Pronor®

Finasteride

Androgen Suppressant

COMPOSITION

Pronor® tablet : Each tablet contains Finasteride INN 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 and control of benign prostatic hyperplasia (BPH) to cause regression of the enlarged prostate, improve urinary flow, and improve the symptoms associated with BPH.

DOSAGE AND ADMINISTRATION

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

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 long term. *Use in renal insufficiency*: Dosage adjustments are not necessary in patients with varying degrees of renal insufficiency (creatinine clearances as low as 9 ml/min), as pharmacokinetic studies do not indicate any change in the disposition of finasteride. *Use in hepatic insufficiency:* There are no data available in patients with hepatic insufficiency. *Use in the elderly*: No dosage adjustment is required in elderly patients. *Use in children*: Pronor® is contra-indicated in children.

CONTRAINDICATION AND PRECAUTION

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

Since the beneficial response to Pronor® 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 Pronor®: impotence (3.7%), decreased libido (3.3%), and decreased volume of ejaculate (2.8%).

DRUG INTERACTION

No clinically important drug interactions have been identified. Pronor® 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, Pronor® was used concomitantly with ACE inhibitors, alpha blockers, beta-blockers, 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

Pronor® is contra-indicated in women who are or may become pregnant. Pronor® 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 Pronor® 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 (see Pregnancy).

Similarly, small amounts of finasteride have been recovered from the semen in subjects receiving Pronor® 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 Pronor® (see 'Contra-indications' and 'Pregnancy').

STORAGE CONDITION

Protect from light. Crushed or broken Pronor® tablets should not be handled by women who are or may become pregnant.

HOW SUPPLIED

Pronor® tablet : Box containing 3 x 10 tablets in blister pack