PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPECIA® 1 mg Film-coated Tablets

Finasteride

Contains sugar (110,4 mg lactose monohydrate per film-coated tablet)

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- PROPECIA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PROPECIA is and what it is used for
2. What you need to know before you take PROPECIA
3. How to take PROPECIA
4. Possible side effects
5. How to store PROPECIA
6. Contents of the pack and other information

1. What PROPECIA is and what it is used for

PROPECIA blocks an enzyme (Type II 5-alpha reductase) involved in the regulation of the hair follicle. It temporarily delays further hair loss and increases hair density on the scalp in men between the ages of 18 and 41 years.

Your doctor has prescribed PROPECIA because you have male pattern hair loss (also known as androgenetic alopecia).

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

2. What you need to know before you take PROPECIA

PROPECIA is not for use by women.

In women who were studied, PROPECIA was not effective in the treatment of hair loss (androgenetic alopecia).

Do not take PROPECIA

Women must not use PROPECIA. Women should also not handle crushed or broken tablets of PROPECIA (see **Pregnancy and breastfeeding**).

Do not take PROPECIA if you are allergic to finasteride or any of the other ingredients of PROPECIA.

PROPECIA should not be taken by women or children.

Warnings and precautions

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

Children and adolescents

PROPECIA is not indicated for use in children.

Elderly

Clinical studies with PROPECIA have not been conducted in elderly men with male pattern hair loss.

Other medicines and PROPECIA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

Pregnancy and breastfeeding

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 the tablets are not broken or crushed.

It is not known whether finasteride is excreted in human milk.

Driving and using machines

PROPECIA should not affect your ability to drive or operate machinery.

It is not always possible to predict to what extent PROPECIA may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PROPECIA affects you.

PROPECIA contains lactose

Each PROPECIA film-coated tablet contains 110,4 mg lactose monohydrate which is a type of sugar.

If you have been told by your doctor that you have an intolerance to some sugars, tell your doctor before taking PROPECIA.

3. How to take PROPECIA

Do not share medicines prescribed for you with any other person.

Always take PROPECIA exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

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

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.

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.

Your doctor will tell you how long your treatment with PROPECIA will last. Do not stop treatment early.

If you have the impression that the effect of PROPECIA is too strong or too weak for you, tell your doctor or pharmacist.

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.

If you take more PROPECIA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison information centre.

If you forget to take PROPECIA

Try to take PROPECIA as your doctor has prescribed. However, if you miss a dose, do not take an extra tablet. Just take the next tablet as usual, at the next scheduled time.

Do not take a double dose to make up for the forgotten individual dose.

If you stop taking PROPECIA

Continued use of PROPECIA is recommended to obtain maximum benefit. If you stop taking PROPECIA, you may lose the hair you have gained within 12 months of stopping treatment.

4. Possible side effects

PROPECIA can have side effects.

Not all side effects reported for PROPECIA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PROPECIA, please consult your health care provider for advice.

If any of the following happens, stop taking PROPECIA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the lips, tongue, throat and face which may cause difficulty in swallowing or breathing
- Rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PROPECIA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- breast tenderness and enlargement
- depression
- decrease in sex drive that may continue after stopping the medication
- problems with ejaculation that may continue after stopping the medication
- testicular pain
- blood in semen
- difficulty in achieving an erection that continues after stopping treatment with PROPECIA
- a decrease in the amount of semen released during sex, that does not appear to interfere with normal sexual function
- male infertility and/or poor quality of semen, though improvement in the quality of semen has been reported after stopping PROPECIA
- cases of male breast cancer have been reported.

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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of PROPECIA.

5. How to store PROPECIA

Do not use PROPECIA after the month and year following EXP.: on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

PROPECIA should be kept in a dry place at or below 30 ºC.

Keep PROPECIA in the original container and keep the container closed.

Do not give your PROPECIA Tablets to anyone else.

Keep all medicines out of reach of children.

6. Contents of the pack and other information

What PROPECIA contains

The active substance is finasteride.

The other ingredients are:

Tablet core**:** Docusate sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate.

Film-coating: Hydroxypropyl cellulose, hydroxypropyl methylcellulose, red ferric oxide, talc, titanium dioxide, yellow ferric oxide.

What PROPECIA looks like and contents of the pack

Tan coloured, octagonal, convex, film-coated compressed tablets, embossed P on one side and PROPECIA on the other side.

PROPECIA Tablets are available in blister packs of 28 tablets.

Holder of Certificate of Registration

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