

PACKAGE LEAFLET INFORMATION FOR THE USER

PROPECIA 1 mg film-coated tablets

Finasteride

Read all of this leaflet carefully before you start taking this medicine.

- 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. 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 gets 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
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1. WHAT PROPECIA IS AND WHAT IT IS USED FOR

Propecia is for use in men only and should not be taken by women or children.

Propecia contains a medicine called finasteride.

Propecia is used for the treatment of male pattern hair loss (also known as androgenetic alopecia). If after reading this leaflet, you have any questions about male pattern hair loss, ask your doctor.

Male pattern hair loss is a common condition thought to be caused by a combination of genetic factors and a particular hormone, called dihydrotestosterone (DHT). DHT contributes to shortening of the growth phase of the hair and to thinning of the hair.

In the scalp, Propecia specifically lowers the levels of DHT by blocking an enzyme (Type II 5-alpha reductase) that converts testosterone to DHT. Only men with mild to moderate, but not complete hair loss can expect to benefit from the use of Propecia. In most of the men treated with Propecia for 5 years, the progression of hair loss was slowed, and at least half of these men also had some kind of improved hair growth.

2. BEFORE YOU TAKE PROPECIA

Do not take Propecia if:

- you are a woman (because this medicine is for men, see Pregnancy). 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)
If you are not sure, talk to your doctor or pharmacist.

Take special care with Propecia

- Propecia should not be taken by children.
- Tell your doctor or pharmacist about any medical problems you have or have had, and about any allergies

Taking other medicines

Propecia can usually be taken with other medicines. Always tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Propecia with food and drink

Propecia can be taken with or without food.

Pregnancy

Propecia is for the treatment of male pattern hair loss in men only.

- **Women must not use Propecia due to the risk in pregnancy.**
- **Do not touch crushed or broken tablets of Propecia if you are a woman who is pregnant or may potentially be pregnant.**
- If the active ingredient in Propecia 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.
- If a woman who is pregnant comes into contact with the active ingredient in Propecia, a doctor should be consulted.
- Propecia tablets are coated and will prevent contact with the active ingredient during normal use.

If you have questions, ask your doctor.

Driving and using machines

There are no data indicating that Propecia affects your ability to drive or operate machinery.

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 have an intolerance to some sugars, talk to your doctor before taking this medicine.

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.
- The tablets can be taken with or without food.
- Propecia will not work faster or better if you take it more than once a day.

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

If you take more Propecia than you should

If you take too many tablets by mistake, talk to your doctor promptly.

If you forgot 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 the 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 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicine, Propecia 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

Frequency unknown:

- 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
- fast heart beat
- 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 effect of finasteride on fertility in men have not been conducted.
- elevated liver enzymes

Stop taking Propecia 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**

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PROPECIA

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Propecia after the expiry date which is stated on the carton after EXP. The first two numbers indicate the month; the last four numbers indicate the year. 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 are:
Tablet core: Lactose monohydrate 110.4 mg, microcrystalline cellulose, pregelatinized corn starch, sodium starch glycolate, docusate sodium, magnesium stearate,
Coating: Talc, hypromellose, hydroxypropyl cellulose, titanium dioxide (color E171), yellow and red iron oxide (color E172).

What Propecia looks like and contents of the pack

- Propecia film-coated tablets are supplied in blisters.
- The tablets are tan, octagonal, film-coated, convex tablets, embossed with “P” on one side and PROPECIA on the other side.
- Pack sizes: 7, 28, 30, 84 or 98 tablets
- Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

<[To be completed nationally]>

This medicinal product is authorized in Austria, Denmark, Finland, France, Germany, Greece, Iceland, Italy, Luxembourg, Netherlands Portugal, Spain and Sweden under the name PROPECIA.

This leaflet was last approved in

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