For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

FINAST - T

1. Generic Name

Tamsulosin Hcl 0.4 mg (MR) and Finasteride 5 mg Capsules

2. Qualitative and quantitative composition

FINAST – T

Each hard gelatin capsule contains:

Tamsulosin Hydrochloride I.P…….0.4 mg

(As modified release pellets)

Finasteride I.P……..5 mg

(As film-coated Capsule)

Excipients……q.s.

Colours: Ferric oxide USP-NF red & Titanium Dioxide I.P.

Approved Colours used in capsule shell.

The excipients used are Lactose, Pregelatinized Starch, Microcrystalline Cellulose, Sodium Starch Glycolate,Docusate Sodium, Sodium Starch Glycolate, Magnesium Stearate, Sugar Spheres, HydroxyPropyl Methyl Cellulose, Mannitol, Ethyl cellulose, Methacrylic Acid Copolymer Dispersion, Sodium Hydroxide, Polysorbate, Propylene Glycol, Isopropyl Alcohol, Purified water

3. Dosage form and strength

Dosage form: capsule

Strength: Tamsulosin Hydrochloride 0.4 mg and Finasteride 5 mg

4. Clinical particulars

4.1 Therapeutic indication

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

4.2 Posology and method of administration

Posology

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.

Method of administration

Oral use

It can be administered with or without a meal.

4.3 Contraindications

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.

4.4 Special warnings and precautions for use

General

Consideration for Other Urological Conditions

Prior to initiating treatment with finasteride, 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

Orthostasis

The signs and symptoms of orthostasis (postural hypotension, dizziness, and vertigo) were detected more frequently in tamsulosin hydrochloride treated patients than in placebo recipients. As with other alpha-adrenergic blocking agents, there is a potential risk of syncope. Patients beginning treatment with FINAST – T capsules should be cautioned to avoid situations in which injury could result should syncope occur.

Priapism

Rarely (probably less than 1 in 50,000 patients), tamsulosin hydrochloride, like other alpha1- antagonists, has been associated with priapism (persistent painful penile erection unrelated to sexual activity). Because this condition can lead to permanent impotence if not properly treated, patients must be advised about the seriousness of the condition.

Intraoperative Floppy Iris Syndrome

Intraoperative floppy iris syndrome (IFIS) has been observed during cataract surgery in some patients treated with alpha1-blockers, including tamsulosin hydrochloride.

Most reports were in patients taking the alpha1-blocker when IFIS occurred. In most of these cases, the alpha1-blocker had been stopped recently prior to surgery (2-14 days), but in a few cases, IFIS was reported after the patient had been off the alpha1-blocker for a longer period (5 weeks-9 months). IFIS is a variant of small-pupil syndrome and is characterized by the combination of a flaccid iris that billows in response to intraoperative irrigation currents, progressive intraoperative miosis despite preoperative dilation with standard mydriatic drugs, and potential prolapse of the iris toward the phacoemulsification incisions. The patient' s ophthalmologist should be prepared for possible modifications to their surgical technique, such as the utilization of iris hooks, iris dilator rings or viscoelastic substances.

IFIS may increase the risk of eye complications during and after the operation. The benefit of stopping alpha1-blocker therapy prior to cataract surgery has not been established. The initiation of therapy with tamsulosin hydrochloride in patients for whom cataract surgery is scheduled is not recommended**.**

Sulpha Allergy

In patients with sulpha allergy, an allergic reaction to tamsulosin hydrochloride has been rarely reported. If a patient reports a serious or life-threatening sulpha allergy, caution is warranted when administering FINAST - Tcapsules.

Exposure of Women - Risk to Male Foetus

Women should not handle broken FINAST - Tcapsules when they are pregnant or may potentially be pregnant because of the possibility of the absorption of finasteride and the subsequent potential risk to the male foetus.

Pediatric Patients and Women

FINAST - Tis not indicated for use in pediatric patients or women.

Increased Risk of High-Grade Prostate Cancer

Men aged 55 years and over, with a normal digital rectal examination and PSA 3.0 ng/mL at baseline, who were taking finasteride 5 mg/day in the 7-year Prostate Cancer Prevention Trial, had an increased risk of Gleason score 8-10 prostate cancer (finasteride 1.8% vs placebo 1.1%). Similar results were observed in a 4-year placebo-controlled clinical trial with another 5 alpha-reductase inhibitor, dutasteride (1% dutasteride vs 0.5% placebo). The 5 alpha-reductase inhibitors may increase the risk of development of high-grade prostate cancer. It has not been established as to whether the effect of 5 alpha-reductase inhibitors to reduce prostate volume, or study-related factors, impacted the results of these studies.

Effect on Prostate Specific Antigen (PSA) and Use of PSA in Prostate Cancer Detection

In Reported studies, finasteride reduced serum PSA concentration by approximately 50% within 6 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. For interpretation of serial PSAs in men taking finasteride, a new PSA baseline should be established at least 6 months after starting treatment and the PSA monitored periodically thereafter. Any confirmed increase from the lowest PSA value while on finasteride may signal the presence of prostate cancer and should be evaluated, even if PSA levels are still within the normal range for men not taking a 5 alpha-reductase inhibitor. Non-compliance with finasteride therapy may also affect the PSA test results. To interpret an isolated PSA value in patients treated with finasteride for 6 months or more, PSA values should be doubled for comparison with normal ranges in untreated men. These adjustments preserve the utility of PSA to detect prostate cancer in men treated with finasteride. Finasteride may also cause decreases in serum PSA in the presence of prostate cancer. The ratio of free to total PSA (percent-free PSA) remains constant even under the influence of finasteride. If clinicians elect to use percent-free PSA as an aid in the detection of prostate cancer in men undergoing finasteride therapy, no adjustment to its value appears necessary.

Effect on Semen Characteristics

Treatment with finasteride for 24 weeks to evaluate semen parameters in healthy male volunteers revealed no clinically meaningful effects on sperm concentration, mobility, morphology or pH. A 0.6 mL (22.1%) median 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.

4.5 Drugs interactions

Strong and Moderate Inhibitors of CYP3A4 or CYP2D6

Tamsulosin hydrochloride is extensively metabolized, mainly by CYP3A4 and CYP2D6. FINAST - Tcapsules which contain tamsulosin hydrochloride as one of its component should not be used in combination with strong inhibitors of CYP3A4 (e.g., ketoconazole). Concomitant treatment with ketoconazole (a strong inhibitor of CYP3A4) resulted in an increase in the Cmax and AUC of tamsulosin hydrochloride by a factor of 2.2 and 2.8, respectively. In patients known to be CYP2D6 poor metabolizers, FINAST - Tcapsules should be used with caution in combination with moderate inhibitors of CYP3A4 (e.g., erythromycin), and in combination with strong (e.g., paroxetine) or moderate (e.g., terbinafine) inhibitors of CYP2D6, particularly at a dose higher than 0.4 mg (e.g., 0.8 mg). Concomitant treatment with paroxetine (a strong inhibitor of CYP2D6) resulted in an increase in the Cmax and AUC of tamsulosin hydrochloride by a factor of 1.3 and 1.6, respectively. The effects of co-administration of both a CYP3A4 and a CYP2D6 inhibitor with tamsulosin hydrochloride have not been evaluated. However, there is a potential for significant increase in tamsulosin hydrochloride exposure when FINAST - Tcapsules 0.4 mg is co-administered with a combination of both CYP3A4 and CYP2D6 inhibitors.

Other Alpha-Adrenergic Blocking Agents

The pharmacokinetic and pharmacodynamic interactions between tamsulosin hydrochloride and other alpha-adrenergic blocking agents have not been determined. However, interactions may be expected and FINAST - Tcapsules should not be used in combination with other alpha-adrenergic blocking agents.

Cimetidine

The effect of cimetidine at the highest recommended dose (400 mg every 6 hours for 6 days) on the pharmacokinetics of a single tamsulosin hydrochloride 0.4 mg dose was investigated in 10 healthy volunteers (age range 21 to 38 years). Treatment with cimetidine resulted in a significant decrease (26%) in the clearance of tamsulosin hydrochloride, which resulted in a moderate increase in the tamsulosin hydrochloride AUC (44%). Therefore, FINAST - Tcapsules should be used with caution in combination with cimetidine.

Warfarin

A definitive drug-drug interaction study between tamsulosin hydrochloride and warfarin was not conducted. Results from limited in vitro and in vivo studies are inconclusive. Caution should be exercised with concomitant administration of warfarin and FINAST - Tcapsules.

PDE5 Inhibitors

Caution is advised when alpha-adrenergic blocking agents including tamsulosin hydrochloride capsules, are co-administered with PDE5 inhibitors. Alpha-adrenergic blockers and PDE5 inhibitors are both vasodilators that can lower blood pressure. Concomitant use of these two drug classes can potentially cause symptomatic hypotension.

Nifedipine, Atenolol, Enalapril

In three studies in hypertensive subjects (age range 47 to 79 years) whose blood pressure was controlled with stable doses of nifedipine, atenolol, or enalapril for at least 3 months, tamsulosin hydrochloride capsules 0.4 mg for 7 days followed by tamsulosin hydrochloride capsules 0.8 mg for another 7 days (n=8 per study) resulted in no clinically significant effects on blood pressure and pulse rate compared to placebo (n=4 per study). Therefore, dosage adjustments are not necessary when tamsulosin hydrochloride containing FINAST - Tcapsules are administered concomitantly with nifedipine, atenolol or enalapril.

Digoxin and Theophylline

In two studies in healthy volunteers (n=10 per study; age range 19 to 39 years) receiving tamsulosin hydrochloride capsules 0.4 mg/day for 2 days, followed by tamsulosin hydrochloride capsules 0.8 mg/day for 5 to 8 days, single intravenous doses of digoxin 0.5 mg or theophylline 5 mg/kg resulted in no change in the pharmacokinetics of digoxin or theophylline. Therefore, dosage adjustments are not necessary when a FINAST - Tcapsule is administered concomitantly with digoxin or theophylline.

Furosemide

The pharmacokinetic and pharmacodynamic interaction between tamsulosin hydrochloride 0.8 mg/day (steady-state) and furosemide 20 mg intravenously (single dose) was evaluated in 10 healthy volunteers (age range: 21 to 40 years). Tamsulosin hydrochloride had no effect on the pharmacodynamics (excretion of electrolytes) of furosemide. While furosemide produced an 11-12% reduction in the tamsulosin hydrochloride Cmax and AUC, these changes are expected to be clinically insignificant and do not require adjustment of the dosage of FINAST - Tcapsules containing tamsulosin hydrochloride as one of its component.

4.6 Use in special populations

Pregnancy

FINAST - Tcapsules are not indicated for use in women. Use is contraindicated in women when they are or may be pregnant due to the potential risk to the male foetus caused by the finasteride component of the FINAST - Tcapsules. Finasteride is a Type II 5 alpha-reductase inhibitor that prevents conversion of testosterone to 5α-dihydrotestosterone (DHT), a hormone necessary for normal development of male genitalia. In animal studies, finasteride caused abnormal development of external genitalia in male fetuses. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the male fetus.

Abnormal male genital development is an expected consequence when conversion of testosterone to 5 alpha-dihydrotestosterone (DHT) is inhibited by 5 alpha-reductase inhibitors. These outcomes are similar to those reported in male infants with genetic 5 alpha-reductase deficiency. Women could be exposed to finasteride through contact with crushed or broken finasteride Capsules or semen from a male partner taking finasteride. With regard to finasteride exposure through the skin, finasteride Capsules are coated and will prevent skin contact with finasteride during normal handling if the Capsules have not been crushed or broken. Women who are pregnant or may become pregnant should not handle crushed or broken finasteride Capsules because of possible exposure of a male fetus. If a pregnant woman comes in contact with crushed or broken finasteride Capsules, the contact area should be washed immediately with soap and water. With regard to potential finasteride exposure through semen, two studies have been conducted in men receiving finasteride 5 mg/day that measured finasteride concentrations in semen.

Lactation

FINAST - Tcapsules are not indicated for use in nursing mothers.

Paediatric Use

FINAST - Tcapsules are not indicated for use in the paediatric population.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Tamsulosin Hydrochloride

Because Reported studies are conducted under widely varying conditions, adverse reactions rates observed in the Reported studies of a drug cannot be directly compared to rates in the Reported studies of another drug and may not reflect the rates observed in practice.

