

Package Leaflet: Information for the user

PROSCAR[®] 5mg film-coated tablets

(finasteride)

This medicine is for use in men only

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

- * Keep this leaflet. You may want to read it again.
- * If you have any further questions, ask your doctor or pharmacist.
- * This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- * 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.

In this leaflet:

- 1 What Proscar is and what it is used for
- 2 Before you take Proscar
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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 Before you take Proscar

Do not take Proscar if:

- * you are a woman (because this medicine is for men)
- * you are allergic (hypersensitive) to finasteride 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 in children.

Take special care with Proscar

Check with your doctor or pharmacist before taking your medicine 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.
 - * 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.

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.

Taking other medicines

Proscar does not usually affect other medicines. Always tell your doctor about all medicines you are taking or planning to take, including any obtained without a prescription.

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.

Important information about some of the ingredients of Proscar

Proscar contains lactose monohydrate which 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 before taking this medicine.

3 How to take Proscar

You should take your tablets exactly as your doctor 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.

Package Leaflet: Information for the user (continued)**PROSCAR® 5mg film-coated tablets**

(finasteride)

4 Possible side effects

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

Allergic reactions

Stop using Proscar and immediately contact a doctor if you experience any of the following symptoms (angiooedema):

- * swelling of face, tongue or throat
- * difficulty swallowing
- * hives and breathing difficulties.
- * Skin rash, itching

Other side effects may include:

- * You may be unable to have an erection (impotence)
- * You may have less desire to have sex (decreased libido)
- * 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.

Other side effects reported in some men are:

- * Breast swelling or tenderness
- * Heart palpitations
- * Pain in your testicles
- * 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

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.

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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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 store above 30°C.

Store in original package in order to protect from light.

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.

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 Further information**What Proscar contains:**

- * The active ingredient in Proscar Tablets is finasteride. Each tablet contains 5 mg finasteride.
- * The other ingredients in Proscar tablets are: Lactose monohydrate, Microcrystalline cellulose, Pregelatinised maize starch, Poly (o-carboxymethyl)-starch sodium, Docusate sodium, Magnesium stearate, Hypromellose, Hydroxypropyl cellulose, Talc, as well as dyes, Iron oxide (E172), Titanium dioxide (E171) and Indigo carmine aluminum lake (E132).

What Proscar looks like and the content of the pack

Proscar is available as blue, apple-shaped tablets marked 'PROSCAR' on one side and 'MSD 72' on the other. Proscar Tablets are supplied in blister packs of 28 tablets.

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.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

Merck Sharp & Dohme BV, Haarlem/Netherlands

Proscar is a registered trademark of Merck Sharp & Dohme Corp.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0)1527 505414 for help.