PACKAGE INSERT
(For the use of a Registered Medical Practitioner or a Hospital)

NAME OF THE MEDICINAL PRODUCT

FINAINTAS 5 (Finasteride Tablets USP 5 mg)

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains Finasteride Ph.Eur. 5 mg
For a full list of excipients, see Pharmaceutical particulars section

PHARMACEUTICAL FORM

Film-coated tablet

"Blue, 7 mm, round, biconvex, film coated tablets, marked ‘F5’ on one side and plain on other side."

THERAPEUTIC CLASS

Finasteride, a synthetic 4-azasteroid compound, is a specific inhibitor of Type II 5α-reductase, an intracellular enzyme which metabolizes testosterone into the more potent androgen dihydrotestosterone (DHT). In benign prostatic hyperplasia (BPH), enlargement of the prostate gland is dependent upon the conversion of testosterone to DHT within the prostate. Finasteride is highly effective in reducing circulating and intraprostatic DHT. Finasteride has no affinity for the androgen receptor.

In the Finasteride Long-Term Efficacy and Safety Study (PLESS), the effect of therapy with Finasteride on BPH-related urologic events (surgical intervention [e.g., transurethral resection of the prostate and prostatectomy] or acute urinary retention requiring catheterization) was assessed over a 4-year period in 3016 patients with moderate to severe symptoms of BPH. In this double-blind, randomized, placebo-controlled multicenter study, treatment with Finasteride reduced the risk of total urologic events by 51% and was also associated with a marked and sustained regression in prostate volume, and a sustained increase in maximum urinary flow rate and improvement in symptoms.

INDICATIONS

FINAINTAS tablets are indicated for the treatment and control of benign prostatic hyperplasia (BPH) and for the prevention of urologic events as it:
- May reduce the risk of acute urinary retention
- May reduce the risk of surgery including transurethral resection of the prostate (TURP) and prostatectomy.

FINAINTAS tablets causes regression of the enlarged prostate, improves urinary flow and improves the symptoms associated with BPH.

Patients with an enlarged prostate are the appropriate candidates for therapy with FINAINTAS tablets.

DOSAGE AND ADMINISTRATION

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

Dosage in renal insufficiency

No adjustment in dosage is required in patients with varying degrees of renal insufficiency (creatinine clearances as low as 9 mL/min) as pharmacokinetic studies did not indicate any change in the disposition of finasteride.

Dosage in the elderly

No adjustment in dosage is required although pharmacokinetic studies indicated the elimination of finasteride is somewhat decreased in patients more than 70 years of age.

CONTRAINDICATIONS

Finasteride is not indicated for use in women or children.
Finasteride is contraindicated in the following:

- Hypersensitivity to any component of this product.
- Pregnancy - Use in women when they are or may potentially be pregnant (See PRECAUTIONS: PREGNANCY and EXPOSURE TO FINASTERIDE - RISK TO MALE FETUS).

PRECAUTIONS

General

Patients with large residual urine volume and/or severely diminished urinary flow should be carefully monitored for obstructive uropathy.

Effects on PSA and prostate cancer detection

No clinical benefit has yet been demonstrated in patients with prostate cancer treated with Finasteride. Patients with BPH and elevated prostate-specific antigen (PSA) were monitored in controlled clinical studies with serial PSAs and prostate biopsies. In these BPH studies, Finasteride did not appear to alter the rate of prostate cancer detection and the overall incidence of prostate cancer was not significantly different in patients treated with Finasteride or placebo.

Digital rectal examinations as well as other evaluations for prostate cancer are recommended prior to initiating therapy with Finasteride and periodically thereafter. Serum PSA is also used for prostate cancer detection. Generally, a baseline PSA >10 ng/mL (Hybritech) prompts further evaluation and consideration of biopsy; for PSA levels between 4 and 10 ng/mL, further evaluation is advisable. There is considerable overlap in PSA levels among men with and without prostate cancer. Therefore, in men with BPH, PSA values within the normal reference range do not rule out prostate cancer, regardless of treatment with Finasteride. A baseline PSA <4 ng/mL does not exclude prostate cancer.

