For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

FINAPECIA 1

(Finasteride Tablets 1mg)

Name and strength of active ingredient
Finasteride 1mg

Dosage form
Film Coated Tablet

Product Classification
Dermatologicals (ATC Code: D11AX10)

Product Description
Reddish brown, 7 mm, round, biconvex, film coated tablets marked 'F1' on one side and plain on other side.

Pharmacodynamics & Pharmacokinetics
Pharmacodynamic properties
Finasteride is a competitive and specific inhibitor of type II 5 α-reductase. Finasteride has no affinity for the androgen receptor and has no androgenic, anti-androgenic, oestrogenic, anti-oestrogenic, or progestational effects. Inhibition of this enzyme blocks the peripheral conversion of testosterone to the androgen DHT, resulting in significant decreases in serum and tissue DHT concentrations. Finasteride produces a rapid reduction in serum DHT concentration, reaching significant suppression within 24 hours of dosing.

Hair follicles contain type II 5α-reductase. In men with male pattern hair loss, the balding scalp contains miniaturised hair follicles and increased amounts of DHT. Administration of finasteride decreases scalp and serum DHT concentrations in these men. Men with a genetic deficiency of type II 5 α-reductase do not suffer from male pattern hair loss. Finasteride inhibits a process responsible for miniaturisation of the scalp hair follicles, which can lead to reversal of the balding process.

Pharmacokinetic properties
Absorption
Relative to an intravenous reference dose, the oral bioavailability of finasteride is approximately 80%. The bioavailability is not affected by food. Maximum finasteride plasma concentrations are reached approximately two hours after dosing and the absorption is complete after six to eight hours.

Distribution
Protein binding is approximately 93%. The volume of distribution of finasteride is approximately 76 litres.

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 postdose; $AUC_{(0\text{-}24\ hr)}$ was 53 ng•hr/ml.

Finasteride has been recovered in the cerebrospinal fluid (CSF), but the drug does not appear to concentrate preferentially to the CSF. A small amount of finasteride has also been detected in the seminal fluid of subjects receiving the drug.

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 the drug were identified that possess only a small fraction of the 5 α-reductase inhibitory activity of finasteride.

Elimination
Following an oral dose of ^{14}C-finasteride in man, 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.

Plasma clearance is approximately 165 ml/min.

The elimination rate of finasteride decreases somewhat with age. Mean terminal half-life is approximately 5-6 hours in men 18-60 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 patients
No adjustment in dosage is necessary in non-dialysed patients with renal impairment.

Indication/Usage
Finasteride Tablets 1 mg is indicated for the treatment of men with male pattern hair loss (androgenetic alopecia) to increase hair growth and prevent further hair loss.
Finasteride Tablets 1 mg is not indicated for use in women or children.

Recommended Dose
The recommended dosage is one 1 mg tablet daily. Finasteride Tablets 1mg may be taken with or without food.
Efficacy and duration of treatment should continuously be assessed by the treating physician. Generally, three to six months of once daily treatment are 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.

Route of Administration
1mg orally

Contraindication
Finasteride Tablets 1mg is contraindicated for use in women due to the risk in pregnancy (see 'Pregnancy and lactation') and in patients with hypersensitivity to any component of this product.

Finasteride Tablets 1mg is not indicated for use in women or children and adolescents.

Finasteride Tablets 1mg should not be taken by men who are taking Finasteride Tablets 5mg or any other 5α-reductase inhibitor for benign prostatic hyperplasia or any other condition.

Warnings & Precaution
Breast cancer has been reported in men taking Finasteride [dose, mg] during the post-marketing period. Physicians should instruct their patients to promptly report any changes in their breast tissue such as lumps, pain, gynaecosmatia or nipple discharge.

Increased Risk of High-Grade Prostate Cancer
Men aged 55 and over with a normal digital rectal examination and PSA ≤3.0ng/ml at baseline taking Finasteride 5 mg/day (5 times the dose of FINAPECIA 1 in the 7 Year Prostate Cancer Prevention Trial (PCPT) had an increased risk of Gleason Score 8-10 prostate Cancer(Finasteride 1.8% vs placebo 1.1%) Similar results were observed in a 4- year placebo-controlled clinical trial with another 5- alpha reductase inhibitor (dutasteride, AVODART) (1% dutasteride vs 0.5% placebo).

Front Side

File Name : RFIN01I1639-FINAPECIA 1(Malaysia)PIL
Size : 140 x 210 (mm)
Colour : Pantone Black
Date : 31/01/20, 28/02/22, 01/03/22, 10/01/23, 12/01/23

5- alpha reductase inhibitors may increase the risk of development of high-grade prostate cancer. Whether the effect of 5 – alpha reductase inhibitors to reduce prostate volume, or study –related factors, impacted the results of these studies has not been established.
This decrease in serum prostate-specific antigen (PSA) concentrations needs to be considered, if during treatment with Finasteride Tablets 1mg, a patient requires a PSA assay. In this case the PSA value should be doubled before making a comparison with the results from untreated men.

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

Pregnancy and Lactation
Use during pregnancy
Finasteride Tablets 1mg is contra-indicated for use in women due to the risk in pregnancy.
Because of the ability of type II 5α-reductase inhibitors to inhibit conversion of testosterone to dihydrotestosterone (DHT) in some tissues, these drugs, including finasteride, may cause abnormalities of the external genitalia of a male foetus when administered to a pregnant woman.
Crushed or broken tablets of Finasteride Tablets 1mg should not be handled by women 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. Finasteride Tablets 1mg tablets are coated to prevent contact with the active ingredient during normal handling, provided that the tablets are not broken or crushed.

Use during lactation
Finasteride Tablets 1mg is contraindicated for use in lactation.

Side effects/Adverse Reactions
Side effects, which usually have been mild, generally have not required discontinuation of therapy.
The following undesirable effects have been reported: ejaculation disorder; breast tenderness and enlargement; hypersensitivity reactions including rash, pruritus, urticaria and swelling of the lips and face; and testicular pain. Post marketing experience: Male breast cancer.

Signs & Symptoms of overdose and Treatment
No specific treatment of overdosage with Finasteride Tablets 1mg is recommended.

Storage Conditions
Do not store above 30°C. Store the tablets in original container/pack.

Shelf life
36 months

Pack size
Blister of 10 tablets. Each Carton contains 3 such strip. (3 x 10T)
Finasteride Tablets 1mg PVC/PVdC-Alu blister pack of 10 Tablets. Each Carton contains 3 such strip. (3 x 10T)

Manufactured by:
INTAS
INTAS PHARMACEUTICALS LTD.
Matoda-382 210, Dist. : Ahmedabad. INDIA
Marketing Authorization Holder:
Jetpharma Sdn Bhd, No.13, Jalan Rajawali 2,
Bandar Puchong Jaya, 47100 Puchong, Selangor, Malaysia

Date of Revision: January 2023

RFIN01I1639

INP011

Back Side

File Name : RFIN01I1639-FINAPECIA 1(Malaysia)PIL
Size : 140 x 210 (mm)
Colour : Pantone Black
Date : 31/01/20, 28/02/22, 01/03/22, 10/01/23, 12/01/23