



**PACKAGE LEAFLET:
INFORMATION FOR THE
USER**

**Finasteride 5 mg
film-coated tablets**

Finasteride

Read all of this leaflet carefully before you start taking 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 Finasteride is and what it is used for
2. What you need to know before you take Finasteride
3. How to take Finasteride
4. Possible side effects
5. How to store Finasteride
6. Contents of the pack and other information

1. What Finasteride is and what it is used for

Finasteride belongs to the group of medicines, called 5-alpha reductase inhibitors. Finasteride 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 Finasteride, 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 Finasteride

Do not take Finasteride

- if you are allergic (hypersensitive) to finasteride or any of the other ingredients of this medicine (listed in section 6)
- if you are a woman (because this medicine is for men)
- Do not take Finasteride if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Finasteride.

- your partner is pregnant or planning to become pregnant. You should use a condom or other barrier method of contraception when taking Finasteride. This is because your semen could contain a tiny amount of the drug and may affect the normal development of the baby's sex organs.
- you are going to have a blood test called PSA. This is because Finasteride can affect the results of this test.

If you are not sure, talk to your doctor or pharmacist before taking Finasteride.

Mood alterations and depression

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

Children

Children should not use this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Finasteride does not usually affect other medicines.

Finasteride with food and drink and alcohol

Finasteride can be taken with or without food.

Pregnancy, breast-feeding and fertility

- Finasteride should not be taken by women.
- Do not touch crushed or broken Finasteride 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 Finasteride tablets, speak to your doctor.

Driving and using machines

Finasteride is not likely to affect you being able to drive, use tools or machines.

Finasteride contains lactose. This 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 or pharmacist before taking this medicine.

Finasteride contains Sodium: This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Finasteride

Always take this medicine exactly as your doctor or pharmacist 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 Finasteride along with another medicine (called doxazosin) to help control your BPH.

If you take more Finasteride than you should

If you take too many tablets by mistake, contact your doctor immediately.

If you forget to take Finasteride

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 Finasteride

Your condition may show an early improvement after taking Finasteride. However, it may take at least six months for the full effect to develop. It is important to keep taking Finasteride for as long as your doctor tells you, even if you do not feel any benefit straight away.

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If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with this medicine:

Allergic reactions

Stop using Finasteride and immediately contact a doctor if you experience any of the following symptoms:

- Swelling of face, lips, tongue or throat, difficulty swallowing and breathing difficulties (angioedema)
- Skin rashes, itching, or lumps under your skin (hives)
- **Other side effects may include:** You may be unable to have an erection (impotence)
- You may have less desire to have sex
- 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.

These side effects above may disappear after a while if you continue taking Finasteride. If not, they usually resolve after stopping Finasteride. Other side effects reported in some men are:

- Breast swelling or tenderness
- Palpitations (feeling your heartbeat)
- Changes in the way your liver is working, which can be shown by a blood test
- Pain in your testicles
- Blood in semen
- An inability to have an erection which may continue 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
- Depression
- Decrease in sex drive that may continue after stopping the medication
- Problems with ejaculation that may continue after stopping the medication
- Anxiety
- Suicidal thoughts

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.

What else should you know about Finasteride?

Finasteride is not licensed to treat prostate cancer. Information collected for a clinical trial in men taking finasteride for 7 years showed:

- The number of men who developed prostate cancer was lower in men taking finasteride compared with those taking nothing.

The number of men who had a high score in a tumour grading system was higher in some of those taking finasteride compared to those taking nothing.

- The effect of long-term use of finasteride on tumours of this kind is not known. If you would like further information about the tumour grading system or this trial, please talk to your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 expiry date, which is stated on the blister and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Finasteride contains

- The active substance is finasteride. Each film-coated tablet contains 5mg of finasteride.
- The other ingredients are: lactose monohydrate, cellulose microcrystalline, sodium starch glycolate (Type A), starch pregelatinised (maize), docusate sodium, magnesium stearate, hydroxypropyl cellulose, hypromellose, titanium dioxide, talc, indigo carmine aluminium lake (E132), iron oxide yellow (E172).

What Finasteride looks like and contents of the pack

Film coated tablet.

Blue coloured, circular, biconvex, beveled edged film-coated tablet debossed with 'E' on one side and '61' on the other side.

Finasteride 5 mg tablets are available in PVC/PE/PVdC-aluminium foil blister packs and white opaque HDPE bottle closed with polypropylene closure.

Blister Packs: 10, 14, 15, 20, 28, 30, 45, 50, 60, 90, 98, 100 and 120 film-coated tablets.

HDPE Packs: 30, 50, 60, 90, 98, 100 and 500 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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