Pronor™

Finasteride USP

COMPOSITION

Pronor™ tablet: Each film coated tablet contains Finasteride USP 5 mg.

PHARMACOLOGY

The development of the prostate gland and subsequent Benign Prostatic Hyperplasia (BPH) is dependent upon conversion of testosterone to dihydrotestosterone (DHT) within the prostate. **Pronor**™ belongs to a new class of specific inhibitors of 5-alpha reductase, an intracellular enzyme which metabolizes testosterone into the more potent androgen dihydrotestosterone (DHT). Finasteride has no affinity for the androgen receptor.

INDICATION

Pronor™ is indicated for the treatment of symptomatic Benign Prostatic Hyperplasia (BPH) in man with enlarged prostate to:

- improve symptoms
- reduce the risk of acute urinary retention
- reduce the risk of the need for surgery including transurethral resection of the prostate (TRUP) and prostatectomy.

Pronor ™ administered in combination with the alpha-blocker is indicated to reduce the risk of symptomatic progression of BPH.

DOSAGE AND ADMINISTRATION

The recommended dose is 5 mg orally once a day. **Pronor**™ can be administered alone or in combination with alpha-blocker **Pronor**™ may be administered with or without meals. No dosage adjustment is necessary for patients with renal impairment or for the elderly.

CONTRAINDICATION AND PRECAUTION

Hypersensitivity to any component of this product; women who are or may become pregnant; children. 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.

SIDE EFFECT

Pronor™ is well tolerated. The most frequently reported side-effects have been related to sexual function. In clinical studies, the following adverse experiences have been reported as possibly, probably or definitely drug related in 1% of patients treated for 12 months with 5 mg a day of Finasteride impotence (3.7%), decreased libido (3.3%), and decreased volume of ejaculate (2.8%).

DRUG INTERACTION

No clinically important drug interactions have been identified. Finasteride does not appear to significantly affect the cytochrome P450-link drug metabolizing enzyme system. Compounds, which have been tested in man include propranolol, digoxin, glibenclamide, warfarin, theophylline, and antipyrine.

Although specific interaction studies were not performed in clinical studies, Finasteride was used concomitantly with ACE inhibitors, alpha blockers, betablockers, calcium channel blockers, cardiac nitrates, diuretics, H_2 antagonists, HMG-CoA reductase inhibitors, non-steroidal anti-inflammatory drugs (NSAIDs), quinolones and benzodiazepines without evidence of clinically significant adverse interactions.

USE IN PREGNANCY AND LACTATION

Finasteride is contra-indicated in women who are or may become pregnant.

Finasteride is not indicated for use in women. It is not known whether finasteride is excreted in human milk.

Exposure to finasteride - risk to male fetus:

Crushed or broken Finasteride Tablets should not be handled by women who are or may become pregnant because of the possibility of absorption of finasteride and the subsequent

potential risk to a male fetus.

Similarly, small amounts of finasteride have been recovered from the semen in subjects receiving Finasteride 5 mg/day. It is not known whether a male fetus may be adversely affected if his mother is exposed to the semen of a patient being treated with finasteride. Therefore, when the patients sexual partner is or may become pregnant, the patient should either avoid exposure of his partner to semen (e.g. by use of a condom) or discontinue Finasteride.

STORAGE CONDITION

Store at cool and dry place (below 30°C). Protect from light and moisture. Keep all the medicines out of the reach of children.

PRECAUTION

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HOW SUPPLIED

Pronor™ tablet: Box containing 30 tablets in blister pack.

Manufactured by

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH