



Package Leaflet:
Information for the user
Finasteride
1 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
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1. What Finasteride is and what it is used for

- Finasteride 1 mg film-coated tablets contains the active substance called finasteride.

Finasteride is for use in men only.

- Finasteride is used for the treatment of male pattern hair loss (also known as androgenetic alopecia) in men aged 18-41. If after reading this leaflet, you have any questions about male pattern hair loss, ask your doctor.
- Male pattern hair loss is a common condition thought to be caused by a combination of genetic factors and a particular hormone, called dihydrotestosterone (DHT). DHT contributes to shortening of the growth phase of the hair and to thinning of the hair.
- In the scalp, Finasteride specifically lowers the levels of DHT by blocking an enzyme (Type II 5-alpha reductase) that converts testosterone to DHT. Only men with mild to moderate, but not complete hair loss can expect to benefit from the use of Finasteride. In most of the men treated with Finasteride for 5 years, the progression of hair loss was slowed, and at least half of these men also had some kind of improved hair growth.

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).
- you are a woman (because this medicine is for men, see Pregnancy). It has been shown in clinical trials that Finasteride does not work in women with hair loss

Warnings and precautions

Talk to your doctor or pharmacist before taking Finasteride.

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 stop taking Finasteride and contact your doctor for further medical advice as soon as possible.

Effects on Prostate Specific Antigen (PSA)

Finasteride can affect a blood test called PSA (Prostate-Specific Antigen) for the screening of prostate cancer. If you have a PSA test done you should tell your doctor or pharmacist that you are taking Finasteride because Finasteride decreases PSA levels.

Effects on fertility

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. Long-term clinical studies about the effect of finasteride on fertility in men have not been conducted.

Breast cancer

See section 4.

Children and adolescents

Finasteride should not be used in children. There are no data demonstrating efficacy or safety of finasteride in children under the age of 18.

Other medicines and Finasteride

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

Pregnancy, breast-feeding and fertility

Finasteride is for the treatment of male pattern hair loss in men only. For effects on fertility in men see section 2.

- **Women must not use Finasteride due to the risk in pregnancy.**
- **Do not touch crushed or broken tablets of Finasteride if you are a woman who is pregnant or may potentially be pregnant.**
- If the active ingredient in Finasteride is absorbed after oral use or through the skin by a woman who is pregnant with a male baby, this may cause the male baby to be born with abnormalities of the sex organs.
- If a woman who is pregnant comes into contact with the active ingredient in Finasteride, a doctor should be consulted.
- Finasteride tablets are coated and will prevent contact with the active ingredient during normal use.
- If you have questions, ask your doctor.

Driving and using machines

There are no data indicating that Finasteride affects your ability to drive or operate machinery.

Finasteride contains lactose, patients who are intolerant should note that Finasteride film-coated tablets contains lactose. If you have ever been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

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 each day.
- The tablets can be taken with or without food.

Your doctor will help you to determine if Finasteride is working for you. It is important to take Finasteride for as long as your doctor prescribes it. Finasteride can only work over the long term if you continue taking it.

If you take more Finasteride than you should

If you take too many tablets by mistake, talk to your doctor promptly. Finasteride will not work faster or better if you take it more than once a day.

If you forget to take Finasteride

Do not take a double dose to make up for the forgotten tablet.

If you stop taking Finasteride
It may take 3 to 6 months for the full effect to develop. It is important to keep taking Finasteride as long as your doctor tells you. If you stop taking Finasteride,

you are likely to lose the hair you have gained within 9 to 12 months.

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 side effects have usually been temporary with continued treatment or disappeared when treatment is stopped.

Stop taking Finasteride and talk to your doctor immediately if you have any of the following symptoms: swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties.

You should promptly report to your doctor any changes in the 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.

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

- less desire to have sex
- difficulty having an erection
- problems with ejaculation such as a decrease in the amount of semen released
- depression

Not known: frequency cannot be estimated from the available data

- allergic reactions such as rash and itching, breast swelling or tenderness
- pain in the testicles
- fast heart beat
- persistent difficulty having an erection after discontinuation of treatment
- persistent decrease in sex drive after discontinuation of treatment
- persistent problems with ejaculation after discontinuation of treatment
- male infertility and/or poor quality of semen
- elevated liver enzymes
- Anxiety

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Malta

ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website:
www.medicinesauthority.gov.mt
e-mail:
postlicensing.medicinesauthority@gov.mt

The United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

5. How to store Finasteride

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label, carton, bottle 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. Each film-coated tablet contains 1 mg finasteride.
- The other ingredients are:
Tablet core: Lactose monohydrate, cellulose, microcrystalline, sodium starch glycolate, starch pregelatinized [maize starch], docusate sodium, magnesium stearate
Tablet coat: Hypromellose, hydroxy propyl cellulose, talc, titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172).

What Finasteride looks like and contents of the pack

Film-coated tablet

Brown coloured, octagonal, biconvex, film-coated tablets debossed with 'J' on one side and '81' on the other side.

Finasteride film-coated tablets are available in white opaque PVC/PE/PVdC – Aluminium foil blister pack and HDPE bottle with polypropylene cap containing silica gel as desiccant.

Package size:

Blister pack: 28, 56, 84, & 98 film-coated tablets

HDPE bottle pack: 30 & 1000 film-coated tablets

Not all pack sizes may be marketed

Marketing Authorization Holder

UK - Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

MT - Aurobindo Pharma (Malta) Limited
Vault 14, Level 2, Valletta Waterfront
Floriana FRN 1913
Malta

Manufacturer

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

or

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

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

France: FINASTERIDE
ARROW LAB 1 mg,
comprimé pelliculé
Germany: Finasterid Aurobindo
1 mg Filmtabletten
Italy: Finasteride Aurobindo
Pharma Italia 1 mg
compresse rivestite
con film
Malta: Finasteride 1 mg film-
coated tablets
Portugal: Finasterida Aurobindo
Spain: FINASTERIDA
AUROVITAS 1 mg
comprimidos
recubiertos con
película EFG
United Kingdom: Finasteride 1 mg film-
coated tablets

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