

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

## **PACKAGE LEAFLET INFORMATION FOR PATIENTS**

**Romanian National Authority of Medicines and Medical Devices  
Finasteride 5 mg film-coated tablets  
Permission number: 5885/2013/01-02-03**

Active ingredient: finasteride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Keep the leaflet. You might want to read it again. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Do not pass it on to others. It can harm other people, even if they have the same symptoms as you. If you get any side effects, talk to your doctor or pharmacist. This also applies to side effects that are not listed in this leaflet. See section 4.

What is in this leaflet

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

### **1. WHAT FINASTERIDE IS AND WHAT IT IS USED FOR**

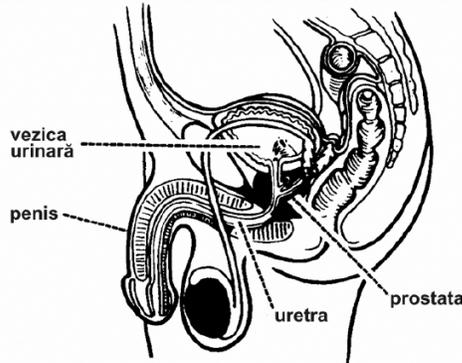
Finasteride is used by men to treat and control:

- **Benign enlargement of the prostate (non-aggressive prostate growth).**

Finasteride belongs to a group of medicines called 5-alpha reductase inhibitors. It shrinks the prostate gland in men, improves urinary flow and other symptoms caused by BPH. finasteride reduces the risk of acute urinary retention and the need for surgery.

### What is the prostate?

The prostate is a gland the size of a chestnuts found only in men. It is located under the bladder and surrounds the urethra, a tubular organ that transports urine from the bladder to the tip of the penis (see image). The main function of the prostate is producing fluid seminal, the transport fluid sperm.



## 2. BEFORE YOU TAKE FINASTERIDE

finasteride must not be taken If you

- are allergic to:
  - finasteride
  - or any of the other ingredients of this medicine (listed in section 6)
- are a woman
- are a youth or child under 18 years of age

If you are taking finasteride to treat an enlarged prostate, you should see a urologist.

### Warnings and Precautions

Talk to your doctor before taking finasteride. Tell your doctor if any of the following apply to you:

- If you have difficulty emptying your bladder completely or have a strong void have decreased urinary flow Your doctor will examine you carefully before you start treatment with finasteride Rule out the possibility of another urinary tract disease.
- if you need a blood test for PSA, a determination of the prostate-specific antigen (PSA) Talk to your doctor or nurse about taking finasteride take as it may affect your test results.
- if you have impaired liver function

Women who are pregnant or may be pregnant should not use finasteride come into contact with (for example via the semen or broken or crumbled tablets. See section Pregnancy and breast-feeding).

### Mood changes and depression

In patients treated with finasteride, mood changes such as depressed mood, depression and, less commonly reported, suicidal thoughts. If you notice any of these symptoms, consult your doctor immediately.

### Taking finasteride with other medicines

Tell your doctor or pharmacist if you are taking any other medicines are taking/using, have recently taken/used other medicines or plan to take/use other medicines. finasteride is not known to affect or be affected by any other medicines other medicines.

## **Pregnancy and breastfeeding period**

finasteride should not be taken by women.

- If your sexual partner is pregnant or may be pregnant: The semen may contain traces of finasteride. That's why your sperm can go with you not come into contact with your partner, e.g. by using a condom.
- Women who are pregnant or may become pregnant should not use broken ones or crushed finasteride film-coated tablets.

If finasteride by a pregnant woman with a male fetus is ingested, the child may be born with malformed genitals will. The tablets are therefore film coated to prevent contact with finasteride. There have been reports of infertility following the marketing of finasteride-containing products (infertility) and/or poor semen quality. Patients present other risk factors that may have contributed to infertility. A normalization or improvement in semen quality was observed after weaning finasteride reported. If you have any questions about this, please seeing your doctor.

