

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.

What is in this leaflet

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

1. What Finasteride 1 mg film-coated tablets are and what they are used for

Finasteride belongs to a group of medicines called 5-alpha reductase inhibitors. Finasteride works by shrinking the prostate gland in men when it is swollen.

Your doctor has prescribed Finasteride 1 mg film-coated tablets because you have male pattern hair loss (also known as androgenetic alopecia). Finasteride 1 mg film-coated tablets prevent further hair loss in men. Men with mild to moderate, but not complete hair loss, can benefit from using Finasteride 1 mg film-coated tablets. Finasteride 1 mg film-coated tablets block an important enzyme (Type II 5 α -reductase), which is involved in the regulation of the hair follicle. In the scalp, Finasteride 1 mg film-coated tablets specifically lower the levels of DHT, a major cause of male pattern hair loss. In this way, Finasteride 1 mg film-coated tablets help to reverse the balding process and prevent further hair loss.

2. What you need to know before you take Finasteride 1 mg film-coated tablets

Do not take Finasteride 1 mg film-coated tablets

- if you are a woman (because this medicine is for men). Finasteride has been found to be ineffective in the treatment of hair loss (androgenetic alopecia) in women in clinical studies.
- if you are allergic (hypersensitive) to finasteride or any of the other ingredients of this medicine (listed in section 6).
- if you are a child or adolescent.
- if you are already taking finasteride or any other 5 α -reductase inhibitor for benign prostatic hyperplasia (BPH) or any other condition.

Do not take Finasteride 1 mg film-coated tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Finasteride 1 mg film-coated tablets if:

- your partner is pregnant or planning to become pregnant. You should use a condom or other barrier method of contraception when taking finasteride. This is because your semen could contain a tiny amount of the drug and may affect the normal development of the baby's sex organs.
- If you are going to have a blood test called PSA. This is because finasteride can affect the results of this test.

If you are not sure, talk to your doctor or pharmacist before taking Finasteride 1 mg film-coated tablets.

Effects on fertility

Infertility has been reported in men who took finasteride for a 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 effects of finasteride on fertility in men have not been conducted.

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.

Children and adolescents

Finasteride 1 mg film-coated tablets should not be used in children. There are no data demonstrating efficacy or safety of finasteride in children under the age of 18.

Taking other medicines

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.

- Do not take Finasteride 1 mg film-coated tablets if you are already taking finasteride or dustasteride, used for a prostate problem called benign prostatic hyperplasia (BPH).
- No information is available about the use of finasteride with minoxidil, another type of medicine for male pattern hair loss which is applied to the head.

Taking Finasteride with food and drink

Finasteride 1 mg film-coated tablets can be taken with or without food.

Pregnancy and breast feeding

- Finasteride 1 mg film-coated tablets should not be taken by women.
- Do not touch crushed or broken Finasteride 1 mg film-coated tablets if you are a woman who is pregnant or planning to become pregnant (whole tablets are coated to stop contact with the medicine during normal use). This is because this medicine may affect the normal development of the baby's sex organs.
- If a woman who is pregnant comes into contact with crushed or broken Finasteride 1 mg film-coated tablets, speak to your doctor.

Driving and using machines

Finasteride is not likely to affect you being able to drive, use tools or machines.

Finasteride contains:

- Lactose. This is a type of sugar. If you have ever been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor or pharmacist before taking this medicine.

3. How to take Finasteride 1 mg film-coated 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.

Taking this medicine

- The recommended dose is one tablet each day to be taken with or without food.
- Take this medicine by mouth.

If you take more Finasteride 1 mg film-coated tablets than you should

- If you take too many tablets by mistake, contact your doctor immediately. Finasteride 1 mg film-coated tablets will not work faster or better if you take it more than once a day.

If you forget to take Finasteride 1 mg film-coated tablets

- If you forget to take a tablet, skip the missed dose
- Take the next dose as usual
- Do not take a double dose to make up for a forgotten dose

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 1 mg film-coated tablets for 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 following side effects may happen with this medicine:

Stop using Finasteride 1 mg film-coated tablets and immediately contact a doctor if you experience any of the following symptoms:

- Symptoms of an allergic reaction: swelling of face, lips, tongue or throat, difficulty swallowing and breathing difficulties (angioedema), skin rashes, itching, or lumps under your skin (hives).
- Depression (feeling of severe sadness and unworthiness)

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.

Uncommon: may affect up to 1 in 100 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

Frequency unknown:

- breast swelling or tenderness
- palpitations (feeling your heartbeat)
- changes in the way your liver is working, which can be shown by a blood test
- pain in the testicles
- 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

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.

Will the use of Finasteride 1 mg film-coated tablets affect the hair on other parts of your body?

Finasteride 1 mg film-coated tablets do not affect hair on other parts of the body.

What else should you know about Finasteride?

Finasteride can also be used for a type of prostate problem called benign prostatic hyperplasia or BPH. Information collected for a clinical trial in men taking finasteride 5 mg (a dose five times higher than Finasteride 1 mg film-coated tablets) for 7 years showed:

- The number of men who developed prostate cancer was lower in men taking finasteride compared with those taking nothing.
- The number of men who had a high score in a tumour grading system was higher in some of those taking finasteride compared to those taking nothing.
- The effect of long-term use of finasteride on tumours of this kind is not known

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 1 mg film-coated tablets

- Keep this medicine out of the sight and reach of children.
- Do not store your tablets above 25°C. Keep them in the original package.
- Do not use this medicine after the expiry date which is stated on the carton after the letters 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.
- If you notice signs of your medicine deteriorating, consult your pharmacist.

Important

This medicine has been prescribed for you. Never give it to anyone else because it may harm them even though they may seem to have the same symptoms as you.

6. Contents of the pack and other information

What Finasteride 1 mg film-coated tablets contain

The active substance is finasteride. Each tablet contains 1 mg finasteride.

- The other ingredients are lactose monohydrate, maize starch, docusate sodium, sodium starch glycolate, microcrystalline cellulose, silica, magnesium stearate, hydroxypropyl cellulose, hypromellose, titanium dioxide, talc, iron oxide red (E172), iron oxide yellow (E172).

What Finasteride 1 mg film-coated tablets look like and the content of the pack

Finasteride 1 mg film-coated tablets are available as red, round biconvex tablets. Finasteride 1 mg film-coated tablets are supplied in blister packs of 28 or 84 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

Avianta Pharma Limited.

87a Worship Street
London
EC2A 2BE
United Kingdom

Manufacturer:

Genepharm S.A.,

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153 51 Pallini Attikis, Greece.

This leaflet was last revised in April 2020.

This leaflet gives you some important patient information about Finasteride 1 mg film-coated tablets. If you have questions after you read it, ask you doctor or pharmacist, who will give you further information.