

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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 contains the active substance finasteride which belongs to the group of medicines called 5-alpha reductase inhibitors. They act by reducing the size of the prostate gland in men.

Finasteride is used in the treatment and control of benign (non-cancerous) enlargement of the prostate (benign prostatic hyperplasia BPH). It reduces the risk of you developing a sudden inability to pass urine (known as acute urinary retention) and the need for surgery.

2. What you need to know before you take Finasteride

Do not take Finasteride:

- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman (see also under 'Pregnancy, breast-feeding and fertility').
- if you are a child.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Finasteride

- if you have reduced liver function.
- if you have difficulty emptying your bladder completely or a greatly reduced flow of urine, your doctor should examine you thoroughly before you start taking Finasteride to exclude other obstructions in the urinary tract.
- if you notice any changes in your breast tissue such as lumps, pain, enlargement of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer. You should promptly report to your doctor if you notice any of these changes.

If your sexual partner is or may potentially be pregnant, you should avoid exposing her to your semen which could contain a tiny amount of the drug (see also 'Pregnancy and breast-feeding' in this section).

If you need to have a blood test called "PSA", make sure you tell your doctor or nurse first since finasteride may alter the results of the 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.

Other medicines and Finasteride

Finasteride does not usually interfere with other medicines. Please ask your doctor before you take other medicines at the same time.

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

Finasteride with food and drink

Finasteride can be taken with or without food.

Pregnancy, breast-feeding and fertility

Finasteride is only intended for men.

If your sexual partner is or may potentially be pregnant, you should avoid exposing her to your semen which could contain a tiny amount of the drug.

Women who are or may potentially be pregnant should not handle broken or crushed Finasteride tablets. If finasteride is absorbed through the skin or taken by mouth by a woman pregnant with a male foetus, the child may be born with malformed genital organs. The tablets are film-coated which prevents contact with finasteride provided the tablets are not broken or crushed.

Driving and using machines

There is no evidence to suggest that Finasteride affects the ability to drive or to use machines.

Finasteride contains lactose

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 (23mg) per film-coated 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.

The recommended dose is one tablet daily (equivalent to 5 mg finasteride).

The film-coated tablet should be swallowed whole and should not be broken or crushed. It may be taken with or without food.

Your doctor may prescribe finasteride along with another medicine (called doxazosin) to help control your BPH.

If you take more Finasteride than you should

Immediately contact a doctor, the nearest hospital casualty department or the centre for poison information for advice.

If you forget to take Finasteride

Do not take a double dose to make up for a forgotten dose. Just take the next one when it is due.

If you stop taking Finasteride

Although an improvement is often noticed after a short time, it may be necessary to continue the treatment for at least 6 months. Do not alter the dose or stop treatment without asking your doctor.

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.

Stop using Finasteride and immediately contact your doctor if you experience any of the following symptoms (angioedema): Swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties. These symptoms can be signs of an allergic reaction, which is reported as not known (frequency cannot be estimated from the available data).

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

- Decreased volume of ejaculate
- You may be unable to have an erection (impotence)
- You may have less desire to have sex

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

- Rash
- Problems with ejaculation that may continue after stopping the medication
- Breast swelling or tenderness

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

- Pruritus (itching), urticaria (hives)
- Palpitations (abnormal heartbeat)
- Increased hepatic enzymes (liver enzymes of which levels are assessed via blood test)
- Pain in your testicles
- An inability to obtain an erection, which may continue after stopping the medication
- Male infertility and/or poor seminal quality of semen
- Depression
- Decrease in sex drive that may continue after stopping the medication
- Anxiety

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

Combination therapy with doxazosin

The following adverse effects have been reported more frequently when finasteride was used together with the alpha-receptor blocker doxazosin: asthenia 16.8% (placebo 7.1%), postural hypotension 17.8% (placebo 8.0%), dizziness 23.2% (placebo 8.1%), and ejaculation disorders 14.1% (placebo 2.3%).

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.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label 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 protect the environment.

6. Contents of the pack and other information

What Finasteride contains

The active substance is finasteride. One film-coated tablet contains 5 mg of finasteride.

The other ingredients are:

Tablet core: lactose monohydrate, microcrystalline cellulose, starch pregelatinized, sodium starch glycolate, docusate sodium, magnesium stearate.

Film coating: hypromellose (E464), titanium dioxide (E171), indigo carmine aluminium lake (E132), talc, iron oxide yellow (E172).

What Finasteride looks like and contents of the pack

Film-coated Tablet.

Blue coloured, round film coated tablets, debossed with 'H' on one side and '37' on the other side.

Finasteride tablets are available in blister packs containing 15, 28, 30, 50, 90, 98 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Amarox Limited
Congress House
14 Lyon Road
Harrow, Middlesex HA1
2EN United Kingdom

Manufacturer

Pharmadox Healthcare Ltd.
KW20 A Kordin Industrial Park
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Malta

or

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

Germany:	Finasterid Amarox 5 mg Filmtabletten
Denmark:	Finasterid Amarox 5 mg Filmovertrukne tabletter
France:	Finasteride Amarox 5 mg comprimé pelliculé
Spain:	Finasterida Tarbis 5 mg comprimidos recubiertos con película EFG
Italy:	Finasterida Amarox
Netherlands:	Finasteride Amarox 5 mg filmomhulde tabletten
Portugal:	Finasterida Amarox

Sweden: Finasteride AmaroX 5 mg Filmtabletten
United Kingdom: Finasteride 5 mg film-coated tablets

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