The incidence of treatment-emergent adverse events has been ascertained from six short-term U.S. and European placebo-controlled clinical trials in which daily doses of 0.1 to 0.8 mg tamsulosin hydrochloride were used. These studies evaluated safety in 1783 patients treated with tamsulosin hydrochloride and 798 patients who were administered placebo. Table 1 summarizes the treatmentemergent adverse events that occurred in ≥2% of patients receiving either tamsulosin hydrochloride 0.4 mg or 0.8 mg and at an incidence numerically higher than that in the placebo group during two 13-week U.S. trials conducted in 1,487 men.

Table 1: Treatment-Emergent1 Adverse Events occurring in ≥2% of Tamsulosin Hydrochloride or Placebo Patients in Two U.S. Short-Term Placebo-Controlled Reported Studies

Body System/ Adverse Event	**Tamsulosin Hydrochloride Groups**		**Placebo**
	0.4 m*g*	0.8 mg	
	n = 502	n = 492	n = 493
Body As Whole Headache	97 (19.3)	104 (21.1%)	99 (20.1%)
Infection2	45 (9.0%)	53 (10.8%)	37 (7.5%)
Asthenia	39 (7.8%)	42 (8.5%)	27 (5.5%)
Back pain	35 (7.0%)	41 (8.3%)	27 (5.5%)
Chest pain	20 (4.1%)	20 (4.0%)	18 (3.7%)
Nervous System			
Dizziness	75 (14.9%)	84 (17.1%)	50 (10.1%)
Somnolence	15 (3.0%)	21 (4.3%)	8 (1.6%)
Insomnia	12 (2.4%)	7 (1.4%)	3 (0.6%)
Libido decreased	5 (1.0%)	10 (2.0%)	6 (1.2%)
Respiratory System			
Rhinitis	66 (13.1%)	88 (17.9%)	41 (8.3%)
Pharyngitis	29 (5.8%)	25 (5.1%)	23 (4.7%)
Cough increased	17 (3.4%)	22 (4.5%)	12 (2.4%)
Sinusitis	11 (2.2%)	18 (3.7%)	8 (1.6%)
Digestive System			
Diarrhoea			
Digestive System	31 (6.2%)	21 (4.3%)	22 (4.5%)

Nausea	13 (2.6%)	19 (3.9%)	16 (3.2%)
Tooth disorder	6 (1.2%)	10 (2.0%)	7 (1.4%)
Urogenital System			
Abnormal ejaculation	42 (8.4%)	89 (18.1%)	1 (0.2%)
Special Senses			
Blurred vision	1 (0.2%)	10 (2.0%)	2 (0.4%)

1. A treatment-emergent adverse event was defined as any event satisfying one of the following criteria:

- The adverse event occurred for the first time after initial dosing with the double-blind study medication.
- The adverse event was present prior to or at the time of initial dosing with the double-blind study medication and subsequently increased in severity during double-blind treatment; or,
- The adverse event was present prior to or at the time of initial dosing with the double-blind study medication, disappeared completely, and then reappeared during double-blind treatment.

2. Coding preferred terms also include cold, common cold, head cold, flu and flu-like symptoms.

3. Coding preferred terms also include nasal congestion, stuffy nose, runny nose, sinus congestion and hay fever.

Signs and Symptoms of Orthostasis

In the two U.S. studies, symptomatic postural hypotension was reported by 0.2% of patients (1 of 502) in the 0.4 mg group, 0.4% of patients (2 of 492) in the 0.8 mg group, and by no patients in the placebo group. Syncope was reported by 0.2% of patients (1 of 502) in the 0.4 mg group, 0.4% of patients (2 of 492) in the 0.8 mg group, and 0.6% of patients (3 of 493) in the placebo group. Dizziness was reported by 15% of patients (75 of 502) in the 0.4 mg group, 17% of patients (84 of 492) in the 0.8 mg group, and 10% of patients (50 of 493) in the placebo group. Vertigo was reported by 0.6% of patients (3 of 502) in the 0.4 mg group, 1% of patients (5 of 492) in the 0.8 mg group, and by 0.6% of patients (3 of 493) in the placebo group.

Multiple testing for orthostatic hypotension was conducted in a number of studies. Such a test was considered positive if it met one or more of the following criteria: (1) a decrease in systolic blood pressure of ≥20 mmHg upon standing from the supine position during the orthostatic tests; (2) a decrease in diastolic blood pressure ≥10 mmHg upon standing, with the standing diastolic blood pressure <65 mmHg during the orthostatic test; (3) an increase of ≥20 bpm in the pulse rate upon standing, with a standing pulse rate ≥100 bpm during the orthostatic test; and (4) the presence of clinical symptoms (faintness, light headedness/lightheaded, dizziness, spinning sensation, vertigo or postural hypotension) upon standing during the orthostatic test.

Following the first dose of reported double-blind medication in Study 1, a positive orthostatic test result at 4 hours post-dose was observed in 7% of patients (37 of 498) who received tamsulosin hydrochloride 0.4 mg once daily and in 3% of the patients (8 of 253) who received placebo. At 8 hours post-dose, a positive orthostatic test result was observed for 6% of the patients (31 of 498) who received tamsulosin hydrochloride 0.4 mg once

daily and 4% (9 of 250) who received placebo (Note: Patients in the 0.8 mg group received 0.4 mg once daily for the first week of Study 1).

In Studies 1 and 2, at least one positive orthostatic test result was observed during the course of these studies for 81 of the 502 patients (16%) in the tamsulosin hydrochloride 0.4 mg once-daily group, 92 of the 491 patients (19%) in the tamsulosin hydrochloride 0.8 mg once-daily group, and 54 of the 493 patients (11%) in the placebo group.

Because orthostasis was detected more frequently in tamsulosin hydrochloride treated patients than in placebo recipients, there is a potential risk of syncope.

Abnormal Ejaculation

Abnormal ejaculation includes ejaculation failure, ejaculation disorder, retrograde ejaculation and ejaculation decrease. As shown in Table 1, in the US studies, abnormal ejaculation was associated with tamsulosin hydrochloride administration and was dose-related. Withdrawal from these Reported studies of tamsulosin hydrochloride because of abnormal ejaculation was also dose-dependent, with 8 of 492 patients (1.6%) in the 0.8 mg group and no patients in the 0.4 mg or placebo groups discontinuing treatment due to abnormal ejaculation.

Laboratory Tests

No laboratory test interactions with tamsulosin hydrochloride are known. Treatment with tamsulosin hydrochloride for up to 12 months had no significant effect on the prostate-specific antigen (PSA).

Finasteride

Finasteride is generally well-tolerated; adverse reactions usually have been mild and transient.

