SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

PROPECIA® Tablets

COMPOSITION

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

Each film-coated tablet contains the following inactive ingredients: 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).

PHARMACOLOGICAL CLASSIFICATION

A.21.12 Hormone Inhibitors

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

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.

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.

Metabolism

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.

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.

CONTRAINDICATIONS

PROPECIA is contraindicated in the following:

- Contraindicated in women (see **PREGNANCY AND LACTATION**).
- Hypersensitivity to any component of PROPECIA.
- PROPECIA is not indicated for use in children.

WARNINGS AND SPECIAL PRECAUTIONS

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.

Effects on ability to drive and use machines

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

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.

INTERACTIONS

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.

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.

Lactation

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 **WARNINGS AND SPECIAL PRECAUTIONS**.

DOSAGE AND DIRECTIONS FOR USE

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.

SIDE 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.

Reproductive systems and breast disorders

Uncommon: Erectile dysfunction, decreased volume of ejaculate

Psychiatric disorders

Uncommon: Decreased libido.

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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

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.

IDENTIFICATION

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

PRESENTATION

PROPECIA Tablets are available in blister packs of 28 tablets.

STORAGE INSTRUCTIONS

Store at or below 30 °C.

Store in the original package and protect from moisture.

Keep out of reach of children.

REGISTRATION NUMBER

32/21.12/0303

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