

Package leaflet: Information for the user

/.../ 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 /.../ is and what it is used for
2. What you need to know before you take /.../
3. How to take /.../
4. Possible side effects
5. How to store /.../
6. Contents of the pack and other information

1. What /.../ is and what it is used for

/.../ contains a medicine called finasteride. This belongs to a group of medicines called Type II ‘5-alpha reductase inhibitors’.

Your doctor has prescribed /.../ because you have male pattern hair loss (also known as androgenetic alopecia). /.../ 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 /.../.

How does the hair on your head grow?

On average your hair grows about 1 centimeter (half an inch) each month. Hair grows from hair follicles, which are located under your skin.

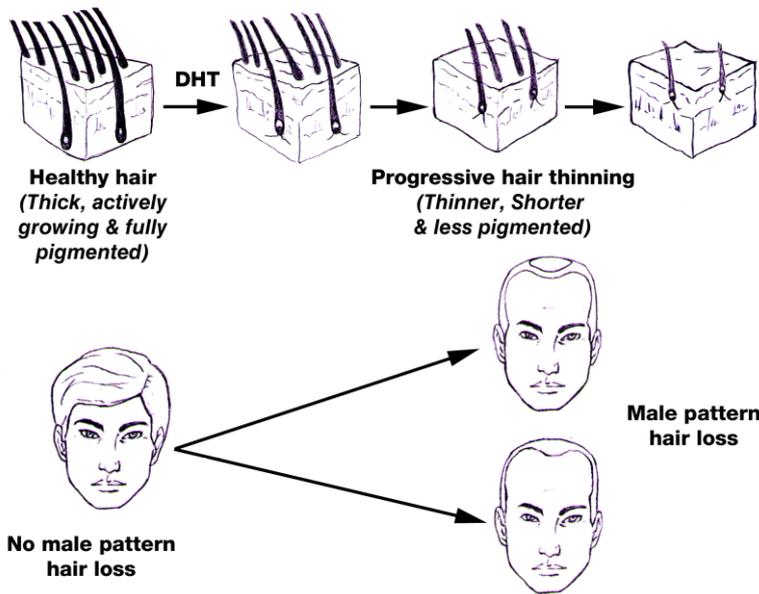
A single scalp hair grows continuously for 2-4 years (growth phase) and then stops growing for 2-4 months (rest phase). After this the hair falls out. In its place a new healthy hair begins to grow, and the cycle is repeated. The hairs on your scalp are always in different stages of this cycle so it is normal to lose scalp hair every day.

What is male pattern hair loss?

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 (see picture). 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.

MALE PATTERN HAIR LOSS



How does /.../ work?

/.../ 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 /.../

Do not take /.../:

- you are a woman (because this medicine is for men, see Pregnancy). It has been shown in clinical trials that /.../ does not work in women with hair loss;
- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6);
- if you are already taking 5 mg finasteride or any other 5 α -reductase inhibitor for benign prostatic hyperplasia (BPH) or any other condition.

Do not take /.../ if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

Warning and precautions

Talk to your doctor or pharmacist before taking Finasteride if:

- you are going to have a blood test for prostate cancer called PSA. This is because Finasteride can affect the results of this test.

Mood alterations and depression

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

If you are not sure, talk to your doctor or pharmacist before taking /.../.

Children and adolescents

/.../ should not be used in children.

Other medicines and /.../

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

/.../ with food and drink

/.../ can be taken with or without food.

Pregnancy and breast-feeding

- Finasteride should not be taken by women.
- Do not touch crushed or broken Finasteride 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 baby's sex organs.
- If a woman who is pregnant comes into contact with crushed or broken Finasteride tablets, speak to your doctor.

Driving and using machines

There is no information to suggest that /.../ affect the ability to drive and use machines.

/.../ contains lactose

If you have been told by your doctor that you have intolerance to some sugars talk your doctor before taking this medicinal product.

3. How to take /.../

Always take this medicine exactly as your doctor 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.
- The tablets can be taken on with or without food. The tablets should be swallowed whole and should not be divided or crushed.
- /.../ will not work faster or better if you take them more than once a day.

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

If you take more /.../ than you should

If you have taken more tablets than you were told to, or if someone else has taken any 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 /.../

If you forget to take a dose of /.../, 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 /.../

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

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

Uncommon (occur in less than 1 in 100 users):

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

Frequency unknown:

- allergic reactions such as rash, itching, lumps under your skin (hives) and angioedema (including swelling of your lips, tongue, throat and face)
- breast swelling or tenderness
- anxiety
- 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 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.
- elevated liver enzymes

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.

Stop taking /.../ and talk to your doctor immediately if you have any of the following symptoms:

- **swelling of your face, tongue or throat**
- **difficulty swallowing**
- **lumps under your skin (hives)**
- **breathing difficulties**

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 national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

Will the use of finasteride affect the hair on other parts of your body?

Finasteride does 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 from a clinical trial in men taking finasteride 5 mg (a dose 5 times higher than /.../) 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 tumor grading system was higher in some of those taking finasteride compared to those taking nothing

- the effect of long-term use of finasteride on tumors of this kind is unknown.

If you would like further information about the tumor grading system or this trial, please talk to your doctor.

5. How to store /.../

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 label 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 /.../ contains

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

The other ingredients are:

- Tablet core: lactose monohydrate, microcrystalline cellulose, starch pregelatinized (maize), sodium starch glycolate (type A), docusate sodium, magnesium stearate.
- Film coating: hypromellose (E464), titanium dioxide (E171), talc, iron oxide yellow (E172), iron oxide red (E172).

What /.../ looks like and contents of the pack

Brown colour, round film coated tablets, debossed with 'H' on one side and '36' on the other side packed in Al/Al blisters.

Pack sizes: 7, 10, 14, 15, 20, 28, 30, 49, 50, 56, 60, 84, 90, 98, 100, 112, 120, 250, 300, 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

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

<To be completed nationally>

This leaflet was last revised in MM/YYYY.