

FINAST-T

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory
abbreviated prescribing information for FINAST-T (Tamsulosin Hcl and Finasteride
Capsules)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Finasteride: The development and enlargement of the prostate gland is dependent on the potent androgen, DHT. Type II 5 alpha-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.

Tamsulosin hydrochloride exhibits linear kinetics following single and multiple dosing, with achievement of steady-state concentrations by the fifth day of once a- day dosing.

INDICATION: Finast-T capsules are indicated for the treatments of signs and symptoms of benign prostatic hyperplasia (BPH) in adults.

DOSAGE AND ADMINISTRATION: The recommended dose of Finast – T is one capsule once daily, with or without food. The capsule should be swallowed whole and should not be crunched or chewed. It can be administered orally with or without a meal.

CONTRAINDICATION: Finast – T capsules are contraindicated in patients known to be hypersensitive to tamsulosin hydrochloride or any component of the formulation. Reactions have included skin rash, urticaria, pruritus, angioedema and respiratory symptoms. Finast – T capsules containing finasteride as one of its component are contraindicated in women when they are or may potentially be pregnant. Because of the ability of Type II 5 alpha-reductase inhibitors to inhibit the conversion of testosterone to 5 alpha-dihydrotestosterone (DHT), finasteride may cause abnormalities of the external genitalia of a male foetus of a pregnant woman who receives finasteride. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the pregnant woman should be apprised of the potential hazard to the male foetus.

WARNINGS & PRECAUTIONS:

The warning and precautions before taking Finast-T consideration for Other Urological Conditions, Orthostasis, Priapism, Intraoperative Floppy Iris Syndrome, Sulpha Allergy, Exposure of Women - Risk to Male Foetus, FINAST-T is not indicated for use in pediatric patients or women, Increased Risk of High-Grade Prostate Cancer, Effect on Prostate Specific Antigen (PSA) use of PSA in Prostate Cancer Detection and Effect on Semen Characteristics.

DRUG INTERACTIONS: The interaction of FINAST-T with Strong and Moderate Inhibitors of CYP3A4 or CYP2D6, Other Alpha-Adrenergic Blocking Agents, Cimetidine, Warfarin, PDE5 Inhibitors, Nifedipine, Atenolol, Enalapril, Digoxin and Theophylline and Furosemide.

ADVERSE REACTIONS: Body as whole headache, infection, asthenia, back pain, chest pain, dizziness, somnolence, insomnia, libido decreased, rhinitis, Pharyngitis, Cough increased, Sinusitis, Diarrhoea, Digestive System Abnormal ejaculation, Nausea, Blurred vision and tooth disorder.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)