4-Year Placebo-Controlled Study

In a reported trial, 1,524 patients treated with finasteride and 1,516 patients treated with placebo were evaluated for safety over a period of 4 years. The most frequently reported adverse reactions were related to sexual function; 3.7% (57 patients) treated with finasteride and 2.1% (32 patients) treated with placebo discontinued therapy as a result of such adverse reactions related to sexual function, which are the most frequently reported adverse reactions.

Table 2 presents the only clinical adverse reactions considered possibly, probably or definitely drugrelated by the investigator, for which the incidence on finasteride was ≥1% and greater than placebo over the 4 years of the study. In years 2-4 of the study, there was no significant difference between treatment groups in the incidences of impotence, decreased libido and ejaculation disorder.

Table 2: Drug-related adverse experiences

	Year 1(%)		**Years 2, 3 and 4*(%)**	
	Finasteride	**Placebo**	**Finasteride**	**Placebo**
Impotence	8.1	3.7	5.1	5.1
Decreased libido	6.4	3.4	2.6	2.6
Decreased volume of ejaculate	3.7	0.8	1.5	0.5

Ejaculation disorder	0.8	0.1	0.2	0.1
Breast enlargement	0.5	0.1	1.8	1.1
Breast tenderness	0.4	0.1	0.7	0.3
Rash	0.5	0.2	0.5	0.1

*Combined years 2-4

N =1,524 and 1,516, finasteride vs placebo, respectively

Phase III Studies and 5-Year Open Extensions

The adverse experience profile in the 1-year, placebo-controlled, Phase III studies, the 5-year open extensions, and 4-year placebo-controlled study were similar.

Combination with Alpha1-blocker Therapy

In the reported Medical Therapy of Prostatic Symptoms (MTOPS) study, 3047 men with symptomatic BPH were randomized to receive finasteride 5 mg/day (n=768), doxazosin 4 or 8 mg/day (n=756), the combination of finasteride 5 mg/day and doxazosin 4 or 8 mg/day (n=786), or placebo (n=737) for 4 to 6 years. The individual adverse effects which occurred more frequently in the group treated with finasteride and doxazosin combination compared to either drug alone were: asthenia, postural hypotension, peripheral edema, dizziness, decreased libido, rhinitis, abnormal ejaculation, impotence and abnormal sexual function. Of these, the incidence of abnormal ejaculation in patients receiving combination therapy was comparable to the sum of the incidences of this adverse experience reported for the two monotherapies.

Combination therapy with finasteride and doxazosin was associated with no new clinical adverse experience. Four patients in MTOPS reported the adverse experience breast cancer. Three of these patients were on finasteride only and one was on combination therapy. The MTOPS Study was not specifically designed to make statistical comparisons between groups for reported adverse experiences. In addition, direct comparisons of safety data between the MTOPS study and previous studies of the single agents may not be appropriate based upon differences in patient population, dosage or dose regimen, and other procedural and study design elements.

Long-Term Data

High-Grade Prostate Cancer

In a reported 7-year randomized, double-blind, placebo-controlled trial, 18,882 men aged 55 years and older with a normal digital rectal examination and a PSA? 3.0 ng/mL were enrolled. The men received either finasteride 5 mg or placebo daily. Patients were evaluated annually with PSA and digital rectal exams. Biopsies were performed for elevated PSA, an abnormal digital rectal exam, or at the end of the study. The incidence of Gleason score 8-10 prostate cancer was higher in men treated with finasteride (1.8%) than in those treated with placebo (1.1%). In a 4-year placebo-controlled clinical trial with another 5 alpha-reductase inhibitor (dutasteride), similar results for Gleason score 8-10 prostate cancer were observed (1% dutasteride vs. 0.5% placebo).

No clinical benefit has been demonstrated in patients with prostate cancer treated with finasteride.

Breast Cancer

During the reported 4- to 6-year placebo- and comparator-controlled study that enrolled 3,047 men, there were four cases of breast cancer in men treated with finasteride but no cases in men not treated with finasteride. During the 4-year placebo-controlled study that enrolled 3,040 men, there were two cases of breast cancer in placebo-treated men, but no cases were reported in men treated with finasteride. During the 7-year placebo-controlled trial that enrolled 18,882 men, there was 1 case of breast cancer in men treated with finasteride, and 1 case of breast cancer in men treated with placebo. The relationship between the long-term use of finasteride and male breast neoplasia is currently unknown.

Sexual Function

There is no evidence of increased adverse experiences with increased duration of treatment with finasteride. New reports of drug-related sexual adverse experiences decreased with duration of therapy.

Postmarketing Experience

Tamsulosin Hydrochloride

The following adverse reactions have been identified during post-approval use of tamsulosin hydrochloride. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Decisions to include these reactions in the labelling are typically based on one or more of the following factors:

(1) Seriousness of the reaction; (2) frequency of reporting; or (3) strength of causal connection to tamsulosin hydrochloride.

Allergic-type reactions such as skin rash, urticaria, pruritus, angioedema, and respiratory symptoms have been reported, with a positive re-challenge in some cases. Priapism has been reported rarely. Infrequent reports of dyspnoea, palpitations, hypotension, atrial fibrillation, arrhythmia, and tachycardia, skin desquamation, including reports of Stevens - Johnson syndrome, constipation, and vomiting have been received during the postmarketing period.

During cataract surgery, a variant of small-pupil syndrome known as Intraoperative floppy iris syndrome (IFIS) has been reported in association with alpha1-blocker therapy.

Finasteride

The following additional adverse effects have been reported in post-marketing experience with finasteride. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

- hypersensitivity reactions, including pruritus, urticaria, and swelling of the lips and face
- testicular pain
- Erectile dysfunction (ED) that continued after discontinuation of treatment, reported rarely in men taking finasteride for the treatment of BPH. Most men were older and were taking concomitant medications and/or had co-morbid conditions with a known association to ED. The independent role of finasteride in these events is unknown.
- Male infertility and/or poor seminal quality have been reported rarely in men taking finasteride for the treatment of BPH. The independent role of finasteride in these events is unknown.

  Normalization or improvement of seminal quality has been reported after discontinuation of finasteride.
- depression
- decreased libido that continued after discontinuation of treatment
- Male breast cancer.

The following additional adverse event related to sexual dysfunction that continued after discontinuation of treatment has been reported in postmarketing experience with finasteride at lower doses used to treat male pattern baldness. Because the event is reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate its frequency or establish a causal relationship to drug exposure:

- orgasm disorders

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting.

