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

This medicine is marketed upon physician's prescription only

PROPECIA®

Film Coated Tablets

Each film coated 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 INTENDED FOR?

PROPECIA is indicated for the treatment of men with male pattern hair loss (androgenetic alopecia) to increase hair growth and prevent further hair loss

Therapeutic group: 5α-reductase inhibitor

2. BEFORE USING PROPECIA

2.1 Do not use PROPECIA if:

- You are a woman (because this medicine is for men). It has been shown in clinical trials that **PROPECIA** does not work in women with hair loss.
- You are hypersensitive (allergic) to finasteride or any of the other ingredients of this medicine (for a list of inactive ingredients, see section 6.1).
- You are already taking finasteride or dutasteride used for a prostate problem called benign prostatic hyperplasia (BPH).

Do not take **PROPECIA** if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

2.2 Special warnings regarding use of PROPECIA

Talk to your doctor or pharmacist before taking **PROPECIA** if:

- You are going to have a blood test for prostate cancer called PSA (prostate-specific antigen). This is because **PROPECIA** can affect the result of this test.

Breast Cancer

See section 4 "Side effects".

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.

2.3 Interactions with other medicines

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, in order to prevent hazards or lack of efficacy arising from drug interactions. **PROPECIA** does not usually affect other medicines.

- Do not take **PROPECIA** if you are already taking finasteride or dutasteride, used for a prostate problem called benign prostatic hyperplasia (BPH).
- There is no information about the use of **PROPECIA** with minoxidil, another type of medicine for male pattern hair loss which is applied to the head.

2.4 Using PROPECIA with food

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

2.5 Pregnancy, breast feeding and fertility

PROPECIA is for the treatment of male pattern hair loss in men only.

- **PROPECIA should not be taken by women**.
- **Women who are or may potentially be pregnant must not use PROPECIA. Do not touch crushed or broken PROPECIA tablets if you are a woman who is pregnant or planning to become pregnant (whole tablets are coated to stop contact with the medicine during normal use). This is because this medicine may affect the baby's sex organs**.
- If a woman who is pregnant comes into contact with crushed or broken **PROPECIA** tablets, speak to your doctor.

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 effects of finasteride on fertility in men have not been conducted.

2.6 Important information about some of the ingredients of PROPECIA

PROPECIA contains 110.4 mg lactose monohydrate. 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'.

2.7 Driving and using machines

PROPECIA is not likely to affect you being able to drive, use tools or machines.

3. HOW SHOULD YOU USE 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.

No information is available regarding crushing/splitting/chewing of the tablets.
See also section 2.5 " Pregnancy, breast feeding and fertility".

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 medicine has not affected for you within 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.

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.

Stop taking PROPECIA and talk to your doctor if you experience:

- Symptoms of an allergic reaction: swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties. Stop taking **PROPECIA** and talk to your doctor immediately.
- Depression (feeling of severe sadness and unworthiness).

You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement 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
- you may be unable to have an erection (impotence)
- you may have less desire to have sex
- you may have problems with ejaculation, for example a decrease in the amount of semen released during sex. This decrease in the amount of semen does not appear to affect normal sexual function

Frequency unknown:
- breast swelling or tenderness
- palpitations (feeling your heartbeat)
- changes in the way your liver is working, which can be shown by a blood test
- pain in the testicles
- blood in semen
- 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
- anxiety

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.

Will the use of PROPECIA affect the hair on other parts of your body?
PROPECIA does not affect hair on other parts of the body.

What else should you know about PROPECIA?

Finasteride can also be used for a type of prostate problem called 'benign prostatic hyperplasia' or BPH. Information collected from a clinical trial in men taking finasteride 5 mg (a dose 5 times higher than **PROPECIA**) for 7 years showed:

- the number of men who developed prostate cancer was lower in men taking finasteride compared with those taking nothing
- The number of men who had a high score in a tumour grading system was higher in some of those taking finasteride compared to those taking nothing.
- The effect of long-term use of finasteride on tumours of this kind is unknown.

If you would like further information about the tumour grading system or this trial, please talk to your doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: https://sideeffects.health.gov.il/

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 in the original container. 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?

In addition to the active ingredient the medicine also contains:
Lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide, magnesium stearate, talc, docusate sodium, red ferric oxide (E172) and yellow ferric oxide (E172).

6.2 What PROPECIA looks like and contents of the pack

The tablets are tan, octagonal shaped, film-coated, embossed with “P” on one side and PROPECIA on the other side.
Pack sizes: 7, 10, 28, 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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Drug registration no. listed in the official registry of the Ministry of Health:
140 64 29458