

 advertising & communication services ltd.	Artwork No.	-		Colours Used
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	Description	Finasteride 1 mg		
	Market	UK		
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	Version No.	1 (Page 1 of 2) (IA/055)		Keyline
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Package leaflet: Information for the patient

Finasteride 1 mg Film-coated Tablets



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

- What Finasteride 1 mg Tablets are and what they are used for
- What you need to know before you take Finasteride 1 mg Tablets
- How to take Finasteride 1 mg Tablets
- Possible side effects
- How to store Finasteride 1 mg Tablets
- Contents of the pack and other information

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 5α-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 a woman (because this medicine is for men, see Pregnancy). It has been shown in clinical trials that Finasteride 1 mg Tablets does not work in women with hair loss
- If you are allergic (hypersensitive) to finasteride or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions

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

Effects on Prostate Specific Antigen (PSA)
Finasteride 1 mg 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 1 mg Tablets, because it 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 effects of finasteride on fertility in men have not been conducted.

Breast Cancer
See section 4.

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. If you experience any of these symptoms stop taking Finasteride 1 mg and contact your doctor for further medical advice as soon as possible.

Impaired sexual function that may contribute to mood alterations, including suicidal thoughts, has been reported in some patients. If you experience symptoms of impaired sexual function, contact your doctor for further medical advice. Your doctor may consider stopping the treatment (see section 4 below for more information about these side effects).

Impaired sexual function has also been reported without mood alterations or suicidal thoughts.

A patient card reminding of the above is provided with the package of Finasteride 1 mg Tablets.

Children and adolescents
Finasteride 1 mg Tablets 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 1 mg Tablets:

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

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

- Women must not take Finasteride 1 mg Tablets due to the risk in pregnancy.
- Do not touch crushed or broken Finasteride 1 mg Tablets if you are a woman who is pregnant or may potentially be pregnant
- If the active ingredient in Finasteride 1 mg 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.

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.
- Suicidal thoughts

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

Not known (frequency cannot be estimated from the available data):

- allergic reactions such as rash, itching, lumps under your skin (hives) and swelling of your lips and face
- breast swelling or tenderness
- pain in the testicles
- blood in semen
- 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.

Front Side

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- been conducted.
- changes in the way your liver is working, which can be shown by a blood test.
- anxiety
- suicidal thoughts.

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 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 take 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 macrogolglycerides; 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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