4.9 Overdose

Over dosage with FINAST - Tcapsules could potentially lead to hypotension due to the tamsulosin hydrochloride component. In case of hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of the heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, then administration of intravenous fluids should be considered. If necessary, vasopressors should then be used and renal function should be monitored and supported as needed. Dialysis is unlikely to be of benefit.

Patients have received single doses of finasteride up to 400 mg and multiple doses of finasteride up to 80 mg/day for 3 months without adverse effects. Until further experience is obtained, no specific treatment for an overdose with finasteride can be recommended.

5. Pharmacological properties

5.1 Mechanisam of Action

The symptoms associated with benign prostatic hyperplasia (BPH) are related to bladder outlet obstruction, which is comprised of two underlying components: static and dynamic. The static component is related to an increase in the prostate size caused, in part, by a proliferation of smooth muscle cells in the prostatic stroma. However, the severity of BPH symptoms and the degree of urethral obstruction do not correlate well with the size of the prostate.

5.2 Pharmacodynamic properties

Tamsulosin Hydrochloride

The dynamic component is a function of an increase in smooth muscle tone in the prostate and bladder neck leading to constriction of the bladder outlet. Smooth muscle tone is mediated by the sympathetic nervous stimulation of alpha1-adrenoceptors, which are abundant in the prostate, prostatic capsule, prostatic urethra and bladder neck. Blockade of these adrenoceptors can cause smooth muscles in the bladder neck and prostate to relax, resulting in an improvement in urine flow rate and a reduction in the symptoms of BPH.

Tamsulosin hydrochloride, an alpha1-adrenoreceptor blocking agent, exhibits selectivity for alpha1- receptors in the human prostate. At least three discrete alpha1-adrenoceptor subtypes have been identified: alpha1A, alpha1B and alpha1D; their distribution differs between human organs and tissue. Approximately 70% of the alpha1-receptors in the human prostate are of the alpha 1A subtype.

Tamsulosin hydrochloride capsules are not intended for use as an antihypertensive drug.

Finasteride

Mechanism of Action

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.

Finasteride is a competitive and specific inhibitor of Type II 5 alpha-reductase with which it slowly forms a stable enzyme complex. In man, a single 5 mg oral dose of finasteride produces a rapid reduction in serum DHT concentration, with the maximum effect observed 8 hours after the first dose. The suppression of DHT is maintained throughout the 24-hour dosing interval and with continued treatment. Daily dosing of finasteride at 5 mg/day for up to 4 years has been shown to reduce the serum DHT concentration by approximately 70%. The median circulating level of testosterone increased by approximately 10-20%, but remained within the physiologic range.

Adult males with genetically inherited Type II 5 alpha-reductase deficiency also have decreased levels of DHT. Except for the associated urogenital defects present at birth, no other clinical abnormalities related to Type II 5 alpha-reductase deficiency have been observed in these individuals. These individuals have a small prostate gland throughout life and do not develop BPH. In patients with BPH treated with finasteride (1-100 mg/day) for 7-10 days prior to prostatectomy, an approximate 80% lower DHT content was measured in prostatic tissue removed at surgery, compared to placebo; testosterone tissue concentration was increased up to 10 times over pretreatment levels, relative to placebo. Intraprostatic content of the prostate-specific antigen (PSA) was also decreased.

In healthy male volunteers treated with finasteride for 14 days, discontinuation of therapy resulted in a return of DHT levels to pre-treatment levels in approximately 2 weeks. In patients treated for 3 months, prostate volume, which declined by approximately 20%,

returned to close to baseline value after approximately 3 months of discontinuation of therapy.

5.3 Pharmacokinetic properties

Tamsulosin Hydrochloride

Administration under fasting conditions. Tamsulosin hydrochloride exhibits linear kinetics following single and multiple dosing, with achievement of steady-state concentrations by the fifth day of oncea- day dosing.

Effect of Food: The time to maximum concentration (Tmax) is reached by 4-5 hours under fasting conditions and by 6-7 hours when tamsulosin hydrochloride capsules are administered with food.

Distribution: The mean steady-state apparent volume of distribution of tamsulosin hydrochloride after intravenous administration to 10 healthy male adults was 16 L, which is suggestive of distribution into the extracellular fluids in the body. Tamsulosin hydrochloride is extensively bound to human plasma proteins (94-99%), primarily alpha1-acid glycoprotein (AAG), with linear binding over a wide concentration range (20 to 600 ng/mL). The results of two-way in vitro studies indicate that the binding of tamsulosin hydrochloride to human plasma proteins is not affected by amitriptyline, diclofenac, glyburide, simvastatin plus simvastatin hydroxy acid metabolite, warfarin, diazepam, propranolol, trichlormethiazide or chlormadinone. Likewise, tamsulosin hydrochloride had no effect on the extent of binding of these drugs.

Metabolism: There is no enantiomeric bioconversion from tamsulosin hydrochloride [R (-) isomer] to the S(+) isomer in humans. Tamsulosin hydrochloride is extensively metabolized by cytochrome (CY) P450 enzymes in the liver and less than 10% of the dose is excreted in the urine unchanged. However, the pharmacokinetic profile of the metabolites in humans has not been established. Tamsulosin is extensively metabolized, mainly by CYP3A4 and CYP2D6 as well as via some minor participation of other CYP isoenzymes. Inhibition of hepatic drug-metabolizing enzymes may lead to increased exposure to tamsulosin hydrochloride. The metabolites of tamsulosin hydrochloride undergo extensive conjugation to glucuronide or sulphate prior to renal excretion.

Incubations with human liver microsomes showed no evidence of clinically significant metabolic interactions between tamsulosin hydrochloride and amitriptyline, albuterol (beta agonist), glyburide (glibenclamide) and finasteride (5 alpha-reductase inhibitor for treatment of BPH). However, results of the in vitro testing of the tamsulosin hydrochloride interaction with diclofenac and warfarin were equivocal.

Excretion: On administration of the radiolabelled dose of tamsulosin hydrochloride to 4 healthy volunteers, 97% of the administered radioactivity was recovered, with urine (76%) representing the primary route of excretion compared to faeces (21%) over 168 hours. Because of absorption ratecontrolled pharmacokinetics with tamsulosin hydrochloride modified-release capsules, the apparent half-life of tamsulosin hydrochloride is approximately 9-13 hours in healthy volunteers and 14-15 hours in the target population. Tamsulosin hydrochloride undergoes restrictive clearance in humans, with a relatively low systemic clearance (2.88 L/h).

