Front

Finasteride

Prosta-One

5 mg Tablet

5-Alpha Reductase Inhibitor

FORMULATION:

Each Film Coated Tablet Contains

Finasteride ..... 5 mg

PHARMACOKINETICS

Finasteride is absorbed after oral doses and peak plasma concentrations are achieved in 1 to 2 hours. The mean bioavailability has variously been reported as 63% and 80%. It is about 90% bound to plasma protein. Finasteride crosses the blood-brain barrier and is distributed into semen. It is metabolized in the liver primarily by the cytochrome P450 isoenzyme CYP3A4 and excreted in 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.

INDICATIONS

Finasteride is indicated for the management of benign prostatic hyperplasia (BPH) in patients with an enlarged prostate to cause regression of the enlarged prostate, improve urinary flow and improve the symptoms associated with BPH and reduced the incidence of acute urinary retention and the need for surgery including transurethral resection of the prostate (TURP) and prostatectomy. In the treatment of male-pattern baldness (alopecia androgenetica) in men.

DOSAGE and ADMINISTRATION

Benign Prostatic Hyperplasia: Adult dose is 5 mg tablet daily with or without food.
Finasteride can be administered alone or in combination with the alpha-blocker doxazosin. Although early improvement in symptoms maybe seen, treatment for at least six months may be necessary to assess whether a beneficial response has been achieved. Thereafter, treatment should be continued long term. No dosage adjustment is required in the elderly or in patients with varying degrees of renal insufficiency (creatinine clearances as low as 9ml/min).
Alopecia: Adult dose is 1 mg tablet daily. In general, use 3 months or more is required before the benefit is seen.

CONTRAINDICATIONS

Finasteride is contraindicated in the following.

- Hypersensitivity to any component of this product.
- Women who are or may potentially be pregnant
- Children.

WARNINGS and PRECAUTIONS

General: Patients with large residual urine volume and/ or severely diminished urinary flow should be carefully monitored for obstructive uropathy.
Effects on prostate-specific antigen (PSA) and prostate cancer detection: No clinical benefit has yet been demonstrated in patients with prostate cancer treated with Finasteride.
Digital rectal examination, as well as other evaluations for prostate cancer, should be carried out on patients with BPH prior to initiating therapy with Finasteride and periodically thereafter, Generally, when PSA assays are performed baseline PSA.10ng/ml (Hybritech) prompts further evaluation and consideration of biopsy; for PSA levels between 4 and 10 mg/ml, further evaluation is advisable. There is considerable overlap in PSA levels among men with and without prostate cancer. Therefore, in men with BPH, PSA values within the normal reference range do not rule out prostate cancer regardless of treatment of Finasteride A baseline PSA, 4mg/ml does not exclude prostate cancer. Finasteride causes a decrease in serum PSA concentrations by approximately 50% in patients with BPH even in the presence of prostate cancer. This decrease in serum PSA levels in patients with BPH treated with Finasteride should be considered when evaluating PSA data and does not rule out concomitant prostate cancer.
This decrease is predictable over the entire range of PSA values, although it may vary in individual patients. In patients treated with Finasteride for six months or more, PSA values should be doubled for comparison with normal ranges in untreated men. This adjustment preserves the sensitivity and specificity of the PSA assay and maintains its ability to detect prostate cancer. 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 and 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 is necessary.

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DRUG INTERACTIONS:

No clinically important drug interactions have been identified. Finasteride does not appear to significantly affect the cytochrome P450-linked drug metabolising enzyme system. Compounds which have been tested in man include propanolol, digoxin, glibenclamide, 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, alpha-blockers, beta blockers, calcium channel blockers, cardiac nitrates, diuretics, H2 antagonists, HMG-CoA reductase inhibitors, non steroidal anti inflammatory drugs (NSAIDs) including aspirin and paracetamol, quinolones and benzodiazepines without evidence of clinically significant adverse interactions.

ADVERSE EFFECTS:

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 also been reported.

OVERDOSAGE:

No specific treatment of overdosage with Finasteride is recommended. Patients have received single doses of Finasteride up to 400 mg and multiple doses of Finasteride up to 80mg/dayfor up to three moths without any adverse effects.

AVAILABILITY

Alu-alu blister pack by 10's. Box of 50's

STORAGE

Store at temperature not exceeding 25ºC. Protect from light.

CAUTION

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription of the physician.

ADR Reporting:
For suspected Adverse Drug Reaction, report to the FDA website: www.fda.gov.ph or www.synergenpharma.com. Seek medical attention immediately at the first sign of any adverse drug reaction.

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