

## Patient Product Information (PPI)

### INFORMATION FOR THE PATIENT ABOUT PROPECIA®

**PROPECIA is for use by men only.**

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 is PROPECIA?**

PROPECIA (finasteride) is a tan-colored, 8-sided, film-coated tablet. It contains 1 mg of finasteride as the active ingredient.

PROPECIA is only available as 1-mg tablets with a “Flying P” logo on one side and “PROPECIA” on the other. It is supplied in packs of 28 and 84 tablets.

PROPECIA blocks an important enzyme (Type II 5-alpha reductase) involved in the regulation of the hair follicle.

#### **Product Manufacturer:**

AIAC International Pharma, LLC, Puerto Rico, U.S.A.

## Why has my doctor prescribed PROPECIA?

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?**

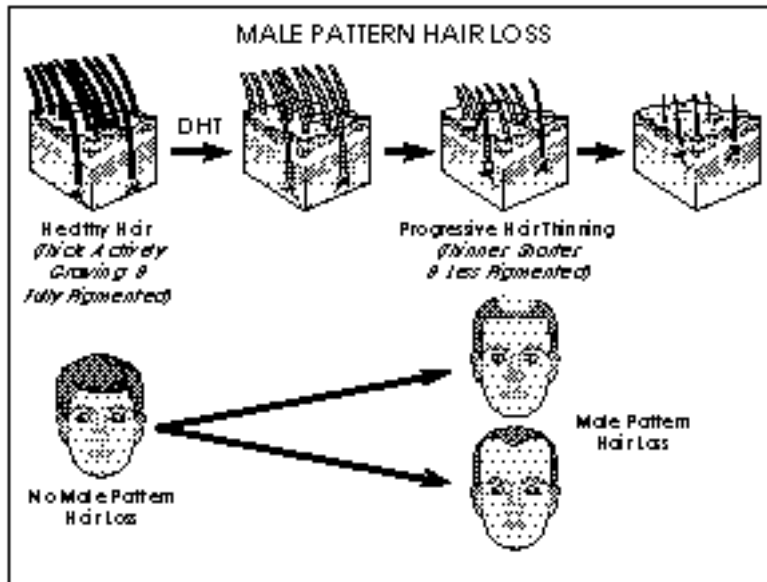
On average, your hair grows about half an inch (1 centimeter) each month. Hairs grow from hair follicles, which are located beneath the skin.

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 does PROPECIA work?

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.

### Results of Clinical Studies

The effect of PROPECIA on male pattern hair loss has been demonstrated in 3 studies in more than 1,800 men. Two of these studies were done over a 5-year period in men with different amounts of hair loss and with balding at the top of the head. The third study was conducted for 1 year in men with balding at the front of the head.

A special photographic method was used to count the number of hairs in a balding area of the scalp. In general, men who took PROPECIA maintained or showed an increase in the number of hairs and noticed improvement in their hair, with benefit continuing with long term use. At the same time, those who did not take PROPECIA continued to lose their hair.

At each clinic visit, men in the studies were also asked to fill out a questionnaire and rate the change in appearance of their hair and their satisfaction with the treatment result. For every question asked, men treated with PROPECIA reported greater improvement than those who did not receive PROPECIA. Men who took PROPECIA reported improvements as early as 3 months after beginning treatment. Improvements continued throughout the 5 years of treatment.

These men were also rated by physicians who determined whether there was an increase or decrease in scalp hair. The ratings were based on a balding scale and on photographs of the patient's head taken before, during, and at the end of the studies. Almost all men treated with PROPECIA for 5 years had no further hair loss and many of these men had improved hair growth as rated by physicians.

## **What should I know before taking PROPECIA?**

### ***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).

### ***Who should not take PROPECIA?***

Women who are or may potentially be pregnant must not use PROPECIA (see Pregnancy).

Do not take PROPECIA if you think you are allergic to any of its ingredients.

PROPECIA should not be taken by women or children.

### ***What should I tell my doctor before taking PROPECIA?***

Tell your doctor about any medical problems you have or have had and about any allergies.

### ***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.

### ***Can I take PROPECIA with 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.

- ***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.

### **How should I take PROPECIA?**

Take one tablet of PROPECIA every day, with or without food. Follow your doctor's advice.

- **Can I use 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 do I need to use PROPECIA?**

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.

### **What should I do in case of an overdose?**

If you take too many tablets, contact your doctor promptly.

### **What should I do if I miss a dose?**

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.

### **What undesirable effects may PROPECIA have?**

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
- 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 ejaculation that 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 quality of semen has been reported after stopping the medication.
- in rare cases, male breast cancer has been reported.
- suicidal thoughts

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

- **Does the use of PROPECIA affect the hair on other parts of my body?**

In clinical studies, PROPECIA did not affect hair on other parts of the body.

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

Not all the information about your medicine is printed here. If 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.

### **How long can I keep my medicine?**

Do not use this medicine after the month and year shown following EXP. (or EXP. DATE) on the container. Three letters or two numbers indicate the month; the last four numbers indicate the year.

### **How should I store PROPECIA?**

PROPECIA should be stored at or below 30°C. Do not freeze.

Do not give your PROPECIA tablets to anyone else. Keep PROPECIA and all medicines out of the reach of children.

### **When was this package leaflet last revised?**

This package leaflet was last revised in July 2022.

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