Pharmacokinetics in special populations

Pediatric Use: Tamsulosin hydrochloride capsules are not indicated for use in paediatric populations.

Geriatric Use: In reported cross-study comparison of tamsulosin hydrochloride capsules

overall exposure (AUC) and half-life indicates that the pharmacokinetic disposition of tamsulosin hydrochloride may be slightly prolonged in geriatric males compared to young, healthy male volunteers. Intrinsic clearance is independent of tamsulosin hydrochloride binding to AAG, but diminishes with age, resulting in a 40% overall higher exposure (AUC) in subjects of age 55 to 75 years compared to subjects of age 20 to 32 years.

Renal Impairment: The pharmacokinetics of tamsulosin hydrochloride have been compared in 6 subjects with mild-moderate (30≤ CLcr 90 mL/min/1.73 m2). While a change in the overall plasma concentration of tamsulosin hydrochloride was observed as the result of altered binding to AAG, the unbound (active) concentration of tamsulosin hydrochloride, as well as the intrinsic clearance, remained relatively constant. Therefore, patients with renal impairment do not require an adjustment in tamsulosin hydrochloride capsules dosing. However, patients with end-stage renal disease (CLcr <10 mL/min/1.73 m2) have not been studied.

Hepatic Impairment: The pharmacokinetics of tamsulosin hydrochloride have been compared in 8 subjects with moderate hepatic impairment (Child-Pugh's classification: Grades A and B) and 8 normal subjects. While a change in the overall plasma concentration of tamsulosin hydrochloride was observed as the result of altered binding to AAG, the unbound (active) concentration of tamsulosin hydrochloride does not change significantly, with only a modest (32%) change in intrinsic clearance of unbound tamsulosin hydrochloride. Therefore, patients with moderate hepatic impairment do not require an adjustment in tamsulosin hydrochloride capsules dosage. Tamsulosin hydrochloride has not been studied in patients with severe hepatic impairment.

Finasteride

Absorption: In a reported study of 15 healthy young subjects, the mean bioavailability of finasteride 5 mg Capsules was 63% (range: 34% to 108%), based on the ratio of area under the curve (AUC) relative to an intravenous reference dose. Maximum finasteride plasma concentration averaged 37 ng/mL (range: 27 to 49 ng/mL) and was reached 1-2 hours post-dose. Bioavailability of finasteride was not affected by food.

Distribution: Mean steady-state volume of distribution was 76 litres (range: 44 to 96 litres). Approximately 90% of circulating finasteride is bound to plasma proteins. There is a slow accumulation phase for finasteride after multiple dosing. After dosing with 5 mg/day of finasteride for 17 days, plasma concentrations of finasteride were 47% and 54% higher than after the first dose in males aged 45 to 60 years (n=12) and 70 years and older (n=12), respectively. Mean trough concentrations after 17 days of dosing were 6.2 ng/mL (range: 2.4 to 9.8 ng/mL) and 8.1 ng/mL (range: 1.8 to 19.7 ng/mL), respectively, in the two age groups. Although the steady state was not reached in this study, the mean trough plasma concentration in another study in patients with BPH (mean age: 65 years) receiving 5 mg/day was 9.4 ng/mL (range: 7.1 to 13.3 ng/mL; n=22) after over a year of dosing.

Finasteride has been shown to cross the blood-brain barrier but does not appear to distribute preferentially to the cerebrospinal fluid (CSF).

In two studies of healthy subjects (n=69) receiving finasteride 5 mg/day for 6- 24 weeks, finasteride concentrations in semen ranged from undetectable (<0.1 ng/mL) to 10.54 ng/mL. In an earlier study using a less sensitive assay, finasteride concentrations in the semen of 16 subjects receiving finasteride 5 mg/day ranged from undetectable (<1.0 ng/mL) to 21 ng/mL. Thus, based on a 5 mL ejaculate volume, the amount of finasteride in semen was estimated to be 50- to 100-fold less than the dose of finasteride (5 g) that

had no effect on circulating DHT levels in males.

Metabolism: Finasteride is extensively metabolized in the liver, primarily via the cytochrome P450 3A4 enzyme subfamily. Two metabolites, the t-butyl side chain monohydroxylated and monocarboxylic acid metabolites, have been identified; that possess no more than 20% of the 5 alpha-reductase inhibitory activity of finasteride.

Excretion: In healthy young subjects (n=15), the mean plasma clearance of finasteride was 165 mL/min (range: 70 to 279 mL/min) and the mean elimination half-life in plasma was 6 hours (range: 3 to 16 hours). Following an oral dose of 14C-finasteride in man (n=6), a mean of 39% (range: 32% to 46%) of the dose was excreted in the urine in the form of metabolites; 57% (range: 51% to 64%) was excreted in the faeces. The mean terminal half-life of finasteride in subjects aged 70 years and older was approximately 8 hours (range: 6 to 15 hours; n=12), compared with 6 hours (range: 4 to 12 hours; n=12) in subjects 45 to 60 years of age. As a result, the mean AUC (0 24 hours) after 17 days of dosing was 15% higher in subjects aged 70 years and older than in subjects who were 45 to 60 years of age (p=0.02).

Pharmacokinetics in special populations

Pediatric: Finasteride pharmacokinetics have not been investigated in patients <18 years of age. Finasteride is not indicated for use in pediatric patients.

Gender: Finasteride is not indicated for use in women.

Geriatric: No dosage adjustment is necessary in the elderly. Although the elimination rate of finasteride is decreased in the elderly, these findings are of no clinical significance.

Race: The effect of race on finasteride pharmacokinetics has not been studied.

Hepatic Impairment: The effect of hepatic impairment on finasteride pharmacokinetics has not been studied. Caution should be exercised in the administration of finasteride in those patients with liver function abnormalities, as finasteride is metabolized extensively in the liver.

