

PACKAGE LEAFLET: INFORMATION FOR THE USER

PROSCAR® 5 mg film-coated tablets (finasteride)

This medicine is for use in men only

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Proscar is and what it is used for
2. What you need to know before you take Proscar
3. How to take Proscar
4. Possible side effects
5. How to store Proscar
6. Contents of the pack and other information

1. What Proscar is and what it is used for

Proscar contains a medicine called finasteride. This belongs to a group of medicines called '5-alpha reductase inhibitors'.

Proscar shrinks the prostate gland in men when it is swollen. The prostate gland is found underneath the bladder (but only in men). It produces the fluid found in semen. A swollen prostate gland can lead to a condition called 'benign prostatic hyperplasia' or BPH.

What is BPH?

If you have BPH it means that your prostate gland is swollen. It can press on the tube that urine passes through, on its way out of your body.

This can lead to problems such as:

- feeling like you need to pass urine more often, especially at night
- feeling that you must pass urine right away
- finding it difficult to start passing urine
- when you pass urine the flow of urine is weak
- when you pass urine the flow stops and starts
- feeling that you cannot empty your bladder completely

In some men, BPH can lead to more serious problems, such as:

- urinary tract infections
- a sudden inability to pass urine
- the need for surgery

What else should you know about BPH?

- BPH is **not** cancer and does not lead to cancer, but the two conditions can be present at the same time.
- Before you start Proscar, your doctor will do some simple tests to check whether you have prostate cancer.

Talk to your doctor if you have any questions about this.

2. What you need to know before you take Proscar

Do not take Proscar:

- if you are a woman (because this medicine is for men)
- if you are allergic (hypersensitive) to finasteride or any of the other ingredients of this medicine (listed in Section 6).

Do not take Proscar if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Proscar if:

- your partner is pregnant or planning to become pregnant. You should use a condom or other barrier method of contraception when taking Proscar. This is because your semen could contain a tiny amount of the drug and may affect the normal development of the baby's sex organs.
- you are going to have a blood test called PSA. This is because Proscar can affect the results of this test.

If you are not sure, talk to your doctor or pharmacist before taking Proscar.

Children

Proscar should not be used in children.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Proscar does not usually affect other medicines.

Taking Proscar with food and drink

Proscar can be taken with or without food.

Pregnancy and breast feeding

- Proscar should not be taken by women.
- Do not touch crushed or broken Proscar tablets if you are a woman who is pregnant or planning to become pregnant (whole tablets are coated to stop contact with the medicine during normal use). This is because this medicine may affect the normal development of the baby's sex organs.
- If a woman who is pregnant comes into contact with crushed or broken Proscar tablets, speak to your doctor.

Driving and using machines

Proscar is not likely to affect you being able to drive, use tools or machines.

Proscar contains

- Lactose. This is a type of sugar. If you have ever been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor or pharmacist before taking this medicine.

3. How to take Proscar

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- The usual dose is one tablet each day.
- Take this medicine by mouth.
- Your doctor may prescribe Proscar along with another medicine (called doxazosin) to help control your BPH.

If you take more Proscar than you should

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

If you forget to take Proscar

- If you forget to take a tablet, skip the missed dose.
- Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Proscar

Your condition may show an early improvement after taking Proscar. However, it may take at least six months for the full effect to develop. It is important to keep taking Proscar for as long as your doctor tells you, even if you do not feel any benefit straight away.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions

If you have an allergic reaction, stop taking it and see your doctor straight away. The signs may include:

- Skin rashes, itching, or lumps under your skin (hives)
- Swelling of your lips, tongue, throat and face.

Other side effects may include:

- You may be unable to have an erection (impotence)
- You may have less desire to have sex
- You may have problems with ejaculation, for example a decrease in the amount of semen released during sex. This decrease in the amount of semen does not appear to affect normal sexual function.

These side effects above may disappear after a while if you continue taking Proscar. If not, they usually resolve after stopping Proscar. Other side effects reported in some men are:

- Breast swelling or tenderness
- Palpitations (feeling your heartbeat)
- Changes in the way your liver is working, which can be shown by a blood test
- Pain in your testicles
- An inability to have an erection which may continue after stopping the medication
- Male infertility and/or poor quality of semen. Improvement in the quality of the semen has been reported after stopping medication
- Depression
- Decrease in sex drive that may continue after stopping the medication
- Problems with ejaculation that may continue 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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist. It will help if you make a note of what happened, when it started and how long it lasted.

What else should you know about Proscar?

Proscar (finasteride) is not licensed to treat prostate cancer. Information collected for a clinical trial in men taking finasteride for 7 years showed:

- The number of men who developed prostate cancer was lower in men taking finasteride compared with those taking nothing.
- The number of men who had a high score in a tumour grading system was higher in some of those taking finasteride compared to those taking nothing.
- The effect of long-term use of finasteride on tumours of this kind is not known.

If you would like further information about the tumour grading system or this trial, please talk to your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard

Malta: ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira Website: www.medicinesauthority.gov.mt, e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Proscar

Keep this medicine out of the sight and reach of children.

Do not store your tablets above 30°C. Keep them in the original package.

If you have been given a calendar pack, do not remove the tablets from the blister until you are ready to take the medicine.

Do not use Proscar after the expiry date which is stated on the carton after the letters EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Proscar contains

- The active substance is finasteride. Each tablet contains 5 mg finasteride.
- The other ingredients are: Docusate sodium, Hydroxypropyl cellulose E463, Hypromellose E464, Indigo carmine aluminium lake E132, Lactose monohydrate, Magnesium stearate E572, Microcrystalline cellulose E460, Pregelatinised maize starch, Sodium starch glycollate Type A, Talc, Titanium dioxide E171, Yellow iron oxide E172.

What Proscar looks like and the content of the pack

Proscar is available as blue, apple-shaped tablets. Proscar Tablets are supplied in blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder

Merck Sharp & Dohme Limited
Hertford Road
Hoddesdon
Hertfordshire EN11 9BU
United Kingdom

Manufacturer

Merck Sharp & Dohme Limited
Shotton Lane
Cramlington
Northumberland NE23 3JU
United Kingdom

This leaflet was last revised in August 2013

This leaflet gives you some important patient information about Proscar. If you have questions after you read it ask your doctor or pharmacist, who will give you further information.

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