

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS
(PREPARATIONS) 1986

This medicine can be sold under doctor's prescription only

PROPECIA[®]

Tablets

Each tablet contains:
Finasteride 1 mg

For a list of inactive ingredients see section 6.1 "What **PROPECIA** contains". See also section 2.6 "Important information about some of the ingredients of **PROPECIA**".

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

- This leaflet contains concise information about **PROPECIA**. 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 medical condition seems similar to yours.
- **This medicine is intended for use in men only and should not be used by women or children.**

1. WHAT PROPECIA IS AND WHAT IT IS USED FOR?

PROPECIA is intended to increase hair growth on the scalp and to prevent further hair loss in men with male pattern hair loss (androgenetic alopecia).

Therapeutic group: 5 α -reductase inhibitor

2. BEFORE YOU TAKE PROPECIA

2.1 Do not take PROPECIA if you:

- are a woman and you are or may potentially be pregnant. Women should also not handle crushed or broken tablets of **PROPECIA** (see also section 2.5 "pregnancy").
- **PROPECIA** should not be taken by women and children.
- are hypersensitive (allergic) to finasteride or any of the other ingredients of **PROPECIA** (for a list of inactive ingredients, see section 6.1).

2.2 Special warnings concerning use of PROPECIA

Before starting treatment with PROPECIA, tell your doctor if:

- You are suffering, or have suffered in the past, from liver function abnormalities or from allergies.
- Tell your doctor about any medical problems that you have or have had in the past.
- If you are sensitive to any type of food or medicine.

2.3 Taking other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or pharmacist, in order to prevent hazards or lack of efficacy arising from drug interactions.

There should be no need to change your usual hair care routine.

2.4 Taking PROPECIA with food

You may take **PROPECIA** with or without food.

2.5 Pregnancy

Women who are or may potentially be pregnant must not use PROPECIA. They should also not handle crushed or broken tablets of PROPECIA.

If a woman who is pregnant with a male baby absorbs the active ingredient in **PROPECIA**, either by swallowing or through the skin, it may cause abnormalities of a male baby's 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.

2.6 Important information about some of the ingredients of PROPECIA

PROPECIA contains lactose.

3. HOW TO TAKE PROPECIA?

Always take **PROPECIA** as instructed by the doctor. You should check with your doctor or pharmacist if you are not sure.

The dosage and duration will be determined by the doctor only.

The usually recommended dose is: One tablet by mouth, each day.

Swallow the medicine with a small amount of water, with or without food.

Do not exceed the recommended dose.

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

You may need to take **PROPECIA** daily for three months or more before you see a benefit from taking **PROPECIA**. **PROPECIA** can only work over the long term if you continue taking it. If the drug has not worked for you in twelve months, further treatment is unlikely to be of benefit.

PROPECIA is not effective in the treatment of hair loss due to androgenetic alopecia in postmenopausal women.

If you take more PROPECIA than you should

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to take PROPECIA

If you forget to take **PROPECIA**, do not take an extra tablet. Just take the next tablet as usual.

Complete the full course of treatment as instructed by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

If you stop taking PROPECIA

If you stop taking **PROPECIA**, you will likely lose the hair you have gained within 12 months of stopping treatment. You should discuss this with your doctor.

How can you contribute to the success of the treatment?

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, **PROPECIA** can cause side effects in some of the users.

Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

Refer to the doctor as soon as possible if you develop any of the following signs

- You should promptly report to your doctor any changes in your breasts such as lumps, pain or nipple discharge.

Additional side effects

In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine.

In clinical studies, side effects from **PROPECIA** were uncommon and did not affect most men.

A small number of men experienced certain sexual side effects. These men reported one or more of the following: less desire for sex; difficulty in achieving an erection and a decrease in the amount of semen. Each of these side effects occurred in less than 2% of men. These side effects went away in men who stopped taking **PROPECIA**. They also disappeared in most men who continued taking **PROPECIA**.

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

In clinical studies, it was found that **PROPECIA** did not affect hair on other parts of the body.

What you need to know while taking **PROPECIA**:

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(s) that you are taking **PROPECIA**. Because **PROPECIA** decreases PSA levels, changes in PSA levels will need to be evaluated by your doctor(s). Any increase in follow-up PSA levels from their lowest point may signal the presence of prostate cancer and should be evaluated even if the test results are still within the normal range for men not taking **PROPECIA**. You should also tell your doctor if you have not been taking **PROPECIA** as prescribed because this may affect the PSA test results.

For more information, talk to your doctor.

There may be an increased risk of a more serious form of prostate cancer in men taking finasteride at 5 times the dose of **PROPECIA**

If a side effect appears, if any of the side effects gets serious or if you suffer from side effects not mentioned in this leaflet, consult your doctor.

5. HOW TO STORE PROPECIA?

- Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not use **PROPECIA** after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions:** Store this medicine closed in the original container and keep the container closed. Store this medicine below 30°C.
- 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

6.1 What PROPECIA contains

- The active substance is: finasteride.
- Each tablet contains 1 mg of finasteride.
- In addition to the active ingredients the medicine also contains inactive ingredients: Lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide, magnesium stearate, talc, docusate sodium, yellow ferric oxide and red ferric oxide.

Each tablet contains 110.4 mg lactose monohydrate.

6.2 What PROPECIA looks like and contents of the pack

The tablets are tan, octagonal shaped, film-coated tablets, embossed with "P" on one side and PROPECIA on the other side.

Pack sizes: 30, 98 tablets in blisters.

Not all pack sizes may be marketed.

Marketing authorization holder:

Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O.Box 7121, Petah-Tikva 49170.

Manufacturer: Merck Sharp & Dohme UK Ltd., Cramlington, England

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