

LEAFLET: INFORMATION FOR THE USER

Proscar 5 mg, film-coated tablets
finasteride

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed only for you. It may harm others, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

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1. WHAT IS PROSCAR AND WHAT IS IT USED FOR?

This medicine contains the active substance finasteride. It belongs to a group of medicines called 5-alpha-reductase inhibitors. The active substance binds to the enzyme 5-alpha-reductase, thereby inhibiting the formation of the substance that plays a role in the enlargement of the prostate. As a result of this inhibition, further enlargement of the prostate is counteracted.

With long-term use, the enlarged prostate is reduced in most cases. This medicine is intended for use by men only.

Why has your doctor prescribed Proscar?

Finasteride is a specific enzyme inhibitor used for the treatment of men with benign prostatic enlargement (benign prostatic hyperplasia, BPH). Proscar reduces the enlarged prostate and relieves urinary symptoms. This medication reduces the risk of suddenly being unable to urinate (acute urinary retention) and the need for surgery.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.

Women and children should not use this medicine.

The condition for which Proscar is prescribed occurs only in men. Women who are pregnant or may be pregnant should not handle broken or crushed tablets (see the section 'Pregnancy, breastfeeding, and fertility').

What you need to know before and during the use of Proscar

If your sexual partner is pregnant or could be, you should not let her come into contact with your semen. It may contain a very small amount of the medication.

When should you be extra cautious with this medicine?

Contact your doctor or pharmacist before using this medicine.

Breast cancer

See section 4.

Effects on prostate-specific antigen (PSA)

This medicine can affect the results of a blood test called PSA (prostate-specific antigen). This test is used in investigations for prostate cancer. If you are having a PSA test, tell your doctor or pharmacist that you are using this medicine, as it lowers the PSA concentration.

Effects on fertility

Infertility has been reported in men who had used finasteride long-term and who also had other risk factors that could affect fertility. After stopping finasteride, it has been reported that semen quality improved or became normal. No long-term studies have been conducted on the effect of finasteride on fertility in men.

Mood changes and depression

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

Children

This medicine should not be used by children. There are no data demonstrating the efficacy or safety of finasteride in children.

The use of Proscar by patients with impaired liver function is not recommended.

Have the effect of the treatment regularly checked by your doctor.

Are you using any other medicines?

Are you using any other medicines besides Proscar, have you recently done so, or are you planning to do so soon? Then tell your doctor or pharmacist.

What should you pay attention to with food and drink?

Proscar can be taken with or without food.

Pregnancy, breastfeeding, and fertility

Proscar is intended solely for the treatment of benign prostatic enlargement in men. For effects on male fertility, see 'Effects on fertility' above.

Women who are pregnant or may become pregnant should not use this medicine. They should not handle broken or crushed tablets. If the active substance in this medicine is absorbed through the mouth or skin by a woman who is pregnant with a male baby, it may cause the boy to be born with abnormalities of the sex organs. If a pregnant woman comes into contact with the active substance in this medicine, she should contact her doctor immediately.

Proscar tablets are coated to prevent contact with the active substance during normal use, provided the tablets are not broken or crushed.

If you have any further questions, please contact your doctor or pharmacist.

Driving and using machines

There are no data showing that this medicine affects the ability to drive or use machines. Fatigue and dizziness have occasionally been reported. You should take this into account when performing these tasks.

Proscar contains lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Proscar contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The recommended dosage is 1 tablet per day. The tablet can be taken with or without food. Your doctor will tell you how long you need to use Proscar.

Remember that it took years for your prostate to become large enough to cause these symptoms. Proscar only works against these symptoms and your condition if you continue to use it long-term.

Your doctor may prescribe Proscar together with another medicine, doxazosin, to better control the BPH in you.

Have you used too much of this medicine?

When you have taken too much of this medicine, no specific treatment is advised. Contact your doctor for advice.

Have you forgotten to use this medicine?

Take Proscar according to the treatment prescription. However, if you have forgotten to take a dose, do not take a double dose to make up for a forgotten tablet. Take the next tablet as usual. Take the next tablet as usual.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like any medicine, this medicine can have side effects. Not everyone gets them. The following side effects have been reported with the use of Proscar.

Stop using this medicine and contact your doctor immediately if you have any of the following symptoms (angioedema): swelling of the face, tongue, or throat; difficulty swallowing; skin rash with severe itching and hives (urticaria) and difficulty breathing.

If you notice changes in your breast tissue, such as lumps, pain, more breast tissue, or discharge from a nipple, you should tell your doctor immediately, as these may be signs of a serious condition, such as breast cancer.

Common (occur in less than 1 in 10 users):

- decreased libido
- problems getting an erection
- a reduction in the amount of ejaculate.

Sometimes (occur in less than 1 in 100 users):

- problems with ejaculation
- skin rash
- swollen and/or tender breasts.

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

- allergic reactions such as rash and itching
- rapid heartbeat
- depression
- suicidal thoughts
- problems achieving an erection that persisted after discontinuation of treatment
- decreased libido that persisted after discontinuation of treatment
- pain in the testicles
- blood in semen
- male infertility and/or poor sperm quality
- elevated liver enzyme levels
- anxiety.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Store below 30°C. Store in the original packaging to protect from light.

Do not use this medicine after the expiry date. You can find it on the label on the packaging after "EXP:". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

- The active substance in this medicine is finasteride. Each film-coated tablet contains 5 mg of finasteride.
- The other substances in this medicine are lactose monohydrate, pregelatinized starch, sodium starchglycolate, sodium docusate, magnesium stearate (E572), talc (E553b), microcrystalline cellulose (E460a), methylhydroxypropylcellulose (E464) and hydroxypropylcellulose (E463). The colorants used are indigotine (E132), titanium dioxide (E171), and yellow iron oxide (E172).

What does Proscar look like and what is in a package?

Proscar film-coated tablets 5 mg are apple-shaped, blue, with an embossed code 'MSD 72' on one side and 'Proscar' on the other.

Packaging: box with two blister packs of 14 tablets.

Registered under

RVG 128073//15482 Proscar 5 mg, film-coated tablets (Poland)

Marketing authorization holder and manufacturer gene and manufacturer

Marketing Authorization Holder:

Euro Registration Collective b.v.

Kempkens 2200

5465 PR Veghel

Repacker (see label on the outer packaging):

Brocef B.V., Marostraat 43, 1060 LG Amsterdam

or

Stephar B.V., Kempkens 2200, 5465 PR Veghel

Manufacturer

Organon Heist bv

Industriepark 30

2220 Heist-op-den-Berg

Belgium

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