

Editor's note: This English translation was done by a third party. The original document can be accessed [here](#).

PATIENT INSTRUCTIONS Proscar

Film-coated tablets, 5 mg, blister, 2 x 14 film-coated tablets (total 28 film-coated tablets)

Manufacturers:

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Applicant:

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Protected name, strength, pharmaceutical form Proscar, 5 mg, film-coated tablets

INN finasteride

The medicine is intended for use in men only

Proscar Leaflet Information for the Consumer

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

- Keep this leaflet. You might need to read it again
- If you have any additional questions ask your doctor or pharmacist
- This medicine is prescribed only to you. Do not recommend it to other people. It might harm them regardless of the similarity of their symptoms to yours.
- If you experience any adverse reactions, inform your doctor or pharmacist. This includes all adverse reactions not described in this leaflet.

What this leaflet contains:

1. What is Proscar 5 mg film-coated tablets and what is it used for
2. What do you have to know before you take Proscar 5 mg film-coated tablets
3. How to take Proscar 5 mg film-coated tablets
4. Possible adverse reactions
5. How to store Proscar 5 mg film-coated tablets
6. Package content and additional information

1. What is Proscar 5 mg film-coated tablets and what is it used for

Proscar 5 mg film-coated tablets contains finasteride. Finasteride belongs to a group of medicines called 5 α -reductase inhibitors.

Proscar contains a medicine called finasteride. It belongs to a group of medicines called 5-alpha-reductase. Proscar reduces the enlarged prostate in men. The prostate is a gland that is located below the bladder (but only in men). It creates fluid that is found in semen. Enlarged prostate can cause a condition called “benign prostatic hyperplasia” or BPH.

2. What you must know before you take Proscar 5 mg film-coated tablets

Do not take Proscar 5 mg:

- If you are allergic to finasteride or any of the other ingredients in this medicine (they are listed in point 6).
- If you are a child or youth.

If you are a woman (see section below: “Pregnancy, breastfeeding and fertility”).

- During the clinical trials, it was concluded that Proscar 5 mg film-coated tablets is not effective in hair loss treatment (androgenic alopecia) in women.
- If you are already taking finasteride or any other 5 α -reductase inhibitor to treat benign prostatic hyperplasia or any other condition.

Warnings and precautions

- Talk to your doctor or pharmacist before you take Proscar 5 mg film-coated tablets.
- Before starting treatment and during the patients' therapy with finasteride, determination for the prostate-specific antigen (PSA) in the serum must be performed.
- Finasteride may affect male fertility. Patients that are planning to have a child must consider stopping the treatment.

Mood swings and depression

Mood swings such as depressive mood, depression and, rarely, suicide thoughts, have been reported in patients treated with Proscar 5 mg film-coated tablets. If you have any of these symptoms, stop taking Proscar 5 mg film-coated tablets and contact your doctor as soon as possible for additional medical help.

Other medicine and Proscar 5 mg film-coated tablets

Inform your doctor or pharmacist if you take or recently have been taking or if it is possible that you are taking other medicine. Proscar 5 mg film-coated tablets usually does not interact with other medicines.

There is no available information regarding the simultaneous usage of Proscar 5 mg film-coated tablets and topical minoxidil (applied on the skin) in male pattern baldness. This combination is not recommended.

Proscar 5 mg film-coated tablets intake with food and beverages.

Proscar 1 mg can be taken with or without food.

Pregnancy, breastfeeding and fertility

Proscar 5 mg film-coated tablets are intended only for men. Women, who are pregnant or have the possibility of becoming pregnant, must not touch broken tablets that contains finasteride. If finasteride is absorbed by the skin or is being taken orally by a pregnant woman with a male baby, the baby might be born with deformed genitals.

When the intimate partner of the patient is pregnant or has the possibility of becoming pregnant, it is recommended that the patient reduce her contact to his semen to a minimum (for example, with the use of a condom) or to stop the treatment with finasteride.

Driving and working with machines

There is no data suggesting that Proscar 5 mg film-coated tablets influences the ability to drive or work with machines.

Important information regarding some ingredients of Proscar 5 mg film-coated tablets

This medical product contains lactose. If your doctor has told you that you have intolerance to some sugars, contact them before beginning to take this medicine.

3. How to take Proscar 5 mg film-coated tablets

Always take the medication exactly the way your doctor has told you. If you are unsure about something, ask your doctor or pharmacist.

The recommended dose is one tablet of Proscar 5 mg daily (that equals 5 mg finasteride). The film-coated tablets can be taken on empty stomach, or with food. The film-coated tablets must be swallowed whole and they must not be divided or broken.

