SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

PROPECIA® 1 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet of PROPECIA contains 1 mg of finasteride.

Excipients with known effect:

PROPECIA film-coated tablets contain sugar (110,4 mg lactose monohydrate per film-coated tablet).

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

PROPECIA temporarily delays further hair loss and increases hair density in the vertex and anterior mid scalp area in men (between 18 and 41 years) with early signs of androgenetic

alopecia.

PROPECIA is not effective in postmenopausal women with androgenetic alopecia.

4.2 Posology and method of administration

The recommended dosage is one 1 mg tablet daily. PROPECIA may be taken with or without food.

In general, daily use for 3 months or more is necessary before increased hair growth and/or prevention of further hair loss is observed.

Continued use is recommended to obtain maximum benefit. Withdrawal of treatment leads to reversibility of effect within 12 months.

PROPECIA is not indicated for use in women or children.

4.3 Contraindications

PROPECIA is contraindicated in the following:

- Contraindicated in women (see **4.6 Fertility, pregnancy and lactation**).
- Hypersensitivity to any component of PROPECIA.
- PROPECIA is not indicated for use in children.

4.4 Special warnings and precautions for use

Breast cancer

Breast cancer has been reported in men taking PROPECIA during the post-marketing period. Medical practitioners should instruct their patients to promptly report any changes in

their breast tissue such as lumps, pain, gynaecomastia or nipple discharge.

Men with family history of male breast carcinoma should be monitored.

Male infertility and/or poor seminal quality have occurred.

In clinical studies with PROPECIA in men 18 to 41 years of age, the mean value of serum prostate-specific antigen (PSA) decreased from 0,7 ng/ml at baseline to 0,5 ng/ml at Month 12. When PROPECIA is used for treatment of male pattern hair loss in older men who also have benign prostatic hyperplasia (BPH), consideration should be given to the fact that, in older men with BPH, PSA levels are decreased by approximately 50 %.

Paediatric use

PROPECIA is not indicated for use in children.

Use in the elderly

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

Information regarding lactose intolerance

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or galactosaemia, should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

No interactions of clinical importance have been identified. Finasteride does not appear to affect the cytochrome P450-linked metabolising enzyme system.

Compounds that have been tested in man have included antipyrine, digoxin, glyburide, propranolol, theophylline, and warfarin and no interactions were found.

Although specific interaction studies were not performed, in clinical studies finasteride doses of 1 mg or more were used concomitantly with ACE inhibitors, paracetamol, alpha-blockers, benzodiazepines, beta-blockers, calcium channel blockers, cardiac nitrates, diuretics, H_2 antagonists, HMG-CoA reductase inhibitors, prostaglandin synthetase inhibitors (NSAIDs) and quinolones, without evidence of clinically significant adverse interactions.

4.6 Fertility, pregnancy and lactation

Pregnancy

PROPECIA is contraindicated for use in women due to the risk in pregnancy.

PROPECIA may cause abnormalities of the external genitalia of a male foetus when administered to a pregnant woman.

Women should not handle crushed or broken tablets of PROPECIA when they are or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male foetus.

PROPECIA Tablets are coated and will prevent contact with the active ingredient during normal handling, provided the tablets have not been broken or crushed.

Breastfeeding

PROPECIA is not indicated for use in women.

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

Fertility

Male infertility and/or poor seminal quality have occurred. See **4.4 Special warnings and precautions for use**.

4.7 Effects on ability to drive and use machines

There are no data to suggest that PROPECIA affects the ability to drive or use machines.

4.8 Undesirable effects

Clinical trial data

Discontinuation of therapy due to any clinical adverse experience occurred in 1,7 % of 945 men treated with PROPECIA.

Frequency of side effects

Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000), including isolated reports.

Psychiatric disorders	Uncommon	Decreased libido
Reproductive systems and breast disorders	Uncommon	Erectile dysfunction, decreased volume of ejaculate

In placebo controlled clinical trials, resolution of these side effects occurred in men who discontinued therapy with PROPECIA and in some men who continued with treatment.