Ability to drive and use machines There is no information that finasteride affects the ability to drive or use machines. Finsterid contains lactose and sodium This medicine contains lactose. Please take finasterideerst afterwards Talk to your doctor if you know you have a suffer from sugar intolerance. This medicinal product contains less than 1 mmol (23 mg) sodium per film-coated tablet, i.e., it is almost "sodium-free."

## **3. HOW TO TAKE FINASTERIDE**

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

- 1 tablet once a day type of administration

Swallow the film-coated tablet whole with a glass of water. You can with or without food can be taken, but always at the same time.

### **Duration of use**

Your doctor will decide how long you should stop taking finasteride. Although improvement is often observed after a short period of time, it is necessary to continue treatment for at least 6 months. If you take more finasteride than you do should, contact your doctor or pharmacist immediately.

### **If you forget to take finasteride**

If you forget to take a dose, do not double the dose. Continue taking the next dose as usual.

### **If you stop taking finasteride**

Do not change or stop treatment without your doctor's permission. This can cause serious injury and impair the success of the treatment. If you have any further questions on the use of this medicine, please contact your doctor or pharmacist.

#### 4. WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicines, this medicine can cause side effects, although these are not common have to appear to everyone. The most common side effects are the inability to get an erection and decreased sexual drive. These side effects occur in the early treatment phase appear and, in most cases, disappear in the further course of treatment. You should inform your doctor immediately if you notice any changes in your breast tissue such as lumps, pain or discharge from the nipples as this could be signs of a serious illness, such as breast cancer.

##### **Allergic reaction**

If you have an allergic reaction, stop taking it and let them know your doctor immediately. The signs of this can be:

- skin rash, itching or blistering under the skin (hives)
- swelling of your lips, tongue, throat and face

Side effects can occur with the following frequencies:

Common, may affect up to 1 in 10 people:

- inability to have an erection
- decreased sexual drive
- decreased sperm volume

Uncommon, may affect up to 1 in 100 people:

- tenderness to touch and/or breast enlargement
- ejaculation disorders
- depression

Very rare, may affect up to 1 in 10,000 people:

- secretion from the male breast
- breast lumps, which in some cases are surgically removed

Not known, frequency cannot be estimated from the available data:

- palpitations
- increased liver enzymes
- testicle pain
- inability to get an erection that persists after stopping treatment
- decreased sexual drive that persists after stopping treatment
- male infertility and/or poor sperm quality. It has been reported that sperm quality improves after stopping treatment returned to normal or improved.
- anxiety

##### **Reporting adverse reactions**

If you develop any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report adverse reactions directly through the national reporting system, details of which are published on the National Agency for Medicines and Medical Devices website <http://www.anm.ro/>.

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

## 5. HOW TO STORE FINASTERIDE

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiration date printed on the carton and blister after "Use by." The expiration date refers to the last day of the specified month. Do not store above 25°C. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use, thus helping to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### **What finasteride contains**

The active substance is finasteride. Each film-coated tablet contains 5 mg Finasteride. The other ingredients are: Docusate Sodium, Hypromellose, Indigo Carmine Salt (E132), Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Povidone K30, Propylene Glycol, Sodium Starch (Type A), Talc, Titanium Dioxide (E171).

### **What finasteride looks like and contents of the pack**

The film-coated tablets are round, blue, biconvex and smooth on both sides. The film-coated tablets are packed in PVC/Alu blisters in an outer carton. Pack sizes: 10, 15, 30, 50, 60, 100, 120 film-coated tablets in a standard blister. 14, 28 and 56 film-coated tablets in a weekly blister. 50 film-coated tablets (50 x 1) in unit dose blisters. Not all pack sizes may be marketed.

### **Marketing Authorization Holder**

ORGANON BIOSCIENCES S.R.L.  
Av. Popișteanu, Nr. 54A  
Expo Business Park, Building 2 Office 306 and Office 307, Floor 3, Sector 1  
Bucharest, Romania

### **Manufacturers**

MERCK SHARP & DOHME BV  
Waarderweg 39  
2031 BN Haarlem  
The Netherlands

SCHERING-PLOUGH LABOR NV  
Industriepark 30  
Heist-op-den-Berg, 2220  
Belgium

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