

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 to 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

The name of your medicine is Finasteride 5 mg Film-coated Tablets. Finasteride tablets are film-coated tablets and contain the active ingredient finasteride. This belongs to a group of medicines called 'testosterone-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 a child
- if you are allergic (hypersensitive) 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.

Warnings and precautions

Take special care with Finasteride

Check with your doctor or pharmacist before taking your medicine if:

- 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.
- 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.

Children:

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

Other medicines and Finasteride

Finasteride does not usually affect other medicines. Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

There are no data to suggest that finasteride affects the ability to drive or use machines

Finasteride tablets contains lactose

Finasteride tablets contains lactose, which 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 before taking this medicine.

3. HOW TO TAKE FINASTERIDE

Always take your tablets exactly as your doctor has told you. You should 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

You should promptly report to your doctor any changes in your breast tissue such as lumps, pain or nipple discharge as these may be signs of a serious condition, such as breast cancer.

Frequency of these allergic reactions is not known.

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 your lips and face.

The following side effects may happen with this medicine:

Common (affects 1 to 10 users in 100):

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 (affects 1 to 10 users in 1,000):

problems with ejaculation, breast swelling and/or tenderness, rash

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

- testicular pain, feeling your heartbeat, increased liver enzymes.
- less desire to have sex even after discontinuing finasteride
- depression
- itching
- hives
- erectile dysfunction that continued after discontinuation of treatment
- male infertility and/or poor quality of semen (normalization or improvement of seminal quality has been reported after discontinuation of finasteride)

Finasteride may affect the result of PSA-laboratory test.

Reporting of side effects

If you get any side effect, 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 via the national reporting system

HPRA Pharmacovigilance

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Website: www.hpra.ie

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

5. HOW TO STORE FINASTERIDE

Keep 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 after "Exp". The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Finasteride tablets contains

- The active substance is finasteride. Each tablet contains 5 mg finasteride.

- The other ingredients are: Lactose monohydrate, sodium starch glycolate Type A, maize starch, colloidal anhydrous silica, docusate sodium, sodium benzoate E211, magnesium stearate, hypromellose 2910, titanium dioxide E171, macrogol/PEG 6000, indigo carmine lake E132.

What Finasteride looks like and contents of the pack

Finasteride 5 mg Film-coated tablets are light blue, circular, biconvex, film-coated tablets, debossed with FIN on one side and plain on the other side.

Finasteride 5 mg Film-coated tablets are supplied in blister packs of 28 tablets.

Marketing Authorisation Holder

Cipla (EU) Limited, Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW, United Kingdom.

Manufacturer

Cipla (EU) Limited, 4th Floor, 1 Kingdom Street, London, W2 6BY, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Cyprus	Finasteride Cipla 5 mg επικαλυμμένο με λεπτό υμένιο δισκία
Greece	Finasteride/Cipla 5 mg επικαλυμμένα με λεπτό υμένιο δισκία
Ireland	Finasteride 5 mg Film-coated Tablets
Malta	Finasteride 5 mg Film-coated Tablets
United Kingdom	Finasteride 5 mg Film-coated Tablets

This leaflet was last revised in Month of Variation approval.