PACKAGE INSERT TEMPLATE FOR FINASTERIDE TABLET

Brand or Product Name
[Product name] Tablet 5mg

Name and Strength of Active Substance(s)
Finasteride …..5mg

Product Description
[Visual description of the appearance of the product (eg colour, viscosity etc)
eg White, circular flat beveled edge tablets marked '5' on one side

Pharmacodynamics
Finasteride, a synthetic 4-azasteroid compound, competitively and specifically inhibits 5alpha-reductase (type 2), an isoenzyme that metabolizes testosterone to dihydrotestosterone (DHT) in the prostate gland, liver, and skin. This inhibition blocks the peripheral conversion of testosterone to DHT, leading to significant reduction in serum and tissue DHT. Finasteride has no affinity for the androgen receptors. In the treatment of benign prostatic hyperplasia, finasteride decreases DHT, which is the potent androgen responsible for the development and enlargement of the prostate gland.

Pharmacokinetics

Absorption

Finasteride is absorbed after oral doses, and peak plasma concentrations occur in 1 to 2 hours and the absorption is complete after six to eight hours.
The mean bioavailability has variously been reported as 63% and 80%.
Effects of Food: May delay the rate of its oral absorption, but has no effect on systemic bioavailability.

Distribution

It is about 90% bound to plasma protein. Finasteride crosses the blood-brain barrier, and is distributed into semen.

Volume of distribution of finasteride are approximately 76 liters.

Metabolism
Finasteride is extensively metabolized by the liver, mainly via the CYP3A4 enzyme pathway

t-butyl side chain monohyroxylated and monocarboxylic acid: active (no more than 20% of the 5alpha-reductase inhibitory activity of finasteride)

Elimination
Excreted in the urine and faeces as metabolites. The mean terminal half-life is about 6 hours in patients under 60 years of age but may be prolonged to about 8 hours in those 70 years of age or older.

Indication

Finasteride is indicated for the treatment and control of benign prostatic hyperplasia (BPH) and for the prevention of urologic events to:

- Reduce the risk of acute urinary retention

- Reduce the risk of surgery including transurethral resection of the prostate (TURP) and prostatectomy.

Finasteride causes regression of the enlarged prostate, improves urinary flow and improves the symptoms associated with BPH.

Patients with an enlarged prostate are the appropriate candidates for therapy with Finasteride.

Finasteride administered in combination with the alpha-blocker doxazosin is indicated to reduce the risk of symptomatic progression of BPH (a confirmed 4 point increase in AUA symptom score).

Recommended Dosage

The recommended dosage is one 5-mg tablet daily with or without food.

Dosage in Renal Insufficiency

No adjustment in dosage is required in patients with varying degrees of renal insufficiency (creatinine clearances as low as 9 mL/min) as pharmacokinetic studies did not indicate any change in the disposition of Finasteride.

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Dosage in The Elderly

No adjustment in dosage is required although pharmacokinetic studies indicated the elimination of Finasteride is somewhat decreased in patients more than 70 years of age.

Mode of Administration
Oral

Contraindications

Finasteride is not indicated for use in women or children.

Finasteride is contraindicated in the following:

- hypersensitivity to any component of the product
- pregnancy, known or suspected

Warnings and Precautions

Finasteride is not indicated for use in children and female patients.

Urethral stricture, infection, cancer, hypotonic bladder and other neurogenic disorders should be excluded before treatment with finasteride is started.

Breast cancer has been reported in men taking finasteride 5 mg . Physicians should instruct their patients to promptly report any changes in their breast tissue such as lumps, pain, gynaecomastia or nipple discharge.

Finasteride should be used with caution in hepatic impairment since the drug is extensively metabolised in the liver.

When used for benign prostatic hyperplasia, finasteride should be used with caution in men at risk of obstructive uropathy.
Studies in animals suggest finasteride could produce feminisation (hypospadia) of a male fetus if used in pregnant women; therefore, its use is contra-indicated in women who are or may become pregnant. In addition, it is recommended that women in this category should not handle crushed or broken finasteride tablets. Finasteride has been detected in semen, therefore use of a condom is recommended if the patient's sexual partner is, or may become, pregnant.