Renal Impairment: No dosage adjustment is necessary in patients with renal impairment. In patients with chronic renal impairment, with creatinine clearances ranging from 9.0 to 55 mL/min, AUC, maximum plasma concentration, half-life, and protein binding after a single dose of 14C-finasteride were similar to values obtained in healthy volunteers. Urinary excretion of metabolites was decreased in patients with renal impairment. This decrease was associated with an increase in fecal excretion of metabolites. Plasma concentrations of metabolites were significantly higher in patients with renal impairment (based on a 60% increase in total radioactivity AUC). However, finasteride has been well tolerated in BPH patients with normal renal function receiving up to 80 mg/day for 12 weeks, where exposure of these patients to metabolites would presumably be much greater

6. Nonclinical properties

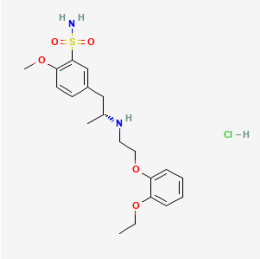
6.1 Animal Toxicology or Pharmacology

No data available

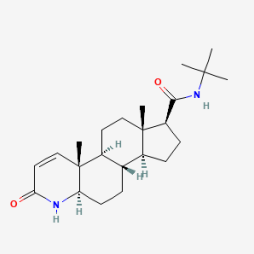
7. Description

Tamsulosin Hydrochloride is (R)-5-(2{[2-(o-ethoxyphenoxy) ethyl]aminopropyl)-2-

methoxybenzenesulfonamide hydrochloride. The molecular formula is $C_{20}H_{28}N_2O_5S,HCl$ and the molecular weight is 445.0. The chemical structure of Tamsulosin Hydrochloride is:



Finasteride is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-l-en3-one. The molecular formula is $C_{23}H_{36}N_2O_2$ and the molecular weight is 372.6. The chemical structure of Finasteride is:



Finast T Capsules are Maroon/Yellow, '1' size hard gelatin capsules filled with white to off white pellets and pink coloured film coated Capsules with break line on one side. The excipients used are Lactose, Pregelatinized Starch, Microcrystalline Cellulose, Sodium Starch Glycolate,Docusate Sodium, Sodium Starch Glycolate, Magnesium Stearate, Sugar Spheres, HydroxyPropyl Methyl Cellulose, Mannitol, Ethyl cellulose, Methacrylic Acid Copolymer Dispersion, Sodium Hydroxide, Polysorbate, Propylene Glycol, Isopropyl Alcohol, Purified water

8. Pharmaceutical particulars

8.1 Incompatibilities

None Stated

8.2 Shelf-life

Do not use later than date of expiry

8.3 Packaging information

Finast-T is available in pack of 30 capsules

8.4 Storage and handing instructions

Store below 30°C, Protect from light & moisture.

9. Patient Counselling Information

Package leaflet: Information for the user

FINAST - T

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

9.1 What FINAST - T is and what it is used for

FINAST - T - Tamsulosin Hcl 0.4 mg (MR) and Finasteride 5 mg Capsules are indicated for the treatments of signs and symptoms of benign prostatic hyperplasia (BPH) in adults.

9.2 What you need to know before you use FINAST - T Do not take FINAST - T:

If you are allergic to any of the other ingredients of this medicine. do not take this medicine and talk to your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking FINAST – T

General

Consideration for Other Urological Conditions

Prior to initiating treatment with finasteride, 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.

Orthostasis

The signs and symptoms of orthostasis (postural hypotension, dizziness, and vertigo) were detected more frequently in tamsulosin hydrochloride treated patients than in placebo recipients. As with other alpha-adrenergic blocking agents, there is a potential risk of syncope. Patients beginning treatment with FINAST- T capsules should be cautioned to avoid situations in which injury could result should syncope occur.

Priapism

Rarely (probably less than 1 in 50,000 patients), tamsulosin hydrochloride, like other alpha1- antagonists, has been associated with priapism (persistent painful penile erection unrelated to sexual activity). Because this condition can lead to permanent impotence if not properly treated, patients must be advised about the seriousness of the condition.

Intraoperative Floppy Iris Syndrome

Intraoperative floppy iris syndrome (IFIS) has been observed during cataract surgery in some patients treated with alpha1-blockers, including tamsulosin hydrochloride. Most reports were in patients taking the alpha1-blocker when IFIS occurred. In most of these cases, the alpha1-blocker had been stopped recently prior to surgery (2-14 days), but in a few cases, IFIS was reported after the patient had been off the alpha1-blocker for a longer period (5 weeks-9 months). IFIS is a variant of small-pupil syndrome and is characterized by the combination of a flaccid iris that billows in response to intraoperative irrigation currents, progressive intraoperative miosis despite preoperative dilation with standard mydriatic drugs, and potential prolapse of the iris toward the phacoemulsification incisions. The patient's ophthalmologist should be prepared for possible modifications to their surgical technique, such as the utilization of iris hooks, iris dilator rings or viscoelastic substances. IFIS may increase the risk of eye complications during and after the operation. The benefit of stopping alpha1-blocker therapy prior to cataract surgery has not been established. The initiation of therapy with tamsulosin hydrochloride in patients for whom cataract surgery is scheduled is not recommended.

Sulpha Allergy

In patients with sulpha allergy, an allergic reaction to tamsulosin hydrochloride has been rarely reported. If a patient reports a serious or life-threatening sulpha allergy, caution is warranted when administering FINAST- T capsules.

Exposure of Women - Risk to Male Foetus

Women should not handle broken FINAST- T capsules when they are pregnant or may potentially be pregnant because of the possibility of the absorption of finasteride and the subsequent potential risk to the male foetus.

Pediatric Patients and Women

FINAST- T is not indicated for use in pediatric patients or women.

Increased Risk of High-Grade Prostate Cancer

Men aged 55 years and over, with a normal digital rectal examination and PSA 3.0 ng/mL at baseline, who were taking finasteride 5 mg/day in the 7-year Prostate Cancer Prevention Trial, had an increased risk of Gleason score 8-10 prostate cancer (finasteride 1.8% vs placebo 1.1%). Similar results were observed in a 4-year placebo-controlled clinical trial with another 5 alpha-reductase inhibitor, dutasteride (1% dutasteride vs 0.5% placebo). The 5 alpha-reductase inhibitors may increase the risk of development of high-grade prostate cancer. It has not been established as to whether the effect of 5 alpha-reductase inhibitors to reduce prostate volume, or study-related factors, impacted the results of these studies.

