

Finasteride Tablets USP

FINPECIA

COMPOSITION

FINPECIA Tablets

Each film-coated tablet contains:

Finasteride USP 1 mg

Colours: Titanium Dioxide and Quinoline Yellow WS

DOSAGE FORM

Film-coated 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 5alpha-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 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 1 to 2 hours post-dose; AUC(0-24 hr) was 53 ng•hr/mL (range, 20-154 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, which is 750 times lower than the exposure from the no-effect dose for developmental abnormalities in Rhesus monkeys and 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

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 5α-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 ¹⁴C-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 to 6 hours in men, 18 to 60 years of age, and 8 hours in men more than 70 years of age.

INDICATIONS

FINPECIA is 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 to moderate hair loss of the vertex and anterior mid-scalp area. **FINPECIA** is 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

Hypersensitivity to any component of this medication. **FINPECIA** use is contraindicated in women when they are or may potentially be pregnant.

WARNINGS AND PRECAUTIONS Drug Interaction

No drug interactions of clinical importance have been identified. Finasteride does not appear to affect the cytochrome P450-linked drug metabolizing enzyme system. Compounds that have been tested in man include antipyrine, digoxin, propranolol, theophylline, and warfarin and no clinically meaningful interactions were found.

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, H₂ antagonists, HMG- CoA reductase inhibitors, prostaglandin synthetase inhibitors (also referred to as NSAIDs), and quinolone anti- infectives without evidence of clinically significant adverse interactions.

Renal Impairment

No dosage adjustments are required.

Hepatic Impairment

To be used with caution since finasteride is metabolized extensively in the liver.

Pregnancy

Pregnancy Category X

FINPECIA is 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.

Lactation

Finpecia is not indicated for use in women.

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

Paediatric Use

FINPECIA is 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 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

FINPECIA is generally well tolerated and side effects have usually been mild and transient. These include decreased libido, erectile dysfunction, and ejaculation disorders (primarily, decreased volume of ejaculate), breast tenderness and enlargement, hypersensitivity reactions, including rash, pruritus, urticaria, and swelling of the lips and face, and testicular pain.

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

Store in a dry place at room temperature.

PACKAGING INFORMATION

FINPECIA Tablets.....Blister pack of 10 tablets

Last updated: May 2010