

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 to take this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Propecia is and what it is used for
2. Before you take Propecia
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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'.

Your doctor has prescribed Propecia because you have 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?

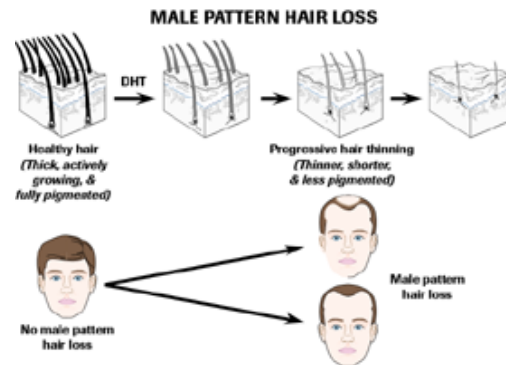
On average your hair grows about 1 centimetre (half an inch) each month. Hair grows from hair follicles, which are located under your skin.

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. 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.
- you are allergic (hypersensitive) to finasteride or any of the other ingredients (listed in Section 6)
- 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 applies to you. If you are not sure, talk to your doctor or pharmacist.

Propecia should not be used in children.

Take special care with Propecia

Check with your doctor or pharmacist before taking your medicine 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.

Taking other medicines

Propecia does not usually affect other medicines. Always tell your doctor about all medicines you are taking or planning to take, including any obtained without a prescription.

Do not take Propecia if you are already taking finasteride or dutasteride, used for a prostate problem called benign prostatic hyperplasia (BPH).

Taking Propecia with food and drink

Propecia can be taken with or without food.

Pregnancy and Breast feeding

- 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.

Important information about some of the ingredients of Propecia.

Propecia contains lactose, which 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 before taking this medicine.

Using other medicine for male pattern hair loss with Propecia

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.

3. How to take Propecia

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

Taking this medicine

- The usual dose is one tablet each day.
- Take this medicine by mouth.
- Propecia will not work faster or better if you take it more than once a day.

If you take more Propecia than you should

If you take too many tablets by mistake, contact your doctor immediately.

If you forget to take Propecia

- If you forget to take a tablet, skip the missed dose.
- Take the next one as usual.
- 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.

4. Possible side effects

Like all medicines, Propecia can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions

If you have an allergic reaction, stop taking it and see your doctor straight away. The signs may include:

- Skin rashes, itching, or lumps under your skin (hives)
- Swelling of lips, face, tongue or throat
- difficulty swallowing
- breathing difficulties.

Other side effects may include:

- 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.

Other side effects reported in men are:

- 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
- 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
- depressed mood.

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 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.

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

5. How to store Propecia

Keep out of the reach and sight of children.

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 use Propecia 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Propecia contains

- The active ingredient in Propecia Tablets is finasteride. Each tablet contains 1 mg finasteride.
- The other ingredients in Propecia are: lactose, microcrystalline cellulose E460, pregelatinised maize starch, sodium starch glycollate, 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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