- Proscar 5 mg film-coated tablets will not have faster or stronger effect if they are taken more than once daily.
- Male pattern baldness is a condition that develops over a long period of time. Most often it is necessary to use daily for 3 to 6 months before noticing any hair growth increase or hair loss decrease.
- Your doctor will help you to evaluate whether Proscar 5 mg film-coated tablets have any effect. It is important to continue taking Proscar 5 mg film-coated tablets as long as your doctor has prescribed to you.

Patients with impaired liver functions

There is no data for the usage of Proscar 5 mg film-coated tablets in patients with impaired liver function.

Patients with impaired kidney functions

There is no need for dosage change in patients with impaired kidney functions.

If you have taken more than the needed dose of Proscar 5 mg film-coated tablets

If you have taken more than the needed dose of Proscar 5 mg film-coated tablets or anyone else has taken Proscar 5 mg film-coated tablets, immediately contact the emergency ward of your nearest hospital. Show the doctor the rest of the tablets and your medicine package.

If you have missed taking Proscar 5 mg film-coated tablets

If you forget to take a dose from Proscar 5 mg film-coated tablets, just take the next dose as usual. Do not take double dose to compensate for the missed one.

If you have stopped taking Proscar 5 mg film-coated tablets

In order to achieve maximum effect, continued use of Proscar 5 mg film-coated tablets is recommended. If, meanwhile, you stop the treatment, in the next 9 to 12 months you will lose the hair that you have acquired.

If you have any questions regarding the usage of this medicine, ask your doctor or pharmacist.

4. Possible adverse reactions

As with every medicine, this medicine can cause adverse reactions despite the fact that not everyone experiences them. Some of the adverse reactions are temporary during the treatment or disappear when you stop the treatment.

Stop Proscar 5 mg film-coated tablets and immediately contact a doctor if you develop any of the following:

- Allergic reaction symptoms, such as swelling of the lips, face, tongue, throat; experience difficulty in swallowing, rash (hives) and difficulty in breathing
- Depression (feeling of strong sadness and low self-esteem).

You must immediately inform your physician for any change in your breast tissue, such as lumps, breast enlargement, nipple secretion as this could be a sign of a serious disease, such as breast cancer.

Uncommon (can affect between 1 and 100 people)

- lower libido;
- erection difficulties;
- ejaculation problems, such as decrease in the ejected semen during sex
- depression

Unknown frequency

- allergic reaction, such as rash, itching, hives, lips and face swelling;
- breast pain and swelling;
- palpitations;
- testicle pain;
- increased heart rate;
- permanent erectile dysfunction after stopping the treatment;
- permanent decrease in libido after stopping the treatment;
- permanent ejaculation problems after stopping the treatment;
- there is data for infertility in men who have taken finasteride for a continued long period and have also had other risk factors that might have affected fertility. Normalization and improvement in the semen quality was reported after stopping the treatment with finasteride. Long-term clinical trials on finasteride's effect on men's fertility rate have not been done.
- changes in the liver function that can be detected in blood tests
- anxiety

Reporting adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can report side effects directly to healthcare professionals, which will help gather more information on the safety of this drug.

5. How to store Proscar 5 mg film-coated tablets

- keep out of reach of children
- this medicinal product does not require special storage conditions
- Do not use Proscar 5 mg film-coated tablets if expired after the date marked on the packaging. The expiration day is the last day of the indicated month.

- These medicines must not be thrown down a drain or into regular trash bins. Ask your pharmacist how to dispose of the medicine that you are no longer using. This measure will help to keep the environment clean.

6. Package content and additional information

What Proscar 5 mg film-coated tablets contain

The active ingredient is finasteride. One film-coated tablet contains 1 mg finasteride.

Other ingredients are:

Tablet's core: lactose monohydrate, microcrystalline cellulose (E460); pregelatinised starch, sodium starch glycolate (type A); lauryl microglycerides, magnesium stearate (E570)

Film coat: Hypromellose (E464), titanium dioxide (E 171), macrogol 6000, red iron oxide (E172), yellow iron oxide (E172)

What do Proscar 5 mg film-coated tablets look like and what does the package contain:

Film-coated tablet.

Proscar 5 mg are reddish-brown, round-shaped, with a sign "F1" from one side and without a sign on the other side.

Proscar 5 mg tablets are packed in blisters aluminum-aluminum, in 28, 30, 84 or 98 package tablets.

Licensee

The company for wholesale pharmaceutical products "Glossary" d.o.o.
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Podgorica, Republic of Montenegro

Manufacturer

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License number: Proscar film-coated tablets, 5 mg, blister, 2x14: 2030/14/280 – 636.

These instructions were last approved August 15, 2014.