Finasteride causes a decrease in serum PSA concentrations by approximately 50% in patients with BPH, even in the presence of prostate cancer. This decrease in serum PSA levels in patients with BPH treated with Finasteride should be considered when evaluating PSA data and does not rule out concomitant prostate cancer. This decrease is predictable over the entire range of PSA values, although it may vary in individual patients. Analysis of PSA data from over 3000 patients in the 4-year, double-blind, placebo-controlled Finasteride Long-Term Efficacy and Safety Study (PLESS) confirmed that in typical patients treated with Finasteride for six months or more, PSA values should be doubled for comparison with normal ranges in untreated men. This adjustment preserves the sensitivity and specificity of the PSA assay and maintains its ability to detect prostate cancer.

Any sustained increase in PSA levels of patients treated with finasteride should be carefully evaluated, including consideration of non-compliance to therapy with Finasteride.
Percent free PSA (free to total PSA ratio) is not significantly decreased by Finasteride. The ratio of free to total PSA remains constant even under the influence of Finasteride. When percent free PSA is used as an aid in the detection of prostate cancer, no adjustment to its value is necessary.

Drug/laboratory test interactions

Effect on levels of PSA

Serum PSA concentration is correlated with patient age and prostatic volume, and prostatic volume is correlated with patient age. When PSA laboratory determinations are evaluated, consideration should be given to the fact that PSA levels decrease in patients treated with Finasteride. In most patients, a rapid decrease in PSA is seen within the first months of therapy, after which time PSA levels stabilize to a new baseline. The post-treatment baseline approximates half of the pre-treatment value. Therefore, in typical patients treated with Finasteride for six months or more, PSA values should be doubled for comparison to normal ranges in untreated men. For clinical interpretation, see PRECAUTIONS, EFFECTS ON PSA AND PROSTATE CANCER DETECTION.

Breast cancer in men

Breast cancer has been reported in men taking finasteride 5 mg during clinical trials and the postmarketing period. Physicians should instruct their patients to promptly report any changes in their breast tissue such as lumps, pain, gynaecomastia, or nipple discharge.

Pregnancy

Finasteride is contraindicated for use in women when they are or may potentially be pregnant (See CONTRAINDICATIONS).
Because of the ability of Type II 5α-reductase inhibitors to inhibit conversion of testosterone to dihydrotestosterone, these drugs, including finasteride, may cause abnormalities of the external genitalia of a male fetus when administered to a pregnant woman.

Exposure to Finasteride - risk to male fetus

Women should not handle crushed or broken tablets of Finasteride when they are or may potentially be pregnant because of the possibility of absorption of finasteride and the

subsequent potential risk to a male fetus (see PREGNANCY). Finasteride tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed.

Nursing mothers

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

Pediatric use

Finasteride is not indicated for use in children.
Safety and effectiveness in children have not been established.

DRUG INTERACTIONS

No drug interactions of clinical importance have been identified. Finasteride does not appear to affect significantly the cytochrome P450-linked drug metabolizing enzyme system. Compounds which have been tested in man have included propranolol, digoxin, glyburide, warfarin, theophylline, and antipyrine and no clinically meaningful interactions were found.

Other concomitant therapy

Although specific interaction studies were not performed, in clinical studies Finasteride was used concomitantly with ACE-inhibitors, acetaminophen, acetylsalicylic acid, alpha-blockers, beta-blockers, calcium channel blockers, cardiac nitrates, diuretics, H2 antagonists, HMG-CoA reductase inhibitors, nonsteroidal anti-inflammatory drugs (NSAIDS), quinolones, and benzodiazepines without evidence of clinically significant adverse interactions.

SIDE EFFECTS

Finasteride is well tolerated.
In PLESS, 1524 patients treated with Finasteride 5 mg daily and 1516 patients treated with placebo were evaluated for safety over a period of 4 years. 4.9% (74 patients) were discontinued from treatment due to side effects associated with Finasteride compared with 3.3% (50 patients) treated with placebo. 3.7% (57 patients) treated with Finasteride and 2.1% (32 patients) treated with placebo discontinued therapy as a result of side effects related to sexual function which were the most frequently reported side effects.

