

PROSCAR®

Finasteride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PROSCAR. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PROSCAR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What PROSCAR is used for

PROSCAR is for use by men only.

PROSCAR is used to treat a medical condition in men called benign prostatic hyperplasia or BPH. BPH is a condition where your prostate gland (which is near your bladder) has become bigger making it more difficult for you to pass urine. This can lead to symptoms such as:

- weak or interrupted stream of urine
- feeling that you cannot empty your bladder completely
- delay before you start to pass urine
- needing to pass urine often, especially at night
- feeling that you must pass urine right away

BPH occurs only in men and is common over the age of 50 years. In some men, BPH can lead to serious problems, including urinary tract infections and the sudden inability to pass urine at all. BPH can also lead to the need for surgery such as procedures to improve the flow of urine.

The prostate gland takes years to grow. Therefore, the symptoms of BPH take a long time to develop. PROSCAR works by slowly reducing the size of your prostate gland. This may lead to gradual improvement in your urine flow and other symptoms over several months. PROSCAR also helps reduce the risk of developing a sudden inability to pass urine (acute urinary retention) and the need for surgery. This may happen whether or not you notice any improvement or change in your symptoms.

Your doctor may have prescribed PROSCAR for another reason. Ask your doctor if you have any questions about why PROSCAR has been prescribed for you.

PROSCAR is not addictive.

Before you take PROSCAR

When you must not take it

Do not take PROSCAR if:

- **you have an allergy to PROSCAR or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction to PROSCAR may include skin

rash, or swelling of the lips or face.

- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking PROSCAR, talk to your doctor.

Do not give PROSCAR to children or women.

Women who are pregnant or may be pregnant must not take PROSCAR or handle crushed or broken tablets.

If the active ingredient in PROSCAR is absorbed after swallowing the tablet 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 the tablets are not broken or crushed.

If a pregnant woman swallows PROSCAR or handles crushed or broken tablets, her doctor must be consulted immediately.

The condition for which PROSCAR is prescribed occurs only in men.

Before you start to take it

Tell your doctor if:

1. **you have or have had any medical conditions**
2. **you have any allergies to any other medicines or any other**

substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you take any PROSCAR.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work. However, PROSCAR has not been shown to interfere with other medicines.

Driving and operating machinery

PROSCAR should not affect your ability to drive or operate machinery.

How to take PROSCAR

How much to take

Take PROSCAR only when prescribed by your doctor.

The usual dose in men is one tablet taken once each day.

Swallow PROSCAR with a glass of water.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take it

Take PROSCAR once a day at about the same time each day.

This will help you to remember to take the tablets.

It does not matter if you take PROSCAR before or after food.

How long to take it

PROSCAR shrinks the prostate gland slowly. Therefore, you may need to take PROSCAR for 6 months or longer to see whether it helps you. If it does help your symptoms, you may need to take PROSCAR every day. Continue taking PROSCAR for as long as your doctor prescribes. If you stop taking the medicine the prostate gland is likely to grow again.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think that you or anyone else may have taken too much PROSCAR. Do this even if there are no signs of discomfort or poisoning.

While you are using PROSCAR

Things you must do

Go to your doctor for regular checkups, including a physical check for prostate cancer once a year if you are over 50.

While BPH is not cancer and does not lead to cancer, the two conditions can exist at the same time.

PROSCAR is used for BPH not prostate cancer.

If you are having a blood test to measure your PSA (prostate-specific antigen) levels, tell your doctor you are taking PROSCAR.

PROSCAR can affect the results of this test.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking PROSCAR.

Things you must not do

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

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PROSCAR.

PROSCAR helps most men with BPH, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- impotence (inability to have an erection) that continues after stopping PROSCAR
- less desire for sex that continues after stopping PROSCAR
- problems with ejaculation that continued after stopping the medication

Changes or problems with ejaculation, such as decreased amount of semen released during sex (this decrease does not appear

to interfere with normal sexual function).

Male infertility and/or poor quality of semen have been reported infrequently.

Improvement in the quality of semen has been reported after stopping PROSCAR.

These are the more common side effects of PROSCAR. For the most part these have been mild. In some cases, these side effects disappeared while the patient continued to take PROSCAR. If symptoms persisted, they usually resolved on stopping the tablets.

Tell your doctor immediately if you notice any of the following:

- breast swelling and/or tenderness
In rare cases, male breast cancer has been reported.
- breast lumps, pain or discharge from the nipples.
- skin rash, itchiness
- hives or nettlerash (pinkish, itchy swellings on the skin)
- testicle pain
- blood in semen
- depressions (feelings of severe sadness and unworthiness) including suicidal thoughts

These are uncommon side effects that have been reported with PROSCAR.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if the following happens:

- swelling of the lips, tongue, throat or face

These may be symptoms of a serious allergic reaction to PROSCAR, which may cause difficulty in swallowing or breathing. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using PROSCAR

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Never put the tablets in another box or container, as they might get mixed up.

Keep PROSCAR in a cool dry place away from light where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

PROSCAR comes as a blue, apple-shaped tablet with 'MSD72' marked on one side and 'PROSCAR' marked on the other.

A pack contains 5 or 30 tablets in a blister pack.

Ingredients

Active ingredient:

- finasteride 5 mg per tablet

Inactive ingredients:

- lactose monohydrate
- pregelatinised maize starch
- sodium starch glycollate
- iron oxide yellow
- docusate sodium
- microcrystalline cellulose
- magnesium stearate
- hypromellose
- hyplose
- titanium dioxide
- purified talc
- indigo carmine

PROSCAR does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Organon Pharma Pty Ltd

Building A,

26 Talavera Road

MACQUARIE PARK NSW 2113

Australia

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