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FINASTERIDE

Rx

FIGNA-5

5 mg Film-Coated Tablet
5-Alpha Reductase Inhibitor

FORMULATION:
Each film-coated tablet contains:
Finasteride ..... 5 mg

PRODUCT DESCRIPTION:
Blue coloured, round shape, biconvex, both side plain film-coated tablets.

PHARMACODYNAMICS:
Pharmacotherapeutic group: Testosterone-5α-reductase-inhibitors.

Finasteride is a competitive inhibitor of human 5 α-reductase, an intracellular enzyme which metabolises testosterone into the more potent androgen, dihydrotestosterone (DHT). In benign prostatic hyperplasia (BPH), enlargement of the prostate gland is dependent upon the conversion of testosterone to DHT within the prostate. Finasteride is highly effective in reducing circulating and intraprostatic DHT. Finasteride has no affinity for the androgen receptor.

In clinical studies of patients with moderate to severe symptoms of BPH, an enlarged prostate on digital rectal examination and low residual urinary volumes, Finasteride reduced the incidence of acute retention of urine from 7/100 to 3/100 over four years and the need for surgery (TURP or prostatectomy) from 10/100 to 5/100. These reductions were associated with a 2-point improvement in QUASI-AUA symptom score (range 0-34), a sustained regression in prostate volume of approximately 20% and a sustained increase in urinary flow rate.

Medical therapy of prostatic symptoms
The Medical Therapy of Prostatic Symptoms (MTOPS) Trial was a 4- to 6-year study in 3047 men with symptomatic BPH who were randomised to receive Finasteride 5 mg/day, Doxazosin 4 or 8 mg/day*, the combination of Finasteride 5 mg/day and Doxazosin 4 or 8 mg/day*, or placebo. The primary endpoint was time to clinical progression of BPH, defined as a ≡4 point confirmed increase from baseline in symptom score, acute urinary retention, BPH-related renal insufficiency, recurrent urinary tract infections or urosepsis, or incontinence. Compared to placebo, treatment with Finasteride, Doxazosin, or combination therapy resulted in a significant reduction in the risk of clinical progression of BPH by 34% (p=0.002), 39% (p<0.001), and 67% (p<0.001), respectively. The majority of the events (274 out of 351) that constituted BPH progression were confirmed ≡4 point increases in symptom score; the risk of symptom score progression was reduced by 30% (95% CI 6 to 48%), 46% (95% CI 25 to 60%), and 64% (95% CI 48 to 75%) in the Finasteride, Doxazosin, and combination groups, respectively, compared to placebo. Acute urinary retention accounted for 41 of the 351 events of BPH progression; the risk of developing acute urinary retention was reduced by 67% (p=0.011), 31% (p=0.296), and 79% (p=0.001) in the Finasteride, Doxazosin, and combination groups, respectively, compared to placebo. Only the Finasteride and combination therapy groups were significantly different from placebo.

* Titrated from 1 mg to 4 or 8 mg as tolerated over a 3-week period.

PHARMACOKINETICS:
Absorption:
The oral bioavailability of Finasteride is approximately 80%. Peak plasma concentrations are reached approximately 2 hours after drug intake, and absorption is complete after 6-8 hours.
Distribution:
Binding to plasma proteins is approximately 93%. Plasma clearance and volume of distribution are approximately 165 mL/min (70-279 mL/min) and 76 L (44-96 L), respectively. Accumulation of small amounts of Finasteride is seen on repeated administration. After a daily dose of 5 mg the lowest steady-state concentration of finasteride has been calculated to be 8-10 ng/mL, which remains stable over time.
Biotransformation:
Finasteride is metabolised in the liver. Finasteride does not significantly affect the cytochrome P 450 enzyme system. Two metabolites with low 5a-reductase-inhibiting effects have been identified.
Elimination:
The plasma half-life averages 6 hours (4-12 hours) (in men >70 years of age, 8 hours, range 6-15 hours). After administration of radioactively labelled Finasteride, approx. 39% (32-46%) of the given dose is excreted in the urine in the form of metabolites. Virtually no unchanged Finasteride is recovered in the urine. Approximately 57% (51-64%) of the total dose is excreted in the faeces.
Finasteride has been found to cross the blood-brain barrier. Small amounts of finasteride have been recovered in the seminal fluid of treated. In 2 studies of healthy subjects (n=69) receiving finasteride 5 mg/day for 6-24 weeks, finasteride concentrations in semen ranged from undetectable (<0.1 ng/mL) to 10.54 ng/mL. In an earlier study using a less sensitive assay, finasteride concentrations in the semen of 16 subjects receiving Finasteride 5 mg/day ranged from undetectable (<1.0 ng/mL) to 21 ng/mL. Thus, based on a 5-mL ejaculate volume, the amount of Finasteride in semen was estimated to be 50- to 100-fold less than the dose of Finasteride (5 µg) that had no effect on circulating DHT levels in men.
In patients with chronic renal impairment, whose creatinine clearance ranged from 9-55 mL/min, the disposition of a single dose of 14C 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, which normally is excreted renally, was excreted in the faeces. It therefore, appears that faecal excretion increases commensurate to the decrease in urinary excretion of metabolites. Dosage adjustment in non-dialysed patients with renal impairment is not necessary.

