APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.

- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

S4

PROFINA

Finasteride

1. WHAT PROFINA CONTAINS

The active substance is Finasteride

Each film-coated tablet contains Finasteride 5 mg.

The other ingredients are Lactose monohydrate, Microcrystalline cellulose, Sodium Starch Glycollate, Pregelatinised Starch, Docusate Sodium and Magnesium Stearate.

2. WHAT PROFINA IS USED FOR

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) and prostatectomy.

3. BEFORE YOU TAKE PROFINA

Do not take PROFINA:

- If you are hypersensitive (allergic) to Finasteride or any of the other ingredients of PROFINA
- The condition for which PROFINA is prescribed occurs ONLY in men. **WOMEN AND CHILDREN SHOULD NOT TAKE PROFINA.**

Take special care with PROFINA:

PROFINA is for the treatment of BPH in MEN only. Women who are or may potentially be pregnant must not use PROFINA. They should also not handle crushed or broken tablets of PROFINA. If the active ingredients in PROFINA are absorbed after oral use or through the skin by a woman who is pregnant with a male baby, it may cause the male baby to be born with abnormalities of the sex organs.

Pregnancy and Breast-feeding:

PROFINA is for use in MEN only.

Taking other medicines with PROFINA:

No interactions of clinical importance have been identified.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of PROFINA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE PROFINA

Always take **PROFINA** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **PROFINA** is too strong or too weak, talk to your doctor or pharmacist.

PROFINA should be swallowed whole with plenty of liquid and may be taken with or without meals.

If you take more PROFINA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take PROFINA:

Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

PROFINA can have 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 disorders

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

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF PROFINA

Store at or 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 THE REACH OF CHILDREN. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF PROFINA

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.

8. IDENTIFICATION OF PROFINA

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

9. REGISTRATION NUMBER/REFERENCE NUMBER

PROFINA 5 mg: 41/21.12/1055

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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