

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 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 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
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1. What Propecia is and what it is used for

Propecia contains the active substance finasteride.

Propecia is for use in men only.

Propecia is used for the treatment of male pattern hair loss (also known as androgenetic alopecia) in men aged 18-41. 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. What you need to know 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
- 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 Propecia.

Effects on Prostate Specific Antigen (PSA)

Propecia 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 Propecia because Propecia 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 effect 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 Propecia. If you experience any of these symptoms stop taking Propecia and contact your doctor for further medical advice as soon as possible.

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.

Other medicines and Propecia

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

Pregnancy, breast-feeding and fertility

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

- **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.

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.

Propecia contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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.

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. Propecia will not work faster or better if you take it more than once a day.

If you forgot to take Propecia

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

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicine, 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.

Stop taking Propecia and talk to your doctor immediately if you have any of the following symptoms: 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 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
- depression

Not known: frequency cannot be estimated from the available data

- allergic reactions such as rash and itching
- 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
- male infertility and/or poor quality of semen
- elevated liver enzymes
- 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Cyprus: Pharmaceutical Services, Ministry of Health, CY-1475, Nicosia, Tel: +357 22608607, Fax: + 357 22608669, Website: www.moh.gov.cy/phs.

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 EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicine 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:
Tablet core: Lactose monohydrate 110.4 mg (see Section 2), microcrystalline cellulose, pregelatinised corn starch, sodium starch glycolate, docusate sodium, magnesium stearate,
Coating: Talc, hypromellose, hydroxypropyl cellulose, titanium dioxide (colour 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 Authorisation Holder

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This medicinal product is authorised in Austria, Finland, France, Germany, Greece, Italy, Luxembourg, Netherlands Portugal, Spain and Sweden under the name Propecia.

This leaflet was last revised in July 2024