Effect on Prostate Specific Antigen (PSA) and Use of PSA in Prostate Cancer detection

In reported clinical studies, finasteride reduced serum PSA concentration by approximately 50% within 6 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. For interpretation of serial PSAs in men taking finasteride, a new PSA baseline should be established at least 6 months after starting treatment and the PSA monitored periodically thereafter. Any confirmed increase from the lowest PSA value while on finasteride may signal the presence of prostate cancer and should be evaluated, even if PSA levels are still within the normal range for men not taking a 5 alpha-reductase inhibitor. Non-compliance with finasteride therapy may also affect the PSA test results. To interpret an isolated PSA value in patients treated with finasteride for 6 months or more, PSA values should be doubled for comparison with normal ranges in untreated men. These adjustments preserve the utility of PSA to detect prostate cancer in men treated with finasteride.

Finasteride may also cause decreases in serum PSA in the presence of prostate cancer. The ratio of free to total PSA (percent-free PSA) remains constant even under the influence of finasteride. If clinicians elect to use percent-free PSA as an aid in the detection of prostate cancer in men undergoing finasteride therapy, no adjustment to its value appears necessary.

Effect on Semen Characteristics

Treatment with finasteride for 24 weeks to evaluate semen parameters in healthy male volunteers revealed no clinically meaningful effects on sperm concentration, mobility,

morphology or pH. A 0.6 mL (22.1%) median 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.

Taking other medicines

Taking another medicine while you are taking Finast- T can affect how it or the other medicine works. Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including those you may have bought yourself without a prescription. Please check with your doctor if you are taking any of the following (or any other medication):

Patients should be told about the possible occurrence of symptoms related to postural hypotension such as dizziness and syncope when taking tamsulosin hydrochloride, and they should be cautioned about driving, operating machinery or performing hazardous tasks.

Patients should be advised about the possibility of priapism as a result of treatment with tamsulosin hydrochloride and other similar medications. Patients should be informed that this reaction is extremely rare, but if not brought to immediate medical attention, can lead to permanent erectile dysfunction (impotence).

Prostate cancer and BPH frequently co-exist; therefore, patients should be screened for the presence of prostate cancer prior to treatment with FINAST - Tcapsules and at regular intervals afterwards.

Patients considering cataract surgery should be advised to tell their ophthalmologist that they have taken FINAST - Tcapsules.

Patients should be advised not to crush or chew the FINAST - Tcapsules.

Patients should be informed that there was an increase in high-grade prostate cancer in men treated with 5 alpha-reductase inhibitors indicated for BPH treatment, including finasteride which is one of the component of FINAST- T, compared to those treated with placebo in studies looking at the use of these drugs to prevent prostate cancer. Physicians should inform patients that women who are pregnant or may potentially be pregnant should not handle crushed FINAST - Tcapsules because of the possibility of absorption of finasteride and the subsequent potential risk to the male foetus. If a woman who is pregnant or may potentially be pregnant comes in contact with crushed or broken FINAST - Tcapsules, the contact area should be washed immediately with soap and water. Physicians should inform patients that the volume of ejaculate may be decreased in some patients during treatment with FINAST - Tcapsules. This decrease does not appear to interfere with normal sexual function. However, impotence and decreased libido may occur in patients treated with FINAST - Tcapsules.

Physicians should instruct their patients to promptly report any changes in their breasts such as lumps, pain or nipple discharge. Breast changes including breast enlargement, tenderness and neoplasm have been reported.

Renal Impairment

Patients with renal impairment do not require any dosage adjustment. However, patients with endstage renal disease (CLcr <10 mL/min/1.73 m2) for tamsulosin hydrochloride have not been studied. In patients with chronic renal impairment, with creatinine clearances ranging from 9.0 to 55 mL/min, the AUC, maximum plasma concentration, half-life and protein binding after a single dose of 14C-finasteride were similar to the values obtained in healthy volunteers. Urinary excretion of metabolites was decreased in patients with renal impairment. This decrease was associated with an increase in the faecal excretion of metabolites. Plasma concentrations of metabolites were significantly higher in patients with renal impairment (based on a 60% increase in total radioactivity AUC). No dosage adjustment is necessary in patients with renal impairment. In patients with chronic renal impairment, with creatinine clearances ranging from 9.0 to 55 mL/min, the AUC, maximum plasma concentration, half-life and protein binding after a single dose of 14C-finasteride were similar to the values obtained in healthy volunteers. Urinary excretion of metabolites was decreased in patients with renal impairment. This decrease was associated with an increase in the faecal excretion of metabolites. Plasma concentrations of metabolites were significantly higher in patients with renal impairment (based on a 60% increase in total radioactivity AUC). However, finasteride has been well tolerated in BPH patients with normal renal function receiving up to 80 mg/day for 12 weeks, where exposure of these patients to metabolites would presumably be much greater.

Hepatic Impairment

Patients with moderate hepatic impairement do not require any dosage adjustment in tamsulosin hydrochloride dosage. Tamsulosin hydrochloride has not been studied in patients with severe hepatic impairment. Exercise caution during use in patients with hepatic impairment as finasteride is metabolized extensively in the liver.

9.3 How to use FINAST - T

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take and when

The amount of **FINAST - T** people have to take varies depending on their condition. Your doctor will tell you exactly how many Capsules of **FINAST - T** to take.

How to take FINAST - T

- Swallow the Capsules whole with some water.

How long to take FINAST - T

- Take FINAST - T every day for as long as your doctor tells you. You may have to take this treatment over a long period of time.

- Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

- If you take too many FINAST - T Capsules, or if someone else has taken your medicine,

talk to your doctor straight away. Medical attention may be needed. If you need to see a doctor or go to the hospital, take the pack with you.

If you forget to take FINAST - T

If you forget to take a dose of this medicine, take it as soon as you remember. Then take your next dose at the usual time. If it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten Capsule.

If you stop taking FINAST - T

Do not stop taking FINAST - T unless your doctor tells you to. If you have questions about how long to take this medicine, talk to your doctor.

9.4 Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- 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
- Tooth disorder

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting.

9.5 How to store FINAST - T

Store below 30°C, Protect from light & moisture.

9.6 Contents of the pack and other information

FINAST - T contain: Tamsulosin Hcl 0.4 mg (MR) and Finasteride 5 mg

Finast-T is available in pack of 30 capsules

10 Details of manufacturer

M/s. Hetero Labs Limited (UNIT-II)

Kalyanpur (Village), Chakkan Road,

Baddi (Tehsil), Solan (Distt),

Himachal Pradesh - 173205.

11 Details of permission or licence number with date

MNB/09/780 issued on 24.03.2015

12 Date of revision

NA

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/FINAST - T/JUNE-2022/01/PI