The only clinical adverse reactions considered possibly, probably or definitely drug related by the investigator, for which the incidence on Finasteride was ≥1% and greater than placebo over the 4 years of the study, were those related to sexual function, breast complaints and rash. In the first year of the study, impotence was reported in 8.1% of patients treated with Finasteride vs. 3.7% of those treated with placebo; decreased libido was reported in 6.4 vs. 3.4%, and ejaculation disorder in 0.8 vs. 0.1%, respectively. In years 2-4 of the study, there was no significant difference between treatment groups in the incidences of these three effects. The cumulative incidences in years 2-4 were: impotence (5.1% on Finasteride, 5.1% on placebo); decreased libido (2.6%, 2.6%); and ejaculation disorder (0.2%, 0.1%). In year 1, decreased volume of ejaculate was reported in 3.7 and 0.8% of patients on Finasteride and placebo, respectively; in years 2-4 the cumulative incidence was 1.5% on Finasteride and

0.5% on placebo. In year 1, breast enlargement (0.5%, 0.1%), breast tenderness (0.4%, 0.1%) and rash (0.5%, 0.2%) were also reported. In years 2-4 the cumulative incidences were: breast enlargement, (1.8%, 1.1%); breast tenderness, (0.7%, 0.3%); and rash (0.5%, 0.1%).

The adverse experience profile in the 1-year, placebo-controlled, Phase III studies and the 5-year extensions, including 853 patients treated for 5-6 years, was similar to that reported in years 2-4 in PLESS. There is no evidence of increased adverse experiences with increased duration of treatment with Finasteride. The incidence of new drug related sexual adverse experiences decreases with duration of treatment.

Other long-term data

In a 7-year placebo-controlled trial that enrolled 18,882 healthy men, of whom 9060 had prostate needle biopsy data available for analysis, prostate cancer was detected in 803 (18.4%) men receiving Finasteride and 1147 (24.4%) men receiving placebo. In the Finasteride group, 280 (6.4%) men had prostate cancer with Gleason scores of 7-10 detected on needle biopsy vs. 237 (5.1%) men in the placebo group. Additional analyses suggest that the increase in the prevalence of high-grade prostate cancer observed in the Finasteride group may be explained by a detection bias due to the effect of Finasteride on prostate volume. Of the total cases of prostate cancer diagnosed in this study, approximately 98% were classified as intracapsular (clinical stage T1 or T2) at diagnosis. The relationship between long-term use of Finasteride and tumors with Gleason scores of 7-10 is unknown.

Post marketing experience

The following additional adverse effects have been reported in postmarketing experience with Finasteride and/or finasteride at lower doses. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.

Immune system disorders: hypersensitivity reactions, such as pruritus, urticaria and angioedema (including swelling of the lips, tongue, throat, and face).

Psychiatric disorders: depression; decreased libido that continued after discontinuation of treatment, suicidal ideation

Reproductive system and breast disorders: breast tenderness, breast enlargement and male breast cancer. (see PRECAUTIONS); sexual dysfunction (erectile dysfunction and ejaculation disorders) that continued after discontinuation of treatment; testicular pain; hematospermia; male infertility and/or poor seminal quality. Normalization or improvement of seminal quality has been reported after discontinuation of finasteride.

Laboratory test findings

When PSA laboratory determinations are evaluated, consideration should be given to the fact that PSA levels are decreased in patients treated with Finasteride (See PRECAUTIONS).

No other difference in standard laboratory parameters was observed between patients treated with placebo or Finasteride.

OVERDOSAGE

Patients have received single doses of Finasteride up to 400 mg and multiple doses of Finasteride up to 80 mg/day for three months without adverse effects.

No specific treatment of overdosage with Finasteride is recommended.

PHARMACEUTICAL PARTICULARS

List of excipients

Tablet core:
Lactose Monohydrate
Microcrystalline Cellulose
Pregelatinized Starch
Sodium Starch Glycolate (Type A)
Lauroyl Macrogolglycerides
Magnesium Stearate

Tablet Coating
Hypromellose
Titanium dioxide
Indigo carmine
Macrogol 6000

Special precautions for storage

Do not store above 30 °C.

Nature and contents of container

FINAINTAS tablets are available in Opaque white PVC/PVDC-Alu blister pack of 10 tablets. Each carton contains 3 such blisters. (3 x 10 Tablets)

NAME AND ADDRESS OF PRODUCT REGISTRANT

Accord Healthcare Private Limited
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DATE OF REVISION OF PACKAGE INSERT

March 2021