PROPECIA® TABLET

Consumer Medication Information Leaflet (RiMUP)

Finasteride 1 mg

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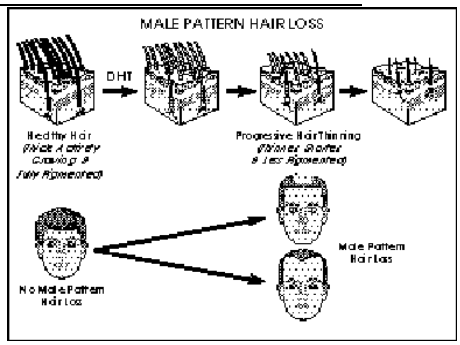
Please read this leaflet carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information in the previous leaflet may have changed.
Remember that this medicine is only for you. Only a doctor can prescribe it for you. Never give it to anyone else.

What *PROPECIA* is used for

***PROPECIA* is for use by men only.**
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.
PROPECIA is for use in men only and should **not** be used by women or children.

How does scalp hair grow?
On average, your hair grows about half an inch (1 centimeter) each month. Hairs grow from hair follicles, which are located beneath the skin.
A single scalp hair grows continuously for 2 to 4 years (growth phase) and then stops growing for 2 to 4 months (rest phase). After that time 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 heredity and a particular hormone, DHT (dihydrotestosterone).
DHT contributes to shortening of the growth phase and thinning of the hair (see picture). This process leads to male pattern hair loss. These changes typically 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 *PROPECIA* works

PROPECIA blocks an important enzyme (Type II 5-alpha reductase) involved in the regulation of the hair follicle. In the scalp, *PROPECIA* specifically lowers the levels of DHT, a major cause of male pattern hair loss. In this way, *PROPECIA* helps to reverse the balding process, leading to increased hair growth and prevention of further hair loss.

In whom is *PROPECIA* expected to work?
Men with mild to moderate, but not complete, hair loss can expect to benefit from the use of *PROPECIA*. In women who were studied, *PROPECIA* was not effective in the treatment of hair loss (androgenetic alopecia).

Before you take *PROPECIA*

- <u>*When you must not take it*</u>
Do not take *PROPECIA* if:
- you are a woman who are or may potentially be pregnant (see **Use in pregnancy**).
- you think you are allergic to any of its ingredients.
- you are a woman or child
- the packaging is torn and shows signs of tampering
- the expiry date on the pack has passed.

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- *Before you start to take it*
Tell your doctor about any medical problems you have or have had and about any allergies.

Use in pregnancy
PROPECIA is for the treatment of male pattern hair loss in men only.
Women who are or may potentially be pregnant must not use *PROPECIA*. They should also not handle crushed or broken tablets of *PROPECIA*. 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, it 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 handling, provided that the tablets are not broken or crushed.
If you have questions, ask your doctor.

- *Taking other medicines*
PROPECIA usually does not interfere with other medicines. However, you should always tell your doctor about all medicines you are taking or plan to take, including those obtained without prescription.

How to take *PROPECIA*

- *How much to take*
Take one tablet of *PROPECIA* every day, with or without food. Follow your doctor's advice.

Can I take *PROPECIA* more than once a day?
PROPECIA will not work faster or better if you take it more than once a day. You should only take one tablet of *PROPECIA* each day.

- *How long to take it*
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.

When can I expect to see results from using *PROPECIA*?
Male pattern hair loss is a condition that develops over a long period of time. In general, daily use for 3 months or more may be necessary before you notice increased hair growth or prevention of further hair loss.

What happens if I stop using *PROPECIA*?
Continued use of *PROPECIA* is recommended to obtain maximum benefit. If you stop taking *PROPECIA*, you will likely lose the hair you have gained within 12 months of stopping treatment.

- *If you forget to take it*
Try to take *PROPECIA* as your doctor has prescribed. However, if you miss a dose, do not take an extra one. Just take the next tablet as usual.

- *If you take too much (overdose)*
If you take too many tablets, contact your doctor promptly.

While you are taking *PROPECIA*

- *Things you must do*
If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking *PROPECIA*.

Things you must not do
Do not give *PROPECIA* to anyone else, even if they have the same condition as you.

- *Things to be careful of*
Can I continue my current hair care routine?
There should be no need to change your usual hair care routine.

Can I drive or operate machinery while using *PROPECIA*?
PROPECIA should not affect your ability to drive or operate machinery.

Side effects

Like any medicine, *PROPECIA* may have unintended or undesirable effects, so-called side effects. These are uncommon and do not affect most men.
Only a small number of men may experience less desire to have sex and/or difficulty in achieving an erection. An even smaller number may have a decrease in the amount of semen released during sex (this does not appear to interfere with normal sexual function). In clinical studies, these side effects disappeared in men who stopped taking *PROPECIA* and in many men who continued treatment.

In general use, the following have been reported infrequently:

- breast tenderness and enlargement
- depression

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- decrease in sex drive that continued after stopping the medication
- allergic reactions including rash, itching, hives, and swelling of the lips, tongue, throat and face
- problems with ejaculationthat continued after stopping the medication
- testicular pain
- blood in semen
- difficulty in achieving an erection that continued after stopping the medication
- male infertility and/or poor quality of semen. Improvement in the qualityof semen has been reportedafter stopping the medication.
- in rare cases, male breast cancer has been reported.
- Suicidal ideation

You should promptly report to your doctor any changes in yourbreasts such as lumps, pain or nipple discharge. Tell your doctor or pharmacist promptly about these or any other unusualsymptoms.

Does the use of *PROPECIA* affect the hair on other partsof my body?
In clinical studies, *PROPECIA* did not affect hair on other partsof the body.

You may report any side effectsor adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

How can I learn more about *PROPECIA* and male pattern hair loss?

Not all the information about your medicine is printed here.after reading this leaflet you have any questions or are not sure about anything, ask your doctor or pharmacist, who have more detailed information about *PROPECIA* and male pattern hair loss.

Storage and Disposal of *PROPECIA*

- *Storage*
PROPECIA should be kept in a dry place at room temperature. Keep *PROPECIA* in the original container and keep the container closed.
Do not give your *PROPECIA* tablets to anyone else. Keep *PROPECIA* and all medicines out of the reach of children.

How long can I keep my medicine?
Do not use this medicine after the month and year shown by thefour numbers following EX (or EXP) on the container. The first two numbers indicate the month;the last two numbers indicate theyear.

- *Disposal*
If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

- *What it looks like*
PROPECIA (finasteride) is a tan-colored, 8-sided, film-coated tablet.
PROPECIA is only available as 1-mg tablets with "P" on one side and "*PROPECIA*" on the other side

Ingredients

- Active ingredient: It contains 1mg of finasteride as the activeingredient.

- Inactive ingredient:
- lactose
- microcrystalline cellulose
- pregelatinised maize starch
- sodium starch glycollate
- docusate sodium
- magnesium stearate
- hypromellose
- hydroxypropylcellulose
- titanium dioxide
- talc purified
- iron oxide yellow CI77492
- iron oxide red CI77491

- *MAL number*
MAL19992040ACRZ

Product Manufacturer
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Product Registration Holder
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Malaysia.

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