INDICATIONS:
Used in the management of benign prostatic hyperplasia to cause regression of the enlarged prostate and to improve symptoms, it may reduce the incidence of acute urinary retention and the need for surgery. It is also used in the treatment of male-pattern baldness (alopecia androgenetica) in men.

DOSAGE AND ADMINISTRATION:
Take Finasteride tablets by mouth. Follow the direction on the prescription label. Swallow the tablets with drink of water. You can take this medicine with or without food. Take your doses at regular intervals. Do not take your medicine in children. Special care may be needed. Or as prescribed by the physician.

CONTRAINDICATIONS:
Hypersensitivity to Finasteride or to any of the excipients.
Contraindicated in women and children.
Pregnancy - Use in women when they are or may potentially be pregnant.

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WARNINGS AND PRECAUTIONS:
Do not donate blood until at least 6 months after your final dose of Finasteride. This will prevent giving Finasteride to a pregnant female through a blood transfusion.
Contact your prescribers or health care professional if there is no improvement in your symptoms. You may need to take Finasteride for 6 to 12 months to get the best result.
Women who are pregnant or may get pregnant must not handle broken or crushed Finasteride tablets, the active ingredient could harm the unborn baby. If a pregnant woman comes into contact with broken or crushed Finasteride tablets she should check with her prescriber or health care professional. Exposure to whole tablets is not expected to cause harm as long as they are not swallowed.
Finasteride can interfere with PSA laboratory test for cancer. If you are schedule to have a lab test for prostate cancer, tell your prescriber or health care professional that you are taking Finasteride.

PREGNANCY AND LACTATION:
Pregnancy: Finasteride is contra indicated in women when they are or may potentially be pregnant.
Because of the ability of type II 5α-reductase-inhibitors to inhibit conversion of testosterone to dihydrotestosterone, these drugs, including finasteride, may cause abnormalities of the external genitalia of a male foetus when administered to a pregnant woman.
Exposure to finasteride - risk to male fetus.
Women should not handle crushed or broken tablets of finasteride when they are or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus.
Finasteride tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed.
Small amounts of finasteride have been recovered from the semen in subjects receiving finasteride 5 mg/day. It is not known whether a male foetus may be adversely affected if his mother is exposed to the semen of a patient being treated with finasteride. When the patient's sexual partner is or may potentially be pregnant, the patient is recommended to minimise exposure of his partner to semen.
Lactation: Finasteride 5 mg tablets are not indicated for use in women. It is not known whether finasteride is excreted in human milk.

ADVERSE DRUG REACTIONS:
Adverse effects that usually do not require medical attention (report to your prescriber or health care professional if they continue or are bothersome):
• breast enlargement or tenderness
• skin rash
• sexual difficulties (less sexual desire or ability to get an erection)
• small amount of semen released during sex.

DRUG INTERACTIONS:
No clinically significant drug interactions have been identified. Finasteride does not appear to significantly affect the cytochrome P450-linked drug metabolizing enzyme system.
Although the risk for finasteride to affect the pharmacokinetics of other drugs is estimated to be small, it is probable that inhibitors and inducers of cytochrome P450 3A4 will affect the plasma concentration of finasteride. However, based on established safety margins, any increase due to concomitant use of such inhibitors is unlikely to be of clinical significance.
The following medicinal products have been investigated in man, and no clinically significant interactions have been found: propranolol, digoxin, glibenclamide, warfarin, theophylline, phenazone and antipyrine and no clinically meaningful interactions were found.

OVERDOSE AND TREATMENT:
Patients have received single doses of finasteride up to 400 mg and multiple doses up to 80 mg/day without adverse effects. There is no specific recommended treatment of overdose of finasteride.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

AVAILABILITY:
Alu/PVC Blister Pack x 14's (Box of 28's).

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Manufactured by:
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