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**APPROVED PROFESSIONAL INFORMATION**

**SCHEDULING STATUS:** S4

**PROPRIETARY NAME AND DOSAGE FORM**

**PROFINA (Tablet)**

**COMPOSITION**

Each film-coated tablet contains Finasteride 5 mg

**PHARMACOLOGICAL CLASSIFICATION**

A21.12 Hormone inhibitors

**PHARMACOLOGICAL ACTION**

Finasteride is a synthetic 4-azasteroid 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 prostate gland and subsequent benign prostrate hyperplasia (BHP) is dependant upon the conversion of testosterone to DHT within the prostate. 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 <sup>14</sup>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**

**PROFINA** 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.
- Improve the symptoms associated with BPH.
- Decrease the incidence of the surgery including transurethral resection of the prostate (TURP) prostatectomy.

## **CONTRA-INDICATIONS:**

### **Hypersensitivity to any of the components of PROFINA:**

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

**PROFINA** - Risk to Male Foetus (see below)

**PROFINA** - is not indicated for use in women.

**PROFINA** - is not indicated for paediatric use.

## **WARNINGS:**

**PROFINA** 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 PROFINA 5mg - Risk to Male Foetus**” below).

It is not known whether **PROFINA** is excreted in breast milk.

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

## **INTERACTIONS:**

No interactions of clinical importance have been identified.

**PROFINA** 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**

**PROFINA** has been used concomitantly with ACE-inhibitors, paracetamol, acetylsalicylic acid, alpha-blockers, beta-blockers, calcium channel blockers, cardiac nitrates, diuretics, H<sub>2</sub> antagonists, HMG-CoA reductase inhibitors, nonsteroidal anti-inflammatory drugs (NSAIDs), quinolones and benzodiazepines with evidence of clinically significant adverse interactions.

## **PREGNANCY AND LACTATION:**

### **Use in Pregnant and lactating Mothers.**

**PROFINA** 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 dihydrotestosterone, these drugs, including **PROFINA**, may cause abnormalities of the external genitalia of a male foetus when administered to a pregnant women.

### **Lactation**

It is not known if **PROFINA** is excreted in human milk.

### **Exposure to **PROFINA** - (by pregnant women) - Risk to Male Foetus**

**PROFINA** 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 **PROFINA** because of the possibility of absorption of **PROFINA** and the subsequent potential risk to male foetus (see ‘Use in Pregnancy’)

In addition since **PROFINA** 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 **PROFINA** as compared to healthy subjects.

#### **Dosage in the Elderly**

No adjustments in dosage are required even though the elimination of **PROFINA 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 **PROFINA** 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 prostate cancer may be reduced in patients taking **PROFINA** such malignancies should be excluded before treatment of benign prostatic hyperplasia is initiated.

## Effects on PSA and prostate cancer detection.

No clinical benefit has been demonstrated in patients with prostate cancer treated with **PROFINA**. Digital rectal examinations as well as other evaluations for prostate cancer are recommended prior to initiating therapy with **PROFINA** and periodically thereafter. Serum prostate-specific antigen (S-PSA) is also used for prostate 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 prostate cancer.

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

Patients treated with **PROFINA** 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 **PROFINA** (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-treatment 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 **PROFINA** 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 prostate cancer. Therefore, in men with BPH, S-PSA values within the normal reference range, prostate cancer should not be ruled out regardless of PROFINA treatment. The ability of S-PSA to distinguish between BPH and cancer is not adversely affected by treatment with **PROFINA**.

### **Laboratory test Findings**

Considerations should be given to the fact that S-PSA levels are decreased in patients treated with **PROFINA** (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 **PROFINA** 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.

**Applicant/PHCR:** AUROGEN SOUTH AFRICA (PTY) LTD  
**Product proprietary name:** PROFINA 5 mg  
**Dosage form and strength:** TABLET, 5 mg Finasteride

Women should not handle crushed or broken tablets when they are or may potentially be pregnant

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

**PROFINA 5 mg:** 41/21.12/1055

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

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