

Package Leaflet: Information for the user
Propecia® 1 mg film-coated Tablets
Finasteride

This medicine is for use in men only

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may want 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 Propecia is and what it is used for
2. What you need to know before you take Propecia
3. How to take Propecia
4. Possible side effects
5. How to store Propecia
6. Contents of the pack and other information

1. What Propecia is and what it is used for

Propecia contains a medicine called finasteride. This belongs to a group of medicines called Type II '5-alpha reductase inhibitors'.

Propecia is used for the treatment of male pattern hair loss (also known as androgenetic alopecia). Propecia 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 Propecia.

How does the hair on your head grow?

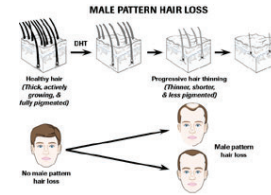
On average your hair grows about 1 centimetre (half an inch) each month. Hair grows from hair follicles, which are located under your skin.

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.



How does Propecia work?

Propecia 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 Propecia

Do not take Propecia:

- if you are a woman (because this medicine is for men). It has been shown in clinical trials that Propecia 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).
- If you are already taking finasteride or dutasteride used for a prostate problem called benign prostatic hyperplasia (BPH).

Do not take Propecia 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 Propecia if:

- you are going to have a blood test for prostate cancer called PSA (prostate-specific antigen). This is because Propecia can affect the result of this test.

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.

Children and adolescents

Propecia should not be used in children. There are no data demonstrating efficacy or safety of finasteride in children under the age of 18.

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Other medicines and Propecia

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Propecia does not usually affect other medicines.

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

Pregnancy, breast feeding and fertility

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

- Propecia should not be taken by women.
- Do not touch crushed or broken Propecia 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 Propecia tablets, speak to your doctor.

Driving and using machines

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

Propecia contains Lactose

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

3. How to take Propecia

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

- The recommended dose is one tablet each day. The tablet can be taken with or without food.

If you take more Propecia than you should

If you take too many tablets by mistake, contact your doctor immediately. Propecia will not work faster or better if you take it more than once a day.

If you forget to take Propecia

- Do not take a double dose to make up for a forgotten dose.

If you stop taking Propecia

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

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4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Propecia and talk to your doctor immediately if you have any of the following symptoms of an allergic reaction: swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties.

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.

These side effects above may disappear after a while if you continue taking Propecia. If these symptoms persist, they usually resolve after stopping Propecia.

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
- depressed mood

If any of these side effects gets serious, or if you notice any side effects not listed on 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 Propecia affect the hair on other parts of your body?

Propecia does not affect hair on other parts of the body.

What else should you know about Propecia?

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 Propecia) 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 unknown.

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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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme at www.mhra.gov.uk/yellowcard

Malta: ADR Reporting at www.medicinesauthority.gov.mt/adrportal

5. How to store Propecia

Keep this medicine out of the sight and reach of children.

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 put the tablets into another container, they might get mixed up. Do not remove the tablet from the pack until you are ready to take it.

Do not store above 30°C. Keep them in the original package.

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 to protect the environment.

6. Contents of the pack and other information

What Propecia contains

- The active substance is finasteride. Each tablet contains 1 mg finasteride.
- The other ingredients are: lactose, microcrystalline cellulose E460, pregelatinised maize starch, sodium starch glycolate, docusate sodium, magnesium stearate E572, hypromellose E464, hydroxypropyl cellulose E463, titanium dioxide, talc, yellow iron oxide E172, red iron oxide E172.

What Propecia looks like and the content of the pack.

- Propecia is available as tan, eight-sided, film-coated tablets, marked with a 'P' logo on one side and PROPECIA on the other.
- Propecia Tablets are supplied in blister packs of 28 tablets or 84 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK.

The Manufacturer of the tablets is Merck Sharp & Dohme Limited, Shotton Lane, Cramlington, Northumberland NE23 3JU, UK.

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