Package leaflet: information for the user

Propecia 1 mg, film-coated tablets
finasteride

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Do you have any questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Please contact your doctor or pharmacist.

Contents of this leaflet

1. What is Propecia and what is it used for?

This medicine contains the active substance finasteride.
This medicine is intended for use by men only.
This medicine is used for the treatment of male pattern baldness (also known as androgenetic alopecia) in men aged 18-41 years. If you have any questions about male pattern baldness after reading this leaflet, please contact your doctor.

Male pattern baldness is common. It is believed to be caused by a combination of genetic factors and a certain hormone called dihydrotestosterone (DHT). Under the influence of DHT, the growth phase of the hair becomes shorter and the hair becomes thinner.

In the scalp, this medication lowers the concentration of DHT by inhibiting an enzyme (5-alpha-reductase type 2) that converts testosterone into DHT. Only men with mild to moderate but not complete hair loss may expect to benefit from using this medication. In most men treated with this medication for 5 years, hair loss was slowed, and at least half of these men also experienced some improvement in hair growth.

2. When should you not use this medication or be extra careful with it?

When should you not use this medication?
- You are a woman (because this medication is intended for use by men only, see the section 'Pregnancy'). Clinical studies have shown that this medication does not work for hair loss in women.

- You are allergic to any of the ingredients in this medication. These ingredients can be found in section 6 of this leaflet.

When should you be extra careful with this medication?
Contact your doctor or pharmacist before using this medication.

Effects on prostate-specific antigen (PSA)
This medication can affect the results of a blood test called PSA (prostate-specific antigen). This test is used in investigations for prostate cancer. If you are having a PSA test, tell your doctor or pharmacist that you are using this medication, as it lowers the PSA concentration.

Effects on fertility
Infertility has been reported in men who had used finasteride long-term and who also had other risk factors that could affect fertility. After stopping finasteride, it has been reported that semen quality improved or returned to normal. No long-term studies have been conducted on the effect of finasteride on fertility in men.

Breast cancer
See section 4.

Mood changes and depression
Mood changes such as depressed mood, depression, and, less frequently, suicidal thoughts have been reported in patients treated with Propecia. Stop using Propecia if you experience any of these symptoms and contact your doctor as soon as possible for medical advice.
Reduced sexual function has been reported in some patients. This may contribute to mood changes, including suicidal thoughts. If you experience symptoms of reduced sexual function, contact your doctor for further medical advice. Your doctor may consider discontinuing treatment (see section 4 below for more information on these side effects).

A patient card reminding of the above is included with the packaging of Propecia.

Children and adolescents under 18 years
This medication should not be used by children. There are no data demonstrating the efficacy or safety of finasteride in children under 18 years of age.

Are you using any other medications?
Are you using any other medicines besides Propecia, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist.

Pregnancy, breastfeeding, and fertility
This medicine is intended only for the treatment of early male pattern baldness. For effects on male fertility, see 'Effects on fertility' above.

- Women who are pregnant or may become pregnant should not use this medicine.
- Do not touch broken or crushed tablets of this medicine if you are a woman and are pregnant or may become pregnant.

- If the active substance in this medicine is ingested or absorbed through the skin by a woman who is pregnant with a male baby, it may cause the boy to be born with genital abnormalities.
- If a pregnant woman comes into contact with the active substance of this medicine, she should contact her doctor.
- The film coating of the tablets will prevent contact with the active substance during normal use, provided the tablets are not broken or crushed.

If you have any further questions, please contact your doctor or pharmacist.

Driving and using machines
There is no data showing that this medicine affects the ability to drive or use machines.

Propecia contains lactose
If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Propecia contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The recommended dosage is one tablet once a day. The tablets can be taken with or without food.

Your doctor will help you determine if this medicine is working for you. It is important to use this medicine for as long as your doctor prescribes it. This medicine can only work in the long term if you continue to use it.

Have you used too much of this medicine?
If you have used too much of this medicine, contact your doctor immediately. This medicine does not work faster or better if you take it more than once a day.

Have you forgotten to use this medicine?
Do not take a double dose to make up for a forgotten tablet.

If you stop using this medicine
It may take 3 to 6 months for the full effect of this medicine to occur. It is important to continue using this medicine as long as your doctor prescribes it. If you stop using this medicine, it is likely that you will lose the regained hair growth within 9 to 12 months.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects. Not everyone gets them. The side effects were generally transient during treatment or disappeared after stopping treatment.

Stop using this medicine and contact your doctor immediately if you have any of the following symptoms (angioedema): swelling of the face, tongue, or throat; difficulty swallowing; skin rash with severe itching and hives (urticaria); difficulty breathing and suicidal thoughts.

If you notice changes in your breast tissue, such as lumps, pain, more breast tissue, or discharge from a nipple, you should tell your doctor immediately, as these may be signs of a serious condition, such as breast cancer.

Sometimes (occur in less than 1 in 100 users):
- decreased libido
- problems getting an erection
- problems with ejaculation, such as a reduction in the amount of semen
- depression.

Not known (frequency cannot be determined from the available data):
- allergic reactions such as rash and itching
- painful or swollen breasts
- pain in the testicles
- blood in the semen
- rapid heartbeat
- persistent problems with getting an erection after discontinuation of treatment
- persistent decreased libido after discontinuation of treatment
- persistent ejaculation problems after discontinuation of treatment
- male infertility and/or poor sperm quality
- elevated liver enzymes
- anxiety
- suicidal thoughts.

Reporting side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after 'EXP'. This refers to the last day of that month.

There are no special storage conditions for this medicine.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. Proper disposal helps to protect the environment.

6. Contents of the pack and other information What does this medicine contain?

- The active substance in this medicine is finasteride. Each tablet contains 1 mg finasteride.
- The other ingredients in this medicine are:
  - Tablet core: lactose monohydrate (110.4 mg, see section 2), microcrystalline cellulose, pregelatinized maize starch, sodium starch glycolate, sodium docusate, magnesium stearate.
  - Film coating: talc, hydroxypropyl cellulose, hypromellose, titanium dioxide (E171), yellow iron oxide (E172), and red iron oxide (E172).

What does Propecia look like and what is in a package?

- Propecia film-coated tablets are supplied in blister packs.
- The tablets are reddish-brown, octagonal, film-coated, and convex, with an embossed 'P' logo on one side and 'Propecia' on the other.
- Pack sizes: 7, 28, 30, 84, or 98 tablets.
- Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder:
N.V. Organon Kloosterstraat 6
5349 AB Oss
Netherlands
Tel.: 00800 66550123
E-mail: dpoc.benelux@organon.com

Manufacturers:
Merck Sharp & Dohme B.V. Waarderweg 39
2031 BN Haarlem Netherlands

Organon Heist bv
Industriepark 30
2220 Heist-op-den-Berg
Belgium

This medicine is registered under RVG 27397.

This medicine is registered in EEA member states under the following name:
Germany, Finland, France, Greece, Italy, Luxembourg, Netherlands, Austria, Portugal, Spain, and Sweden: Propecia.

This leaflet was last approved in November 2025.

More information about this medicine is available on the CBG website (www.cbg-meb.nl).