

Package leaflet: Information for the user

PROSCAR® 5 mg film-coated tablets

finasteride

This medicine is for use by men only

Read all of this leaflet carefully before you start to take 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.

What is 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

What Proscar is

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

How Proscar works

Proscar shrinks the prostate gland in men when it is swollen. The prostate gland is found underneath the bladder (in men only). 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 (this medicine is for men)
- if you are allergic (hypersensitive) to finasteride, lactose or any of the other ingredients (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. Proscar should not be used by children.

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 normal development of the baby's sex organs.
- if you are going to have a PSA blood test. 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.

Mood alterations and depression

Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with Proscar. If you experience any of these symptoms contact your doctor for further medical advice as soon as possible.

Other medicines and Proscar

Proscar does not usually affect other medicines. Always tell your doctor about all medicines you are taking or planning to take, including any non-prescription medication.

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

Proscar contains lactose which is a type of sugar. If you have ever been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Proscar contains sodium

This medicine contains less than 1 mmol (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

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.

How to take Proscar

- The usual dose is one tablet each day.
- This medicine is for oral use
- Your doctor may prescribe Proscar along with another medicine (called doxazosin) to help control your BPH.

If you take more Proscar than you should

Contact your doctor immediately for advice if you take more than the prescribed dose.

If you forget to take Proscar

- If you forget to take a tablet, skip the missed dose and 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, Proscar can cause side effects, although not everybody gets them.

If you experience any of the following, stop taking Proscar and contact your doctor immediately:

Allergic reactions (angioedema)

- Swelling of face, tongue or throat
- Difficulty swallowing
- Hives and breathing difficulties
- Skin rash, itching

The following side-effects have been reported with Proscar:

Common (may affect up to 1 in 10 people):

- Inability to have an erection (impotence)
- Less desire to have sex (decreased libido)
- 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.

Uncommon (may affect up to 1 in 100 people):

- Breast swelling or tenderness

Not known (frequency cannot be estimated from the available data):

- Heart palpitations
- Pain in your testicles
- Blood in semen
- An inability to have an erection which may continue 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 the semen has been reported after stopping medication
- Decrease in sex drive that continued after stopping the medication
- Depression
- Anxiety

You should immediately 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 you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

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 via HPRA Pharmacovigilance, website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Proscar

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30 °C. Store in the original package in order to protect from light and moisture.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Content of the pack and other information

What Proscar contains

The active substance is finasteride. Each tablet contains 5 mg finasteride.

The other ingredients are: microcrystalline cellulose (E460), docusate sodium, lactose monohydrate, magnesium stearate (E572), pregelatinised maize starch, sodium starch glycolate (Type A), yellow iron oxide (E172), hydroxypropylcellulose (E463), indigo carmine aluminium lake (E132), hypromellose (E464), talc, titanium dioxide (E171)

What Proscar looks like and content of the pack

Proscar is available as blue, apple-shaped, film-coated tablets marked 'Proscar' on one side and 'MSD 72' on the other.

Proscar tablets are supplied in blister packs of 14 or 28 tablets contained in an outer cardboard carton. Not all pack sizes may be marketed.

On the blister foil, weekday abbreviations appear in Spanish. Here is a translation of the weekdays in English and Spanish:

<u>English</u>	<u>Spanish</u>
Monday	LUNES
Tuesday	MARTES
Wednesday	MIÉRCOLES
Thursday	JUEVES
Friday	VIERNES
Saturday	SÁBADO
Sunday	DOMINGO

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer

Proscar 5 mg Tablets are manufactured by Schering-Plough Labo NV or Organon Heist bv, Industriepark 30, Heist-op-den-Berg, 2220, Belgium.

Parallel Product Authorisation Number:

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