Professional information for FINIDE 5 TABLETS

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM

FINIDE 5 TABLETS film-coated tablet

COMPOSITION

Active ingredient:

Each film-coated tablet contains 5 mg finasteride.

Inactive ingredients:

Docusate sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry Blue [FD&C Blue No. 2/Indigo carmine aluminium lake (colourant), hypromellose, hydroxypropyl cellulose, iron oxide yellow (colourant), talc, titanium dioxide (colourant)], pregelatinised starch, sodium starch glycolate.

Contains sugar (lactose monohydrate).

PHARMACOLOGICAL CLASSIFICATION

A 21.12 Hormone inhibitors

PHARMACOLOGICAL ACTION

Pharmacodynamic properties:

Finasteride is a synthetic 4-azasteroid compound. Finasteride is an inhibitor of Type II 5-alpha reductase, an intracellular enzyme that metabolises testosterone into the more potent androgen dihydrotestosterone (DHT). Finasteride has no affinity for the androgen receptor.

The development of the prostate gland and subsequent benign prostate hyperplasia (BHP) is dependent upon the conversion of testosterone to DHT within the prostate.

Finasteride reduces circulating and intraprostatic DHT. Within 24 hours after oral administration of finasteride, there is a significant reduction in circulating DHT levels as a result of the inhibition of 5-alpha reductase.

Pharmacokinetic properties:

Following an oral dose of ^{14}C-finasteride in humans, the bioavailability is approximately 80 % (relative to an intravenous reference dose) and is not affected by food.

Maximum finasteride plasma concentrations are reached about 2 hours after dosing and the absorption is complete after 6 to 8 hours. Protein binding is approximately 93 %, plasma clearance about 165 mL/min and the volume of distribution, 76 litres. Finasteride displays a mean plasma elimination half-life of approximately 6 hours (4 – 12 hours) in subjects 46 – 60 years of age and approximately 8 hours in men 70 years of age and older.

Two metabolites of finasteride have been identified which possess only a small fraction of the 5-alpha reductase inhibitory activity of finasteride. 36 % of the dose is excreted in the urine in the form of metabolites and 57 % of the total dose is excreted in the faeces.

INDICATIONS

FINIDE 5 TABLETS is indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to:

- Improve urinary flow and improve the symptoms associated with BPH by causing regression of the enlarged prostate.
- Decrease the incidence of acute urinary retention.
- Reduce the incidence of surgery including transurethral resection of the prostate (TURP) and prostatectomy.

CONTRAINDICATIONS

- Hypersensitivity to finasteride or to any of the inactive ingredients of FINIDE 5 TABLETS (see COMPOSITION).

- Pregnancy and lactation [see PREGNANCY AND LACTATION: Exposure to FINIDE 5 TABLETS (by pregnant women) – Risk to male fetus].
- Use in women.
- Paediatric use.

WARNINGS AND SPECIAL PRECAUTIONS

Effects on serum prostate specific antigen (S-PSA) and prostate cancer detection:

No clinical benefit has been demonstrated in patients with prostate cancer treated with FINIDE 5 TABLETS. Digital rectal examinations as well as other evaluations for prostate cancer are recommended prior to initiating therapy with FINIDE 5 TABLETS and periodically thereafter. Serum prostate specific antigen (S-PSA) is also used for prostate cancer detection. Generally, a baseline S-PSA greater than 10 ng/mL (Hybritech) prompts further evaluation and consideration of biopsy; for S-PSA levels between 4 and 10 ng/mL, further evaluation is advisable. The medical practitioner should be aware that the baseline S-PSA < 4 ng/mL does not exclude prostate cancer.

FINIDE 5 TABLETS causes a decrease in S-PSA concentrations even in the presence of prostate cancer (see Laboratory test interactions). The reduction of levels in patients with benign prostatic hyperplasia (BPH) treated with FINIDE 5 TABLETS should be considered when evaluating S-PSA data and does not rule out concomitant prostate cancer. Patients treated with FINIDE 5 TABLETS who have a sustained increase in S-PSA levels should be carefully evaluated.

Laboratory test interactions:

Prostatic volume is correlated with patient's age whereas serum prostate specific antigen (S-PSA) concentration is correlated with patient's age and prostatic volume. When S-PSA laboratory determinations are evaluated, consideration should be given to the fact that S-PSA levels decrease in patients treated with FINIDE 5 TABLETS [see Effects on serum prostate specific antigen (S-PSA) and prostate cancer detection].

S-PSA levels decrease rapidly within the first months of therapy, after which time S-PSA levels stabilise to a new baseline.

The post-treatment baseline approximates half of the pre-treatment's value. This decrease is predictable over the entire range of S-PSA values, although it may vary in individual patients. Therefore, in typical patients treated with FINIDE 5 TABLETS for six months or more, S-PSA values should be doubled for comparison to normal ranges in untreated men.
There is considerable overlap in S-PSA levels among men with and without prostate cancer. Therefore, in men with benign prostatic hyperplasia (BPH), S-PSA values within the normal reference range do not rule out prostate cancer, regardless of FINIDE 5 TABLETS treatment. The ability of S-PSA to distinguish between BPH and cancer is not adversely affected by treatment with FINIDE 5 TABLETS.

Laboratory test findings:

Consideration should be given to the fact that serum prostate specific antigen (S-PSA) levels are decreased in patients treated with FINIDE 5 TABLETS when S-PSA laboratory test determinations are evaluated.

General:

The beneficial response of FINIDE 5 TABLETS may not be manifested immediately and thus patients with large residual urine volume and/or severely diminished urinary flow should be monitored carefully for obstructive uropathy.
Since serum markers of prostate cancer may be reduced in patients taking FINIDE 5 TABLETS, such malignancies should be excluded before treatment of benign prostatic hyperplasia is initiated.

Contains sugar:

FINIDE 5 TABLETS contains lactose. Patients with the rare hereditary conditions of galactose intolerance, e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance, should not take FINIDE 5 TABLETS.

Effects on ability to drive and use machines:

FINIDE 5 TABLETS may cause dizziness and can affect the ability to drive a vehicle and use machines (see SIDE EFFECTS). Caution is advised before driving a vehicle or operating machinery until the effects of FINIDE 5 TABLETS are known.

INTERACTIONS

No interactions of clinical importance have been identified.

FINIDE 5 TABLETS does not appear to significantly affect the cytochrome P450-linked metabolising enzyme system. Compounds tested in men included digoxin, propranolol, warfarin, glibenclamide, antipyrine and theophylline and no clinically meaningful interactions were found.

Other concomitant therapy:

FINIDE 5 TABLETS has been used concomitantly with angiotensin-converting enzyme (ACE) inhibitors, paracetamol, acetylsalicylic acid, alpha-blockers, beta-blockers, calcium channel blockers, cardiac nitrates, diuretics, H_2-receptor antagonists, HMG-CoA reductase inhibitors, nonsteroidal anti-inflammatory drugs (NSAIDs), quinolones and benzodiazepines without evidence of clinically significant adverse interactions.

PREGNANCY AND LACTATION

Pregnancy:

FINIDE 5 TABLETS is contraindicated in pregnancy (see CONTRAINDICATIONS).

Because of the ability of Type II 5-alpha reductase inhibitors to inhibit conversion of testosterone to dihydrotestosterone, FINIDE 5 TABLETS may cause abnormalities of the external genitalia of a male foetus when administered to a pregnant woman.

Lactation:

It is not known if FINIDE 5 TABLETS is excreted in human milk. FINIDE 5 TABLETS should not be used during lactation (see CONTRAINDICATIONS).

Exposure to FINIDE 5 TABLETS (by pregnant women) – Risk to male fetus:

FINIDE 5 TABLETS are coated and will prevent contamination with the active ingredient during normal handling, provided that the tablets have not been broken or crushed.
Pregnant women should not handle crushed or broken FINIDE 5 TABLETS because of the possibility of absorption of finasteride, as in FINIDE 5 TABLETS, and the subsequent potential risk to a male fetus. In addition, since finasteride, as in FINIDE 5 TABLETS is present in semen, male patients should wear a condom or otherwise avoid exposure of female sexual partners at risk of becoming pregnant.

DOSAGE AND DIRECTIONS FOR USE

Adults:

The recommended dosage is one 5 mg tablet daily with or without food.
Although early improvement in symptoms may be seen, a therapeutic trial of 6 – 12 months may be necessary to assess whether a beneficial response has been achieved.

Dosage in renal insufficiency:

Adjustments in dosage are not required in patients with varying degrees of renal insufficiency (creatinine clearances as low as 9 mL/min) as there are no changes in the disposition of FINIDE 5 TABLETS as compared to healthy subjects.

Dosage in elderly patients:

No adjustments in dosage are required even though the elimination of FINIDE 5 TABLETS is decreased in patients more than 70 years of age.

SIDE EFFECTS

Immune system disorders:

Frequent: Hypersensitivity reactions including rash, pruritus, urticaria and swelling of the lips and face.

Nervous system disorders:

Less frequent: Headache, dizziness.

Gastrointestinal disorders:

Less frequent: Abdominal pain, diarrhoea.

Reproductive system and breast disorders:

Frequent: Impotence, decrease in libido, decrease in volume of ejaculate, ejaculation disorder.

Less frequent: Testicular pain, breast tenderness.

General disorders and administration site conditions:

Less frequent: Back pain.

Post-marketing:

Neoplasms benign and malignant (including cysts and polyps):

Frequency unknown: Male breast cancer.

Psychiatric disorders:

Frequency unknown: Depression.

Reproductive system and breast disorders:

Frequency unknown: Breast enlargement, male infertility and/or poor seminal quality (normalisation or improvement of seminal quality has been reported after discontinuation of FINIDE 5 TABLETS).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms of overdose:

See SIDE EFFECTS for expected signs of overdosage.

Treatment of overdose:

Treatment is symptomatic and supportive.

IDENTIFICATION

Blue coloured, round, biconvex film-coated tablet with a plain surface on both sides. The tablet should be free of all physical defects.

PRESENTATION

Packed in white opaque PVC/PVDC / aluminium foil blister strips of 1 x 14 tablets or 2 x 14 tablets inside an outer cardboard box.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light and moisture.

Keep the blister strips in the outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

42/21.12/0461

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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