

Package leaflet: Information for the user

Finasteride 5mg film-coated tablets

finasteride

This medicine is for use in men only

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
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1. What Finasteride is and what it is used for

This medicine contains the active substance finasteride. This belongs to a group of medicines called '5-alpha reductase inhibitors'.

Finasteride shrinks the prostate gland in adult 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 a woman (because this medicine is for men)
- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6)

Do not take finasteride if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Finasteride should not be used in children.

Warnings and precautions

Talk to your doctor or pharmacist before taking finasteride:

- If you have a large amount of residual urine and/or severely reduced urinary flow. If this is the case, you should be closely monitored for narrowing of the urinary tract
- If you have a PSA test (test used to detect prostate cancer). Tell your doctor that you are taking finasteride. Finasteride can affect the blood levels of the substance being tested, PSA.
- If you notice any change in your breast such as lumps, pain, gynaecomastia (breast enlargement) or nipple discharge
- If you are suffering from any liver disease.
- If 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.
- If you are going to have a blood test called PSA. This is because finasteride can affect the results of this test.

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

Finasteride should not be prescribed to children because safety and effectiveness in children have not been established.

Other medicines and Finasteride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Finasteride does not usually affect other medicines.

Finasteride with food

Finasteride can be taken with or without food.

Pregnancy and breast-feeding

- 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.
- In addition, these women should not be exposed to the drug through sexual contact with a man taking finasteride. Therefore, if your sexual partner is or may potentially be pregnant, you must avoid exposing her to your semen which could contain a tiny amount of the drug – for example, by using a condom during sexual activity.
- 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 tablets contains lactose

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Finasteride contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free', contact your doctor before taking this medicinal product.

Finasteride tablets contains sodium benzoate

This medicine contains 0.075 mg benzoate salt in each tablet.

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

- 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.

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

4. Possible side effects

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

If you have an allergic reaction, stop taking it and see your doctor straight away. The signs may include:

- Skin rashes, itching, or lumps under your skin (hives)
- Swelling of face, lips, tongue or throat, difficulty swallowing and breathing difficulties (angioedema).

Other side effects may include:

Common (may affect up to 1 in 10 people):

- changes with ejaculation (such as a decrease in the amount of semen released during sex which does not appear to interfere with normal sexual function.),
- impotence (an inability to have an erection),
- less desire to have sex

Uncommon (may affect up to 1 in 100 people):

- problems with ejaculation that may continue after stopping the medication, breast swelling or tenderness.

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

- testicular pain, blood in semen, feeling your heartbeat, increased liver enzymes.
- Decrease in sex drive that may continue after stopping the medication
- Depression
- an inability to have an erection which may continue after stopping the medication
- Anxiety
- male infertility and/or poor quality of semen. Improvement in the quality of the semen has been reported after stopping medication
- palpitations (feeling your heartbeat)
- changes in the way your liver is working, which can be shown by a blood test

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly, in UK via the Yellow Card Scheme at: 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.

This product does not require any special storage condition.

Do not use Finasteride after the expiry date which is stated on the carton and blister after “Exp”. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Finasteride tablet contains

- The active substance is finasteride. Each film-coated tablet contains 5 mg finasteride.
- The other ingredients are: lactose monohydrate, sodium starch glycolate (Type A), maize starch, silica, colloidal anhydrous (Aerosil 200), docusate sodium, sodium benzoate (E211), magnesium stearate, hypromellose 15 cp/HPMC 2910, titanium dioxide (E171), macrogol 6000, indigo carmine lake (E132).

What Finasteride looks like and contents of the pack

Finasteride film-coated tablets are light blue, circular, biconvex, film-coated tablets, debossed with FIN on one side and plain on the other side. Diameter 7.00-7.30 mm.

Finasteride tablets are supplied in blister packs of 28 tablets.

Marketing Authorisation Holder

Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom

Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:
United Kingdom Finasteride 5 mg Film-coated Tablets

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