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Laboratory Test Findings

Effect On Levels Of PSA

Serum prostate specific antigen (PSA) concentration is correlated with patient age and prostatic volume, and prostatic volume is correlated with patient age. When PSA laboratory determinations are evaluated, consideration should be given to the fact that PSA levels decrease in patients treated with finasteride. In most patients, a rapid decrease in PSA is seen within the first months of therapy, after which time PSA levels stabilize to a new baseline. The post treatment baseline approximates half of the pre-treatment value. Therefore, in typical patients treated with finasteride for six months or more, PSA values should be doubled for comparison to normal ranges in untreated men.

Effects On PSA And Prostate Cancer Detection

Patients should be evaluated for prostatic carcinoma before and during therapy prior to initiating therapy with finasteride and periodically thereafter. PSA is also used for prostate cancer detection.

When prostate specific antigen (PSA) laboratory determinations are evaluated, consideration should be given to the fact that PSA levels are decreased in patients treated with Finasteride.

Use of finasteride decreases concentrations of serum markers of prostate cancer such as prostate specific antigen (PSA) by up to 50% even when cancer is present, and reference values should be adjusted accordingly; the ratio of free to total PSA (percent free PSA) remains constant. Any sustained increase in PSA levels of patients treated with finasteride should be carefully evaluated, including consideration of non-compliance to therapy with finasteride.

Percent free PSA (free to total PSA ratio) is not significantly decreased by finasteride. The ratio of free to total PSA remains constant even under the influence of finasteride. When percent free PSA is used as an aid in the detection of prostate cancer, no adjustment to its value is necessary.

Effects on the ability to drive and use machines
There is no data to suggest that finasteride affects the ability to drive or use machines.

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

Other Concomitant Therapy: Although specific interaction studies were not performed, in clinical studies Finasteride was used concomitantly with ACE-inhibitors, acetaminophen, acetylsalicylic acid, alpha-blockers, beta-blockers, calcium channel blockers, cardiac nitrates, diuretics, H_2 antagonists, HMG-CoA reductase inhibitors, nonsteroidal anti-inflammatory drugs (NSAIDS), quinolones, and benzodiazepines without evidence of clinically significant adverse interactions.

Concurrent use of Finasteride and St John's Wort may result in decreased plasma exposure and increased metabolism and clearance of finasteride

Finasteride may result in a falsely decreased prostate-specific antigen (PSA) level due to assay interference.

Statement on Usage During Pregnancy and Lactation
Pregnancy

Finasteride is contraindicated for use 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 fetus when administered to a pregnant woman.

Crushed finasteride tablets should not be handled by a woman when she is pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to the male fetus.

Lactation
It is not known whether finasteride is excreted into human breast milk and the potential for adverse effects in the nursing infant from exposure to the drug are unknown. The drug is not indicated for use in women.

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Consider advising breast-feeding women to avoid handling the drug due to the caution in pregnant women.

Crushed finasteride tablets should not be handled by a woman when she is pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to the male fetus.

Adverse Effects / Undesirable Effects

Finasteride is well tolerated.

- The most commonly reported adverse effects of finasteride are decreased libido, erectile dysfunction, ejaculation disorders, and reduced volume of ejaculate.
- Breast tenderness and enlargement (gynaecomastia) may occur, and there have been reports of hypersensitivity reactions such as swelling of the lips and face, pruritus, urticaria, and rashes. Testicular pain has also been reported.
- Neoplasm of male breast, prostate cancer, high-grade

Overdose and Treatment
Single doses up to 400 milligrams and multiple doses of finasteride up to 80 milligrams/day for 3 months have resulted in NO adverse effects.

Treatment is symptomatic and supportive.

Storage Conditions
[eg Store below…. °C]

Dosage Forms and Packaging Available
[Packaging type & pack size]

Name and Address of Manufacturer
[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder
[Name & full address of marketing authorization holder]

Date of Revision of Package Insert
[day/month/year]

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