

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

PROPECIA® Tablets

(1 mg finasteride)

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 or your pharmacist.
- 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.

1. WHAT PROPECIA CONTAINS

The active ingredient is finasteride.

The other ingredients are: docusate sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch, red ferric oxide, sodium starch glycolate, talc, titanium dioxide, yellow ferric oxide.

PROPECIA Tablets contain sugar (lactose monohydrate).

2. WHAT PROPECIA 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.

3. 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.

Take special care with PROPECIA

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

Use in children

PROPECIA is not indicated for use in children.

Use in elderly

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

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 machinery

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

Important information about some of the ingredients of PROPECIA

PROPECIA contains lactose 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.

Taking other medicines with PROPECIA

Always tell your healthcare professional if you are taking any other medicine, (this includes complementary or traditional medicines.)

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

4. HOW TO TAKE PROPECIA

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

Always take PROPECIA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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.

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

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.

Effects when treatment with PROPECIA is stopped

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.

5. POSSIBLE SIDE EFFECTS

PROPECIA may 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 doctor, pharmacist or other healthcare professional 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.

6. STORING AND DISPOSING OF 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 °C. 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.

7. PRESENTATION OF PROPECIA

PROPECIA Tablets are available in blister packs of 28 tablets.

8. IDENTIFICATION OF PROPECIA

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

9. REGISTRATION NUMBER

32/21.12/0303

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

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11. DATE OF PUBLICATION

Date of registration: 07 April 1999

Date of most recent revision: 20 March 2018 (SR-PIN: 31 October 2018)

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S-WPPI-MK0906-1T-072018