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FINPECIA Tablets (Finasteride)

Composition

FINPECIA Tablets
Each film-coated tablet contains:
Finasteride, IP .....1 mg

Dosage Form

Tablet

Pharmacology

Pharmacodynamics

Finasteride, a synthetic 4-azasteroid compound, is a specific inhibitor of type II 5 alpha-reductase, an intracellular enzyme that converts androgenic testosterone into 5-alpha-dihydrotestosterone (DHT). Administration of finasteride 1 mg decreases scalp and serum DHT concentration, increased amounts of which are thought to be responsible for male pattern hair loss (androgenetic alopecia).

Pharmacokinetics

Absorption
In a study in 15 healthy young male subjects, the mean bioavailability of finasteride 1 mg tablets was 65% (range: 26–170%), based on the ratio of area under the curve (AUC) relative to an intravenous reference dose. At the steady state following dosing with 1 mg/day (n=12), maximum finasteride plasma concentration averaged 9.2 ng/mL (range: 4.9–13.7 ng/mL) and was reached at 1–2 hours post-dose, AUC (0-24 hr) was 53 ng•hr/ml. Bioavailability of finasteride was not affected by food.
Distribution
Mean steady-state volume of distribution was 76 litres (range: 44–96 litres; n=15). Approximately 90% of circulating finasteride is bound to plasma proteins. There is a slow accumulation phase for finasteride after multiple dosing.
Finasteride has been found to cross the blood-brain barrier.
Semen levels have been measured in 35 men taking finasteride 1 mg/day for 6 weeks. In 60% (21 of 35) of the samples, finasteride levels were undetectable (<0.2 ng/mL). The mean finasteride level was 0.26 ng/mL and the highest level measured was 1.52 ng/mL. Using the highest semen level measured and assuming 100% absorption from a 5 mL ejaculate per day, human exposure through vaginal absorption would be up to 7.6 ng per day, 650-fold less than the dose of finasteride (5 µg), that had no effect on circulating DHT levels in men.
Metabolism
Finasteride is extensively metabolized in the liver, primarily via the cytochrome (CY) P450 3A4 enzyme subfamily. Two metabolites, the t-butyl side chain monohydroxylated and monocarboxylic acid metabolites

have been identified that possess no more than 20% of the 5-alpha-reductase inhibitory activity of finasteride.

Excretion

Following intravenous infusion in healthy young subjects (n=15), mean plasma clearance of finasteride was 165 mL/min (range: 70–279 mL/min). Mean terminal half-life in plasma was 4.5 hours (range: 3.3–13.4 hours; n=12).

Following an oral dose of ^{14}C-finasteride in men (n=6), a mean of 39% (range: 32–46%) of the dose was excreted in the urine in the form of metabolites; 57% (range: 51–64%) was excreted in the faeces.

Mean terminal half-life is approximately 5–6 hours in men, 18 to 60 years of age, and 8 hours in men more than 70 years of age.

Indications

FINPECIA Tablets are indicated for the treatment of male pattern hair loss (androgenetic alopecia) in MEN ONLY. Safety and efficacy have been demonstrated in men between the ages of 18 to 41 years with mild-t--moderate hair loss of the vertex and anterior mid-scalp area. FINPECIA Tablets are not indicated in women and children.

Dosage And Administration

The recommended dosage is 1 mg orally once a day, with or without meals. In general, daily use for 3 months or more is necessary before benefit is observed. Continued use is recommended to sustain benefits, which should be re-evaluated periodically. Withdrawal of treatment leads to a reversal of effect within 12 months.

Contraindications

FINEPECIA is contraindicated in the following:

Pregnancy: Finasteride use is contraindicated in women when they are or may potentially be pregnant. Because of the ability of Type II 5 alpha-reductase inhibitors to inhibit the conversion of testosterone to 5α-dihydrotestosterone (DHT), finasteride may cause abnormalities of the external genitalia of a male fetus of a pregnant woman who receives finasteride. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the pregnant woman should be apprised of the potential hazard to the male foetus.

Hypersensitivity to any component of this medication.

FINPECIA Tablets is not indicated for use in women or children and adolescents.

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

Warnings And Precautions

▶ Drug Interactions

CYP450-Linked Drug-Metabolizing Enzyme System

No drug interactions of clinical importance have been identified. Finasteride does not appear to affect the CYP450-linked drug-metabolizing enzyme system. Compounds that have been tested in humans include antipyrine, digoxin, propranolol, theophylline and warfarin and no clinically meaningful interactions were

found.

Other Concomitant Therapy

Although specific interaction studies were not performed, finasteride doses of 1 mg or more were concomitantly used in clinical studies with acetaminophen, acetylsalicylic acid, (alpha)-blockers, analgesics, angiotensin-converting enzyme (ACE) inhibitors, anticonvulsants, benzodiazepines, beta-blockers, calcium-channel blockers, cardiac nitrates, diuretics, H_2-antagonists, HMG-CoA reductase inhibitors, prostaglandin synthetase inhibitors (also referred to as NSAIDs), and quinolone anti-infectives without evidence of clinically significant adverse interactions.