Post-marketing experience

The following additional adverse experiences were reported in post-marketing use. Because

these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate the frequency.

Immune system disorders	Hypersensitivity reactions such as rash, pruritus, urticaria and angioedema (including swelling of the lips, tongue, throat and face).
Psychiatric disorders	Depression; decreased libido that continued after discontinuation of treatment.
Reproductive systems and breast disorders	Sexual dysfunction (erectile dysfunction and ejaculation disorders) that continued after discontinuation of treatment, breast tenderness and enlargement, testicular pain, haematospermia, male infertility and/or poor seminal quality*.

* Normalisation or improvement of seminal quality has been reported after discontinuation of finasteride

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions 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.

4.9 Overdose

In clinical studies, single doses of finasteride up to 400 mg and multiple doses of finasteride up to 80 mg/day for three months did not result in side effects.

No specific treatment for overdosage with PROPECIA is recommended. Treatment is

symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A.21.12 Hormone Inhibitors

Finasteride is a synthetic 4-azasteroid compound that is a specific inhibitor of Type II 5-alpha reductase, an intracellular enzyme that metabolises the androgen testosterone into dihydrotestosterone (DHT).

Finasteride decreases scalp and serum DHT concentrations and inhibits the process responsible for miniaturisation of the scalp hair follicles in men with male pattern hair loss.

Finasteride appeared to inhibit both C19 and C21 steroid metabolism and hence appeared to have an inhibitory effect on both hepatic and peripheral Type II 5 alpha-reductase activity. The serum DHT metabolites androstenediol glucuronide and androsterone glucuronide were also significantly reduced.

5.2 Pharmacokinetic properties

Absorption

The oral bioavailability of finasteride is approximately 80 %. The bioavailability is not affected by food. Maximum finasteride plasma concentrations are reached approximately 2 hours after dosing and the absorption is complete after 6 to 8 hours.

Distribution

Protein binding is approximately 93 %. The volume of distribution of finasteride is

approximately 76 litres. There is modest accumulation of finasteride in plasma after multiple dosing. At steady-state following dosing with 1 mg/day, maximum finasteride plasma concentration averaged 9,2 ng/ml and was reached 1 to 2 hours post dose; $AUC_{(0\text{-}24\ hr)}$ was 53 ng•hr/ml.

Biotransformation

Finasteride is metabolised primarily via the cytochrome P450 3A4 enzyme subfamily. Following an oral dose of ^{14}C-finasteride in man, two metabolites of finasteride were identified that possess only a small fraction of the 5-alpha reductase inhibitory activity of finasteride.

Elimination

Following an oral dose of ^{14}C-finasteride in men, 39 % of the dose was excreted in the urine in the form of metabolites (virtually no unchanged drug was excreted in the urine) and 57 % of total dose was excreted in the faeces.

Mean terminal half-life is approximately 5 to 6 hours in men 18 to 60 years of age and 8 hours in men more than 70 years of age. These findings are of no clinical significance and hence, a reduction in dosage in the elderly is not warranted.

Characteristics in renal impairment patients

In patients with chronic renal impairment whose creatinine clearance ranged from 9 to 55 ml/min, the disposition of a single dose of ^{14}C-finasteride was not different from that in healthy volunteers. Protein binding also did not differ in patients with renal impairment. A portion of the metabolites that are normally excreted renally are excreted in the faeces. It therefore appears that faecal excretion increases commensurate to the decrease in urinary

excretion of metabolites. No adjustment in dosage is necessary in non-dialysed patients with renal impairment.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 30 °C.

Store in the original package and protect from moisture.

Keep out of reach of children.

6.5 Nature and contents of container

PROPECIA film-coated tablets are available in blister packs of 28 tablets.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

32/21.12/0303

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 07 April 1999

10 DATE OF REVISION OF THE TEXT

25 July 2025

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