



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. They act by reducing the size of the prostate gland in men.

Finasteride is used in the treatment and control of benign enlargement of the prostate (benign prostatic hyperplasia - BPH). It causes regression of the enlarged prostate, improves urinary flow and symptoms caused by BPH, and reduces the risk of 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 (because this medicine is for men)
- if you are a child.

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 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 and may affect the normal development of the baby's sex organs.

Consult your doctor if any of the above applies to you now or in the past.

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

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.

Women who are pregnant or may become 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. When the patient's sexual partner is or may become pregnant, the patient should either avoid exposure of his partner to semen (e.g. by use of a condom) or discontinue treatment with Finasteride.

Driving and using machines

As far as is known, Finasteride has no influence on the ability to drive or operate machinery.

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 (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.

Adults

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

The film-coated tablets can either be taken on an empty stomach or with a meal. The film-coated tablets should be swallowed whole and should not be divided or crushed.

Although early improvement may be seen, treatment for at least six months may be necessary to assess whether a beneficial response has been achieved.

Your doctor will tell you how long you should continue to take Finasteride 5 mg. Do not interrupt treatment early or the symptoms may come back.

Patients with impaired liver function

There is no experience of the use of Finasteride 5 mg in patients with restricted liver function.

Patients with impaired kidney function

No dosage adjustment is required (see "Adults"). The use of Finasteride 5 mg in patients who have to undergo haemodialysis has not been investigated to date.

Elderly patients

No dosage adjustment is required (see "Adults").

Please speak to your doctor or pharmacist if you feel that the effect of Finasteride 5 mg is too strong or too weak.

If you take more Finasteride than you should

If you take more Finasteride than you should or if children have been taken medicine by accident please notify your doctor or pharmacist immediately.

If you forget to take Finasteride

If you forget to take a dose of Finasteride 5 mg, you can take it as soon as you remember unless it is almost time for the next dose, in which case you should continue with your medication as prescribed.

- Do not take a double dose to make up for a forgotten dose.
- 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:

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

- 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.

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

- Breast swelling or tenderness
- Rash
- Ejaculation problem

Not known: frequency cannot be estimated from the available data

- Palpitations (feeling your heartbeat)
- Changes in the way your liver is working, which can be shown by a blood test
- Pain in your testicles
- Anxiety

Allergic reactions

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, tongue, throat and face.
- depression, decreased libido that continued after discontinuation of treatment
- erectile dysfunction that continued after discontinuation of treatment
- Male infertility and/or poor seminal quality. Infertility has been reported in men who took finasteride for long time and had other risk factors that may affect fertility. Normalisation or improvement of seminal quality has been reported after discontinuation of finasteride.

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 you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. It will help if you make a note of what happened, when it started and how long it lasted.

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. 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

Milpharm Limited,
Ares, Odyssey Business Park,
West End Road,
South Ruislip HA4 6QD,
United Kingdom.

Manufacturer

Milpharm Limited,
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or

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000.
Malta

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

Cyprus	Finasterid Aurobindo 5 mg επικαλυμμένο με λεπτό υμένιο δισκία
Germany	Finasterid Aurobindo 5 mg Filmtabletten
Denmark	Finasterid "Aurobindo"
Spain	FINASTERIDA AUROBINDO 5 mg comprimido recubierto con película EFG
France	FINASTERIDE ARROW LAB 5 mg comprimé pelliculé
Ireland	Fintrid 5 mg film-coated tablets
The Netherlands	Finasteride Aurobindo 5 mg filmomhulde tabletten
Poland	ADASTER
Portugal	Finasterida Aurobindo
Sweden	Finasterid Aurobindo 5 mg filmdragerade tabletter
United Kingdom	Finasteride 5 mg film-coated tablets

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