

Profin[®]

Tablet

Description

Profin is a preparation of Finasteride, a competitive inhibitor of the 5α reductase enzyme which is used in the treatment of benign prostatic hyperplasia. It is selective for 5α reductase type 2 enzyme and has no affinity for androgen receptors. The development of the prostate gland and subsequent BPH is dependent upon conversion of testosterone to dihydrotestosterone (DHT) within the prostate. Profin belongs to a new class of specific inhibitors of 5α reductase, an intracellular enzyme, which metabolises testosterone into the more potent androgen, DHT. Finasteride has no affinity for the androgen receptor.

Indications

Profin is indicated for the treatment and control of benign prostatic hyperplasia (BPH)-

- ◆ to cause regression of the enlarged prostate
- ◆ to improve urinary flow
- ◆ to improve the symptoms associated with BPH.

Dosage and Administration

The recommended dosage is one 5 mg tablet daily.

Although early improvement may be seen, treatment for at least six months may be necessary to assess whether a beneficial response has been achieved. Thereafter, treatment should be continued.

Contraindications

Hypersensitivity to any component of this medication. Finasteride use is also contraindicated in women and paediatric patient.

Precautions

General : Since the beneficial response to Finasteride may not be manifested immediately, patients with large residual urine volume and/or severely diminished urinary flow should be carefully monitored for obstructive uropathy.

Prostate cancer : Digital rectal examination, as well as, other evaluations for prostate cancer, should be performed on patients with BPH prior to initiating therapy with Finasteride and periodically thereafter. Finasteride causes a decrease in serum concentration of markers of prostatic cancer such as prostate specific antigen (PSA); therefore, reduction of serum levels of these markers in patients with BPH treated with Finasteride does not rule out concomitant prostate cancer. No clinical benefit has yet been demonstrated in patients with prostate cancer treated with Finasteride.

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 Propranolol, Digoxin, Glibenclamide, Warfarin, Theophylline, and antipyrine.

Side Effects

Finasteride is well tolerated. In clinical studies, the following adverse experiences have been reported as possibly drug related in 1% of patients treated for 12 months with 5 mg Finasteride daily : impotence (3.7%), decreased libido (3.3%), and decreased volume of ejaculate (2.8%).

Use in Special Populations

Renal insufficiency : Dosage adjustments are not necessary in patients with renal insufficiency since pharmacokinetic studies did not indicate any change in the disposition of Finasteride.

Hepatic insufficiency : There are no data available in patients with hepatic insufficiency.

Elderly : No dosage adjustment is required in elderly patients.

Commercial Pack

Prostin® Tablet : Box containing 3 blister strips of 10 tablets, each tablet contains Finasteride USP 5 mg.