

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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

- are already taking finasteride or dutasteride used for a prostate problem called benign prostatic hyperplasia.
- are a child or an adolescent. Finasteride tablets is not indicated for use in children and adolescents.

Warnings and precautions

Talk to your doctor or pharmacist before taking Finasteride tablets.

Effects on Prostate Specific Antigen (PSA)

Finasteride tablets 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 tablets because Finasteride tablets decreases PSA levels.

Breast cancer

Breast cancer has been reported in men taking finasteride during the post-marketing period. You must inform your doctor if you notice any changes in breast tissue, such as lumps, pain, enlargement of the breast (gynaecomastia) or nipple discharge.

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 tablets and contact your doctor for further medical advice as soon as possible.

Children and adolescents

Finasteride tablets should not be used in children or adolescents under the age of 18.

Other medicines and Finasteride tablets

Finasteride tablets does not usually interfere with other medicines. Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Pregnancy, breast-feeding and fertility

Finasteride tablets is for the treatment of male pattern hair loss in men only.

- **Women must not use Finasteride tablets due to the risk in pregnancy.**
- Do not touch crushed or broken tablets of Finasteride tablets if you are a woman who is pregnant or may potentially be pregnant.
- If the active substance in Finasteride tablets 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 substance in Finasteride tablets, a doctor should be consulted.
- Finasteride tablets are coated and will prevent contact with the active substance during normal use.

It is not known whether finasteride is excreted in human milk.

Infertility has been reported in men who have taken finasteride for a long time, but also had other risk factors.

What is in this leaflet

1. What Finasteride tablets are and what they are used for
2. What you need to know before you take Finasteride tablets
3. How to take Finasteride tablets
4. Possible side effects
5. How to store Finasteride tablets
6. Contents of the pack and other information

1. WHAT FINASTERIDE TABLETS ARE AND WHAT THEY ARE USED FOR

Finasteride tablets contains the active substance finasteride. **Finasteride tablets is for use in men only.** Finasteride tablets is used to **treat early forms of male pattern hair loss** (also called androgenetic alopecia). Finasteride tablets increases hair growth on the scalp and prevents further hair loss in men. Men with mild to moderate, but not complete hair loss, can benefit from using Finasteride tablets.

Male pattern hair loss is a common condition in which men experience thinning of the hair on the scalp, often resulting in a receding hairline and/or balding on the top of the head. This condition is thought to be caused by a combination of genetic factors and a particular hormone, DHT (dihydrotestosterone). DHT causes a decrease in the growth phase and thinning of the hair. This leads to male pattern hair loss. These changes can start to occur in some men in their 20s and become more common with age. Once hair loss has occurred over a long period of time, the hair may be permanently lost. Finasteride tablets lowers the levels of DHT in the scalp. This helps to reverse the balding process, leading to an increased hair growth and prevention of further hair loss.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FINASTERIDE TABLETS

Do not take Finasteride tablets if you

- are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6)
- 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.

Semen quality improves after discontinuation of finasteride.
Talk to your doctor if you have any questions regarding fertility.

Driving and using machines

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

Finasteride Tablets contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.

This medicine contains less than 1 mmol (23 mg) sodium per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Finasteride tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

The recommended dose is 1 mg (1 tablet) daily. **The tablet should be swallowed whole and should not be broken or crushed.** It may be taken **with or without food.**

If you take more Finasteride tablets than you should

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

If you forgot to take Finasteride tablets

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

If you stop taking Finasteride tablets

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

Some of the side effects are temporary with continued treatment or disappear when treatment is stopped.

Stop using Finasteride tablets and immediately contact a doctor if you experience any of the following symptoms (angioedema): swelling of face, tongue or throat; difficulty swallowing; hives and breathing difficulties. Depression (feelings of severe sadness and unworthiness). The frequency is not known (cannot be estimated from the available data).

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. The frequency is not known (cannot be estimated from the available data).

Please tell your doctor or pharmacist if you notice any of the following effects or any side effects not listed.

Uncommon: may affect up to 1 in 100 people

- decrease in sex drive
- 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 heartbeat
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 tablets

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister, carton or bottle 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 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 tablets contains

- the active substance is finasteride 1 mg
- the other ingredients are lactose monohydrate, microcrystalline cellulose, starch, pregelatinised, lauroyl macroglycerides, sodium starch glycolate (Type A), magnesium stearate, hypromellose, titanium dioxide (E171), yellow and red iron oxide (E172) and macrogol 600.

What Finasteride tablets looks like and contents of the pack

Finasteride 1 mg Film-coated Tablets are round, biconvex reddish-brown tablets, marked 'F1'. They are supplied in: Aluminium/PVC or Aluminium/Aluminium blister packs containing 28 tablets Plastic bottles (HDPE) with cap containing 28 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Sandoz Limited, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR. United Kingdom

Manufacturer

Actavis hf, Reykjavikurvegur 78, IS-220 Hafnarfjörður, Iceland. **Or** Actavis Group PTC ehf, Reykjavikurvegur 76 - 78, 220 Hafnarfjörður, Iceland **Or** Salutas Pharma GmbH Otto-von-Guericke-Allee 1, D-39179 Barleben, Germany

This leaflet was last revised in 07/2019.