

FINAST

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory
abbreviated prescribing information for FINAST (Finasteride tablets i.p. 5 mg)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: The development and enlargement of the prostate gland is dependent on the potent androgen, 5 α -dihydrotestosterone (DHT). Type II 5 α -reductase metabolizes testosterone to DHT in the prostate gland, liver and skin. DHT induces androgenic effects by binding to androgen receptors in the cell nuclei of these organs.

INDICATION: It is use in treatment of benign prostatic hypertrophy only.

DOSAGE AND ADMINISTRATION: Finasteride .5 Mg film-coated tablet should be taken as directed by Physician.

CONTRAINDICATION: Hypersensitivity to any component of this medication. Finasteride use is contraindicated in females when they are or may potentially be pregnant. Because of the ability of Type II 5 α -reductase inhibitors to inhibit the conversion of testosterone to 5 α -dihydrotestosterone (DHT), finasteride may cause abnormalities of the external genitalia of a male fetus of a pregnant female who receives finasteride. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the pregnant female should be apprised of the potential hazard to the male fetus. In female rats, low doses of finasteride administered during pregnancy have produced abnormalities of the external genitalia in male offspring.

WARNINGS & PRECAUTIONS: *Effects on Prostate Specific Antigen (PSA) and the Use of PSA in Prostate Cancer Detection:* FINAST reduced serum PSA concentration by approximately 50% within six months of treatment. This decrease is predictable over the entire range of PSA values in patients with symptomatic BPH, although it may vary in individuals, *Increased Risk of High-Grade Prostate Cancer. Exposure of Females — Risk to Male Fetus. Pediatric Patients and Females:* FINAST is not indicated for use in pediatric patients. *Effect on Semen Characteristics:* decrease in ejaculate volume with a concomitant reduction in total sperm per ejaculate was observed. These parameters remained within the normal range and were reversible upon discontinuation of therapy with an average time to return to baseline of 84 weeks. Prior to initiating treatment with FINAST, consideration should be given to other urological conditions that may cause similar symptoms. In addition, prostate cancer and BPH may coexist. Patients with large residual urinary volume and/or severely diminished urinary flow should be carefully monitored for obstructive uropathy. These patients may not be candidates for finasteride therapy.

DRUG INTERACTIONS: *Cytochrome P450-Linked Drug Metabolizing Enzyme System:* Finasteride does not appear to affect the cytochrome P450-linked drug metabolizing enzyme system. Compounds that have been tested in man have included antipyrine, digoxin, propranolol, theophylline, and warfarin and no clinically meaningful interactions were found. *Other Concomitant Therapy:* FINAST was concomitantly used in reported studies with acetaminophen, acetylsalicylic acid, α -blockers, angiotensin-converting enzyme (ACE) inhibitors, analgesics, anti-convulsants, beta-adrenergic blocking agents, diuretics, calcium channel blockers, cardiac nitrates, HMG-CoA reductase inhibitors, nonsteroidal anti-inflammatory drugs (NSAIDs), benzodiazepines, H₂ antagonists and quinolone anti-infectives without evidence of clinically significant adverse interactions.

ADVERSE REACTIONS: Hypersensitivity reactions, such as pruritus, urticaria, and angioedema (including swelling of the lips, tongue, throat, and face), Testicular pain,

Hematospermia, Sexual dysfunction, Breast Enlargement, Breast Tenderness, Asthenia, Headache, Hypotension, Postural Hypotension, Peripheral Edema, Dizziness, Depression, Somnolence, Dyspnea, Rhinitis, Gynecomastia, Sexual Function Abnormal, Male breast cancer, Orgasm disorders.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)