PROPECIA®
(finasteride)

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SmPC) before prescribing

Adverse reactions should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse reactions should be reported to MSD (Tel: 01992-467272), UK.
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Tan octagonal, film-coated, convex tablets, marked with a 'P' logo on one side and 'PROPECIA' on the other, containing 1 mg finasteride.

USES
For the treatment of men with male pattern hair loss (androgenetic alopecia) to increase hair growth and prevent further hair loss. 'Propecia' is **not** indicated for use in women, adolescents or children.

DOSAGE AND ADMINISTRATION
One 1 mg tablet daily, with or without food. There is no evidence that an increase in dosage will result in increased efficacy.

Generally, three to six months of once-daily treatment is required before evidence of stabilisation of hair loss can be expected. Continuous use is recommended to sustain benefit. If treatment is stopped, the beneficial effects begin to reverse by six months and return to baseline by 9 to 12 months.

CONTRA-INDICATIONS
Use in women due to the risk in pregnancy. Hypersensitivity to the active substance or any of the excipients. Use in men who are taking 'Proscar' (finasteride 5 mg) or any other 5α-reductase inhibitor for benign prostatic hyperplasia or any other condition.

'Propecia' is not indicated for use in women or children and adolescents.

PRECAUTIONS
In clinical studies with 'Propecia' in men 18-41 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. Doubling the PSA level in men taking 'Propecia' should be considered before evaluating this test result.

Breast cancer has been reported in men taking 'Propecia'. Instruct patients to promptly report any changes in their breast tissue such as lumps, pain, gynaecomastia or nipple discharge.

Long-term data on fertility in humans are lacking, and specific studies in sub fertile men have not been conducted. Animal studies did not show relevant negative effects on fertility, spontaneous reports of infertility and/or poor seminal quality were received post-marketing. In some of these reports, other risk factors might have contributed to infertility. Normalisation/improvement of seminal quality has been reported after discontinuation of finasteride.

Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported. Monitor patients for psychiatric symptoms. If these occur, discontinue treatment and seek medical advice.

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

Drug Interactions
No drug interactions of clinical importance have been identified.

Pregnancy and Lactation
A small amount of finasteride, less than 0.001% of the 1 mg dose per ejaculation, has been detected in the seminal fluid of men taking 'Propecia'. Studies in Rhesus monkeys have indicated that this amount is unlikely to constitute a risk to the developing male foetus.

Post-marketing reports of exposure to finasteride during pregnancy via semen of men taking 1 mg or higher doses have been

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received for eight live male births, and one retrospectively-reported case concerned an infant with simple hypospadias. Causality cannot be assessed on the basis of this single retrospective report and hypospadias is a relatively common congenital anomaly with an incidence ranging from 0.8 to 8 per 1,000 live male births. In addition, a further nine live male births occurred during clinical trials following exposure to finasteride via semen, during pregnancy, and no congenital anomalies have been reported.

Crushed or broken tablets of 'Propecia' should not be handled by women when they are or may potentially be pregnant. 'Propecia' tablets are coated to prevent contact with the active ingredient during normal handling.

Use during lactation: It is not known whether finasteride is excreted in human milk.

SIDE EFFECTS
Refer to SPC for complete information on side effects.

The overall safety profiles of 'Propecia' and placebo were similar, as evaluated in three 12 month comparable clinical trials in male pattern hair loss.

In a 7-year placebo-controlled prostate cancer prevention trial, the relationship between long-term use of 'Proscar' and tumours with Gleason scores of 7-10 is unknown.

The adverse reactions during clinical trials and/or post-marketing use are listed below, the frequency of adverse reactions reported during post-marketing use cannot be determined as they were derived from spontaneous reports.

Uncommon (≥ 1/1,000, < 1/100): decreased libido*, depression†, erectile dysfunction*, ejaculation disorder (including decreased volume of ejaculate)*.
Not known (cannot be estimated from the available data): palpitation, increased hepatic enzymes, breast tenderness and enlargement, testicular pain, haematospermia, infertility, hypersensitivity reactions, including rash, pruritus, urticaria and angioedema (swelling of the lips, tongue, throat and face), anxiety, persistence of erectile dysfunction, decreased libido or ejaculation disorders after discontinuation of treatment with 'Propecia'; male breast cancer.

* Incidences presented as difference from placebo in clinical studies at Month 12

† This adverse reaction was identified through post-marketing surveillance but the incidence in randomized controlled Phase III clinical trials (Protocols 087, 089, and 092) was not different between finasteride and placebo.

Drug related sexual undesirable effects were more common in the finasteride 1 mg-treated men than the placebo-treated men. The incidence of these effects decreased to 0.6% in finasteride 1 mg–treated men over the following four years.

PACKAGE QUANTITIES AND UK TRADE PRICE
£33.68 for 28 tablets. Available on private prescription only; price to patient will vary.
£88.40 for 84 tablets. Available on private prescription only; price to patient will vary.

Marketing Authorisation Number
PL 00025/0351

Marketing Authorisation Holder
Merck Sharp & Dohme Limited
Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK

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