



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.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Finasteride is and what it is used for
2. Before you take Finasteride
3. How to take Finasteride
4. Possible side effects
5. How to store Finasteride
6. Further 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. Before you take Finasteride

Do not take Finasteride

- if you are allergic (hypersensitive) to finasteride or any of the other ingredients of Finasteride.
- if you are a woman (because this medicine is for men)
- if you are a child.

Take special care with 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.

Taking other medicines

Finasteride does not usually affect other medicines

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

Taking Finasteride with food and drink

Finasteride can be taken with or without food.

Pregnancy and breast-feeding

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.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of Finasteride

This medicinal product 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.

3. How to take Finasteride

Always take Finasteride exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

The usual 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 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 product, ask your doctor or pharmacist.

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4. Possible side effects

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

The following side effects may happen with this medicine:

Common (occur in more than 1 in 100 patients):

- 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 (occur in less than 1 in 100 patients):

- Breast swelling or tenderness

Unknown (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

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 and face.

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.

If you would like further information about the tumour grading system or this trial, please talk to your doctor.

5. How to store Finasteride

Keep out of the reach and sight of children.

Do not use Finasteride 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 medicinal product does not require any special storage conditions.

Do not use Finasteride if you notice visible signs of deterioration.

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. Further 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 is available in PVC/PE/PVdC-aluminium foil blister packs containing 10, 14, 15, 20, 28, 30, 45, 50, 60, 90, 98, 100 or 120 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aurobindo Pharma Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom
Tel: ++ 44 20 8845 8811
Fax: ++ 44 20 8845 8795

Manufacturer

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West End Road
South Ruislip HA4 6QD
United Kingdom
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:

Austria:	Finasterid Aurobindo 5 mg Filmtabletten
Belgium:	Finasteride Aurobindo Pharma 5 mg comprimés pelliculés
Cyprus:	Finasterid Aurobindo 5 mg επικαλυμμένο με λεπτό υμένιο δισκία
Czech Republic:	Finasterid Aurobindo 5 mg potahované tablety
Germany:	Finasterid Aurobindo 5 mg Filmtabletten
Denmark:	Finasterid Aurobindo 5 mg filmovertrukne tabletter
Estonia:	Finasteride Aurobindo
Greece:	FINESCAR 5 mg επικαλυμμένο με λεπτό υμένιο δισκία
Spain:	FINASTERIDA AUROBINDO 5 mg comprimido recubierto con película EFG
Finland:	Finasterid Aurobindo 5 mg kalvopäällysteinen tabletti
France:	FINASTERIDE AUROBINDO 5 mg comprimé pelliculé
Hungary:	Finasteride Aurobindo 5 mg filmtabletta
Ireland:	Finasteride Aurobindo 5 mg film-coated tablets
Italy:	FINASTERIDE DOC Generici 5 mg compresse rivestite con film
Lithuania:	Finasterid Aurobindo 5 mg plėvele dengtos tabletės
Latvia:	Finasterid Aurobindo 5 mg apvalkotās tabletes
The Netherlands:	Finasteride Aurobindo 5 mg filmomhulde tabletten
Norway:	Finasterid Aurobindo 5 mg filmdrasjerte tabletter
Poland:	Finasteride Aurobindo 5 mg
Portugal:	Finasterida Aurobindo
Slovenia:	Finasterid Aurobindo 5 mg filmsko obložene tablete
Slovak Republic:	Finasterid Aurobindo 5 mg filmom obalené tablety
Sweden:	Finasterid Aurobindo 5 mg filmdragerade tabletter
United Kingdom:	Finasteride 5 mg film-coated tablets

This leaflet was approved in 03/2011.