APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S4**

PROPRIETARY NAME AND DOSAGE FORM

AURO FINASTERIDE (Tablet)

COMPOSITION

Each film-coated tablet contains Finasteride 5 mg

PHARMACOLOGICAL CLASSIFICATION

A21.12 Hormone inhibitors

PHARMACOLOGICAL ACTION

Finasteride is a synthetic 4-azasteriod compound. Finasteride is an inhibitor of Type 11 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 prostrate gland and subsequent benign prostrate hyperplasia (BHP) is dependant upon the conversion of testosterone to DHT within the prostrate. Finasteride reduces circulating and intraprostatic DHT. Within 24 hours after oral administration on Finasteride, there is a significant reduction of circulating DHT levels as a result of the inhibition of 5-alpha reductase.

Pharmacokinetics:

Following an oral dose of ^{1}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

AURO FINASTERIDE is indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostrate to:

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

CONTRA-INDICATIONS:

Hypersensitivity to any of the components of AURO FINASTERIDE:

Pregnancy — (See **"Precautions, Use in pregnancy and Lactation and Exposure to**

AURO FINASTERIDE - Risk to Male Foetus (**see below**)

AURO FINASTERIDE - is not indicated for use in women.

AURO FINASTERIDE - is not indicated for paediatric use.

WARNINGS:

AURO FINASTERIDE is contra-indicated for use in women when they are or may potentially be pregnant as it may cause abnormalities of the external genitalia of a male foetus when administered to a pregnant women. (see **Pregnancy and Exposure to AURO FINASTERIDE 5mg - Risk to Male Foetus"** below).

It is not known whether **AURO FINASTERIDE** is excreted in breast milk.

Serum Prostate Specific Antigens (S-PSA) levels decrease in patients treated with **AURO FINASTERIDE.**

INTERACTIONS:

No interactions of clinical importance have been identified.

AURO FINASTERIDE does not appear to significantly affect the cytochrome P450-linked drug metabolising

enzyme system.

Compounds tested in men included digoxin, propranolol, warfarin, glibenclamide and theophylline and no clinically meaningful interactions were found.

Other Concomitant Therapy

AURO FINASTERIDE has been used concomitantly with ACE-inhibitors, paracetamol, acetylsalicylic acid, alpha-blockers, beta-blockers, calcium channel blockers, cardiac nitrates, diuretics, H_2 antagonists, HMG-CoA reductase inhibitors, nonsteroidal anti-inflammatory drugs (NSAIDs), quinlones and benzodiazepines with evidence of clinically significant adverse interactions.

PREGNANCY AND LACTATION:

Use in Pregnant and lactating Mothers.

AURO FINASTERIDE is contra-indicated in pregnancy (see "Contra-indications").

Because of the ability of Type II 5-alpha reductase inhibitors to inhibit conversion of testosterone to dihydrotesterone, these drugs, including **AURO FINASTERIDE**, may cause abnormalities of the external genitalia of a male foetus when administered to a pregnant women.

Lactation

It is not known if **AURO FINASTERIDE** is excreted in human milk.

Exposure to **AURO FINASTERIDE** - **(by pregnant women) - Risk *to* Male Foetus**

AURO FINASTERIDE 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 **AURO FINASTERIDE** because of the possibility of absorption of **AURO FINASTERIDE** and the subsequent potential risk to male foetus (see **'Use in Pregnancy'**)

In addition since **AURO FINASTERIDE** 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:

The recommended dosage is one 5 mg tablet 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 **AURO FINASTERIDE** as compared to healthy subjects.

Dosage in the Elderly

No adjustments in dosage are required even though the elimination of **AURO FINASTERIDE S 5 mg** is decreased in patients more than 70 years of age.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Side Effects

Reproductive system and breast disorders

Less frequent: Impotence, decrease in libido, decrease in volume of ejaculate and ejaculation disorder, breast tenderness

The following side effects have been reported and frequencies are unknown: Testicular pain

Skin and subcutaneous tissue disorder

Less frequent: Rash, hypersensitivity reactions, including pruritus, urticaria, and swelling of the lips and face.

SPECIAL PRECAUTIONS:

General

The beneficial response of **AURO FINASTERIDE** may not be manifested immediately and thus patients with residual urine volume and/or severely diminished urinary flow should be monitored carefully for obstructive

uropathy. Since serum markers of prostrate cancer may be reduced in patients taking **AURO FINASTERIDE** such malignancies should be excluded before treatment of benign prostatic hyperplasia is initiated.

Effects on PSA and prostrate cancer detection.

No clinical benefit has been demonstrated in patients with prostrate cancer treated with **AURO FINASTERIDE** Digital rectal examinations as well as other evaluations for prostrate cancer are recommended prior to initiating therapy with **AURO FINASTERIDE** and periodically thereafter. Serum prostate- specific antigen (S-PSA) is also used for prostrate cancer detection. Generally a baseline S-PSA greater than 100 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 prostrate cancer.

AURO FINASTERIDE causes a decrease in S-PSA concentrations even in the presence of prostrate cancer (see "drug/laboratory test interactions"). The reduction of levels in patients with BPH treated with AURO FINASTERIDE should be considered when evaluating 5-PSA data and does not rule out concomitant prostrate cancer.

Patients treated with **AURO FINASTERIDE** who have a sustained increase in S-PSA levels should be carefully evaluated.

Drug Laboratory Test Interactions

Prostatic volume is correlated with patient's age whereas serum prostate serum 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 **AURO FINASTERIDE** (see "**precautions, prostate cancer**"). S-PSA levels decrease rapidly within the first months of therapy, after which time, S-PSA levels stabilize to a new baseline. The post- treatment baseline approximates half of the pre-treatments 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 **AURO FINASTERIDE** for six months or more, SPSA 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 prostrate cancer. Therefore, in men with BPH, S-PSA values within the normal reference

range, prostrate cancer should not be ruled out regardless of AURO FINASTERIDE treatment. The ability of S-PSA to distinguish between BPH and cancer is not adversely affected by treatment with **AURO FINASTERIDE**.

Laboratory test Findings

Considerations should be given to the fact that S-PSA levels are decreased in patients treated with **AURO FINASTERIDE** (see **"precautions'**) when S-PSA laboratory test determinations are evaluated.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF IT'S TREATMENT:

No specific treatment of over-dosage with **AURO FINASTERIDE** is recommended. Treatment is symptomatic and supportive.

IDENTIFICATION:

Blue coloured, circular, biconvex, beveled edged film-coated tablets debossed with E' on one side and '61' on the other side.

PRESENTATION:

Tablets are packed in a triple laminate, 250 micron white opaque PVC film laminated with 25 micron PE coated with 90 gsm PVdC and 25 microns Printed Aluminium foil with 7 gsm HSL. Each blister contains 10 tablets.

Pack size: 30's — Each carton contains 3 blister of 10 tablets each.

STORAGE INSTRUCTIONS:

Store below 30 °C. Protect from light.

Keep the tablets in the original packaging.

Women should not handle crushed or broken tablets when they are or may potentially be pregnant KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

AURO FINASTERIDE TABLET 5 mg: 41/21.12/1054

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

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