▶ Effects on Prostate Specific Antigen (PSA)

In clinical studies with finasteride, 1 mg 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. Further, in clinical studies with finasteride, 5 mg when used in older men who have benign prostatic hyperplasia (BPH), PSA levels are decreased by approximately 50%. Other studies with finasteride, 5 mg showed it may also cause decreases in serum PSA in the presence of prostate cancer. These findings should be taken into account for proper interpretation of serum PSA when evaluating men treated with finasteride. Any confirmed increase from the lowest PSA value while on finasteride, 1 mg may signal the presence of prostate cancer and should be evaluated, even if PSA levels are still within the normal range for men not taking a 5α-reductase inhibitor. Non-compliance to therapy with finasteride, 1 mg may also affect PSA test results.

▶ Renal Impairment

No dosage adjustment is necessary in patients with renal impairment.

▶ Hepatic Impairment

Caution should be exercised for the administration of FINPECIA Tablets in patients with liver function abnormalities, as finasteride is metabolized extensively in the liver.

▶ Pregnancy

Pregnancy Category X

FINPECIA Tablets are not indicated for use in women. Women should not handle crushed or broken FINPECIA Tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male foetus.

If a pregnant woman comes in contact with crushed or broken FINPECIA tablets, the contact area should be washed immediately with soap and water.

▶ Lactation

FINPECIA Tablets are not indicated for use in women.

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

▶ Paediatric Use

FINPECIA Tablets are not indicated for use in paediatric patients. Safety and effectiveness in paediatric patients have not been established.

▶ Geriatric Use

Clinical efficacy studies with finasteride 1 mg did not include subjects aged 65 years and over. Based on the pharmacokinetics of finasteride 5 mg, no dosage adjustment is necessary in the elderly for finasteride 1 mg. However, the efficacy of finasteride 1 mg in the elderly has not been established.

Undesirable Effects

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Clinical Studies for Finasteride 1 mg in the Treatment of Male Pattern Hair Loss

In three controlled clinical trials for finasteride 1 mg of 12-month duration, 1.4% of patients taking finasteride 1 mg (n=945) were discontinued due to adverse experiences that were considered to be possibly, probably or definitely drug-related (1.6% for placebo; n=934).

Clinical adverse experiences that were reported as possibly, probably or definitely drug-related in 1% of patients treated with finasteride 1 mg or placebo are presented in Table 1.

Table 1: Drug-related adverse experiences for finasteride 1 mg in year 1 (%) male pattern hair loss

	Finesteride 1 mg N=945	Placebo N=934
Decreased Libido	1.8	1.3
Erectile Dysfunction	1.3	0.7
Ejaculation Disorder *(Decreased Volume of Ejaculate)*	1.2 *(0.8)*	0.7 *(0.4)*
Discontinuation due to drug-related sexual adverse experiences	1.2	0.9

Integrated analysis of clinical adverse experiences showed that during treatment with finasteride 1 mg, 36 (3.8%) of 945 men had reported one or more of these adverse experiences as compared to 20 (2.1%) of 934 men treated with placebo (p=0.04). Resolution occurred in men who discontinued therapy with finasteride 1 mg due to these side effects and in most of those who continued therapy. The incidence of each of the above adverse experiences decreased to 0.3% by the fifth year of treatment with finasteride 1 mg.

In a study of finasteride 1 mg daily in healthy men, a median decrease in ejaculate volume of 0.3 mL (-11%) compared with 0.2 mL (-8%) for placebo was observed after 48 weeks of treatment. Two other studies showed that finasteride at 5 times the dosage of finasteride 1 mg (5 mg daily) produced significant median decreases of approximately 0.5 mL (-25%) compared to placebo in ejaculate volume, but this was reversible after discontinuation of treatment.

In the clinical studies with finasteride, the incidences of breast tenderness and enlargement, hypersensitivity reactions and testicular pain in finasteride-treated patients were not different from those in patients treated with placebo.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of finasteride. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

Hypersensitivity Reaction: Hypersensitivity reactions, including rash, pruritus, urticaria, and angioedema

(including swelling of the lips, tongue, throat and face).
Reproductive System: Sexual dysfunction that continued after discontinuation of treatment, including erectile dysfunction, libido disorders, ejaculation disorders, and orgasm disorders; male infertility and/or poor seminal quality (normalization or improvement of seminal quality has been reported after discontinuation of finasteride); testicular pain.
Neoplasms: Male breast cancer.
Breast Disorders: Breast tenderness and enlargement.
Nervous System/Psychiatric: Depression, Anxiety
Cardiac disorder: Palpitation
Hepatobiliary disorders: Increased hepatic enzymes.
If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the national pharmacovigilance program of India by calling on 1800 180 3024.
By reporting side effects you can help provide more information on the safety of this product.

Overdosage

In clinical studies, single doses of finasteride up to 400 mg and multiple doses of finasteride up to 80 mg/day for 3 months did not result in adverse reactions. Until further experience is obtained, no specific treatment for an overdose with finasteride can be recommended.

Shelf-Life

3 years

Storage And Handling Instructions

Protect from light.

Packaging Information

FINPECIA Tablets: Blister pack of 10 tablets
Last updated: Oct 2018
Last reviewed: Oct 2018

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