

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 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

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1. What Finasteride 1 mg Tablets are and what they are used for

Finasteride 1 mg Tablets contain finasteride. Finasteride belongs to the group of medicines called 5-alpha reductase inhibitors.

Your doctor has prescribed Finasteride 1 mg Tablets because you have male pattern hair loss (also known as androgenetic alopecia). Finasteride 1 mg Tablets prevent further hair loss in men. Men with mild to moderate, but not complete hair loss, can benefit from using Finasteride 1 mg Tablets. Finasteride 1 mg 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 Tablets specifically lower the levels of DHT, a major cause of male pattern hair loss. In this way, Finasteride 1 mg Tablets help to reverse the balding process and prevent further hair loss.

2. What you need to know before you take Finasteride 1 mg Tablets

Do not take Finasteride 1 mg Tablets:

- If you are allergic 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 a woman (see also under 'Pregnancy and breast-feeding'). Finasteride 1 mg Tablets have been found to be ineffective in the treatment of hair loss (androgenetic alopecia) in women in clinical studies.
- If you are already taking finasteride or any other 5 α -reductase inhibitor for benign prostatic hyperplasia (BPH) or any other condition.

Warnings and precautions

Talk to your doctor or pharmacist before taking Finasteride 1 mg Tablets

Determination of prostate-specific-antigen (PSA) in serum should be carried out prior to initiating therapy with finasteride and during treatment.

Finasteride may affect male fertility. Patients who are planning to father a child should consider stopping treatment.

Mood alterations and depression

Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with Finasteride 1 mg Tablets. If you experience any of these symptoms stop taking Finasteride 1 mg Tablets and contact your doctor for further medical advice as soon as possible.

Other medicines and Finasteride 1 mg Tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Finasteride 1 mg Tablets do not usually interfere with other medicines.

No information is available on the use of Finasteride 1 mg Tablets together with topical (applied to the skin) minoxidil in male pattern hair loss. The combination is not recommended.

Taking Finasteride 1 mg Tablets with food and drink:

Finasteride 1 mg Tablets can be taken with or without food.

Pregnancy, breast-feeding and fertility:

Finasteride 1 mg Tablets are only intended for men.

Women who are or may potentially be pregnant should not handle Finasteride 1 mg Tablets especially if broken or crushed. If finasteride is absorbed through the skin or taken by mouth by women pregnant with a male foetus, the child may be born with malformed genital organs.

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:

There is no information to suggest that Finasteride 1 mg Tablets affect the ability to drive and use machines.

Important information about some of the ingredients of Finasteride 1 mg Tablets:

This medicinal product contains lactose. If your doctor has told you that you have intolerance to some sugars contact your doctor before taking this medicinal product.

3. How to take Finasteride 1 mg Tablets

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

The recommended dose is one Finasteride 1 mg tablet daily (equivalent to 1 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.

- Finasteride 1 mg Tablets will not work faster or better if you take them more than once a day.
- Male pattern hair loss is a condition that develops over a long period of time. In general, daily use for three to six months may be necessary before you notice any increase in the hair density or reduction in hair loss.
- Your doctor will help you to assess if Finasteride 1 mg Tablets are working. It is important to continue taking Finasteride 1 mg Tablets for as long as your doctor prescribes them.

Patients with impaired liver function

There is no experience of the use of Finasteride 1 mg Tablets in patients with impaired liver function.

Patients with impaired kidney function

No dosage adjustment is required in patients with impaired kidney function.

If you take more Finasteride 1 mg Tablets than you should:

If you have taken more Finasteride 1 mg Tablets than you were told to, or if someone else has taken any Finasteride 1 mg Tablets, contact the accident and emergency department of your nearest hospital. Take any left over tablets or empty box with you for easier identification.

If you forget to take Finasteride 1 mg Tablets:

If you forget to take a dose of Finasteride 1 mg Tablets, just carry on with the next one as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Finasteride 1 mg Tablets:

Continued use of Finasteride 1 mg Tablets is recommended to obtain maximum benefit. If the treatment is stopped in between, you are likely to lose the hair you have gained within the next 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 taking Finasteride 1 mg Tablets and immediately contact a doctor if you have any of the following experience:

- **Symptoms of an allergic reaction: swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties.**
- **Depression (feelings of severe sadness and unworthiness).**

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 during sex.
- depression

Frequency unknown:

- allergic reactions such as rash, itching, lumps under your skin (hives) and swelling of your lips and face
- breast swelling or tenderness
- palpitations
- 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.
- 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 effect of finasteride on fertility in men have not been conducted.
- Changes in the way your liver is working, which can be shown by a blood test.
- 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.

ADR Reporting

Website: www.medicinesauthority.gov.mt//adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Finasteride 1 mg Tablets

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- 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 no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Finasteride 1 mg Tablets contain:

The active substance is finasteride. One film-coated tablet contains 1 mg of finasteride.

The other ingredients are –

Tablet core: Lactose monohydrate; cellulose, microcrystalline (E460); Starch, pregelatinised (maize); sodium starch glycolate (type-A); lauryl macroglycerides; magnesium stearate (E572).

Film coating: Hypromellose (E464), titanium dioxide (E171), macrogol 6000, iron oxide red (E172), iron oxide yellow (E172).

What Finasteride 1 mg Tablets look like and content of the pack:

Film-coated tablet.

Finasteride 1 mg Tablets are reddish brown, round, biconvex, film-coated tablets marked 'F1' on one side and plain on other side.

Finasteride 1 mg Tablets are packed in Alu- Alu blisters in pack of 28 tablets, 30 tablets, 84 tablets and 98 tablets.

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