl cellulose
- titanium dioxide/E171
- talc
- indigo carmine aluminum lake / E132
- purified water

### - MAL number

MAL19985910ACRZ

## Manufacturer

AIAC International Pharma, LLC  
Road #2, Kilometer 60.3  
Sabana Hoyos  
Arecibo, Puerto Rico 00688  
U.S.A.

## Product Registration Holder

Merck Sharp & Dohme (Malaysia) Sdn. Bhd.  
Lot No. B-22-1 & B-22-2, Level 22  
The Ascent, Paradigm No. 1  
Jalan SS 7/26A, Kelana Jaya  
47301 Petaling Jaya  
Selangor, Malaysia

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