SCHEDULING STATUS: S4

PROPRIETARY NAME (AND DOSAGE FORM):

FINPECIA (Tablets)

COMPOSITION:
Each film-coated **FINPECIA** tablet contains 1 mg of finasteride.

PHARMACOLOGICAL CLASSIFICATION:
A 21.12 Hormone inhibitors.

PHARMACOLOGICAL ACTION:
Finasteride is a synthetic 4-azasteroid compound. Finasteride is an inhibitor of Type II 5-alpha-reductase which is an intracellular enzyme that metabolises testosterone into the higher potency androgen dihydrotestosterone (DHT). Finasteride has no affinity for the androgen receptor.
Finasteride decreases concentrations of scalp and serum DHT and the process responsible for miniaturisation of the scalp hair follicles in men with male pattern hair loss is inhibited.

Pharmacokinetics:
Following an oral dose of ^{14}C-finasteride in humans, the bioavailability is approximately 80 % (relative to an intravenous reference dose) and is not affected by food.
Maximum finasteride plasma concentrations are reached about 2 hours after oral dosing and absorption is complete after 6 to 8 hours. The volume of distribution is 76 litres, protein binding about 93 % and plasma clearance about 165 ml/min.
Finasteride displays a mean plasma elimination half-life of approximately 6 hours (4 - 12 hours) in subjects 46 – 60 years of age and approximately 8 hours in men 70 years of age and older.
Two metabolites of finasteride have been identified which possess only a small fraction of the 5-alpha-reductase inhibitory activity of finasteride. 36 % of the dose is excreted in the urine in the form of metabolites and 57 % of the total dose is excreted in the faeces.

INDICATIONS:
FINPECIA temporarily delays further hair loss and increases the density of hair in the vertex and anterior mid-scalp area in males (between 18 and 41 years) displaying early signs of androgenetic alopecia (male pattern hair loss).

CONTRA-INDICATIONS:
Hypersensitivity to any of the components of **FINPECIA**.
Pregnancy – (see **"WARNINGS", "Use in Pregnancy and Lactating Mothers"** and **"Exposure to FINPECIA (by pregnant women) – Risk to Male Foetus"** below).
FINPECIA is not indicated for use in women.
FINPECIA is not indicated for paediatric use.

WARNINGS:
FINPECIA is contra-indicated in women who are or may potentially be pregnant as it may cause abnormalities of the external male foetus genitalia when administered during pregnancy (see **"PREGNANCY AND LACTATION"**).
It has not been established whether **FINPECIA** is excreted in breast milk.
Serum prostate-specific antigen (S-PSA) levels decrease in patients treated with **FINPECIA**.

Exposure to FINPECIA (by pregnant women) - Risk To Male Foetus: FINPECIA tablets are coated and will prevent contamination with finasteride during normal handling, provided that the tablets have not been crushed or broken.
Pregnant women should not handle crushed or broken **FINPECIA** tablets because of the possibility of absorption of **FINPECIA** and the subsequent potential risk to a male foetus (see **"Use in Pregnancy and Lactating Mothers"**).
In addition, since **FINPECIA** is present in semen, male patients should wear a condom or otherwise avoid exposure of female sexual partners at risk of becoming pregnant.

INTERACTIONS:
No interactions of significant clinical importance have been established.
FINPECIA does not appear to significantly affect the cytochrome P450-linked drug metabolising enzyme system.
Compounds tested in males included digoxin, propranolol, warfarin, glibenclamide and theophylline and no clinically meaningful interactions were found.

Other Concomitant Therapy:
FINPECIA has been used concomitantly with ACE-inhibitors, paracetamol, acetylsalicylic acid, alpha-blockers, beta-blockers, calcium-channel blockers, cardiac nitrates, diuretics, H_2-antagonists, HMG-CoA reductase inhibitors, non-steroidal anti-inflammatory drugs (NSAIDs), quinolones and benzodiazepines without any evidence of clinically significant interactions.

PREGNANCY AND LACTATION:
Use in Pregnancy and Lactating Mothers (see **"WARNINGS"** and **"CONTRA-INDICATIONS"**)**:**
FINPECIA is contra-indicated in pregnancy (see **"CONTRA-INDICATIONS"**). Because of the ability of Type II 5-alpha-reductase inhibitors to inhibit conversion of testosterone to dihydrotestosterone, these medicines, including **FINPECIA**, may cause abnormalities of the external male foetus genitalia when administered to a woman during pregnancy.

Lactation:
It is not known if **FINPECIA** is excreted in human milk.

DOSAGE AND DIRECTIONS FOR USE:
The recommended dose is one 1 mg tablet daily with or without food.
In general, daily use for at least 3 months is necessary before increased hair growth and/or prevention of further hair loss is noticable. Continued use is recommended for maximum benefit. Effects may be reversed within 12 months after withdrawal of treatment.

Dosage in Renal Insufficiency:
Adjustments in dosage are not required in patients with varying degrees of renal insufficiency (creatinine clearances as low as 9 ml/min) as there are no changes in the disposition of a single dose of **FINPECIA** as compared to healthy subjects.

Dosage in the Elderly:
No adjustments in dosage are required even though the elimination of **FINPECIA** is decreased in patients more than 70 years of age.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Side-effects:
Reproductive system and breast disorders:

Frequent:	Impotence and decreased libido.
Less Frequent:	Decrease in volume of ejaculate and ejaculation disorder.
The following side-effects have been reported and frequencies are unknown:	Breast tenderness, breast enlargement and testicular pain.

Skin and subcutaneous tissue disorders:

The following side-effects have been reported and frequencies are unknown:	Rash, hypersensitivity reactions, including pruritus, urticaria and swelling of the lips and face.

Special Precautions:
When using **FINPECIA** for treatment of male pattern hair loss in older males who also have been diagnosed with benign prostatic hyperplasia (BPH), consideration should be given to the fact that, in older males with BPH, S-PSA levels are decreased by about 50 %.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
No specific treatment is recommended for overdosage with **FINPECIA**.
Treatment is symptomatic and supportive.

IDENTIFICATION:
Reddish brown coloured, circular, biconvex, film-coated tablets, plain on both sides.

PRESENTATION:
FINPECIA tablets are available in blister packs of 30 tablets.

STORAGE INSTRUCTIONS:
Store below 25°C. Protect from light and moisture.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
41/21.12/0221

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
CIPLA MEDPRO (PTY) LTD
Rosen Heights, Pasita Street,
Rosen Park, Bellville 7530, R.S.A.

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