Patient Information Leaflet

Information for the Patient about

FINCAR 5 Tablets

Read all of this leaflet carefully before you start taking FINCAR 5:

- **Keep this leaflet; you may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **FINCAR 5 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.**

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

FINCAR 5 (Tablets)

WHAT FINCAR 5 TABLETS CONTAIN:

Each film-coated **FINCAR 5** tablet contains 5 mg finasteride.

Inactive ingredients include colloidal silicon dioxide, docusate sodium benzoate, lactose monohydrate, magnesium stearate, maize starch, opadry blue (containing FD & C blue/indigo carmine aluminium lake, hypromellose, macrogol, titanium dioxide), and sodium starch glycolate.

Contains lactose.

WHAT FINCAR 5 IS USED FOR:

FINCAR 5 belongs to a class of medicines called hormone inhibitors. **FINCAR 5** is used to treat the symptoms of an enlarged prostate gland to:

- Improve the flow of urine and to improve the symptoms associated with benign prostatic hyperplasia (BPH – enlarged prostate gland) by causing regression (shrinkage) of the enlarged prostate.
- Reduce the incidence of acute urinary retention (inability to pass urine).
- Reduce the incidence of surgery, including transurethral resection of the prostate (TURP) and prostatectomy (removal of the prostate gland).

BEFORE YOU TAKE FINCAR 5:

Do NOT take FINCAR 5 if you:

- Are known with hypersensitivity (allergy) to finasteride, or to any of the inactive ingredients in the formulation.
- Are pregnant or breastfeeding your baby (see **"Pregnancy and breastfeeding"**).
- Are female or a child.

Take special care with FINCAR 5:

Women who are or may potentially be pregnant, must not use **FINCAR 5**, as it may cause abnormalities of the external genitals of a developing male baby (see **"Do NOT take FINCAR 5 if you"** and **"Pregnancy and breastfeeding"**). It is not known if **FINCAR 5** is excreted in breast milk.

Your doctor will decide whether you qualify for treatment with **FINCAR 5** based on the results of a physical evaluation and digital rectal examination. You may have to go for a cystoscopy (examination of the prostate with a scope).

Please inform your doctor if you have been diagnosed with decreased liver function or liver disease.

If you are scheduled to undergo a blood test to determine your blood levels of prostate-specific antigen (PSA), please inform your doctor that you are taking **FINCAR 5**.

There have been reports of breast cancer in men who took finasteride, as contained in **FINCAR 5**. You should report to your doctor as soon as possible if you notice any changes in your breast tissue, such as lumps, pain, breast enlargement or nipple discharge (see **"POSSIBLE SIDE-EFFECTS"**).

Taking FINCAR 5 with food and drink:

FINCAR 5 can be taken without regard to meals (see **"HOW TO TAKE FINCAR 5"**).

Pregnancy and breastfeeding:

Do NOT take **FINCAR 5** while you are pregnant or breastfeeding your baby (see **"Do NOT take FINCAR 5 if you"**). **FINCAR 5** may cause abnormalities of the external genitals of a developing male baby when taken by a pregnant woman.

The safety of **FINCAR 5** during breastfeeding has not been established.

Exposure to **FINCAR 5** *(by pregnant women) - Risk to male foetus:*

FINCAR 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.

If you are pregnant, you should not handle crushed or broken **FINCAR 5** tablets because of the possibility of absorption of **FINCAR 5** and the potential risk to a developing male baby.

In addition, since **FINCAR 5** is present in semen, your male partner should wear a condom during intercourse.

If you are pregnant or breastfeeding your baby and inadvertently took FINCAR 5, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving or using machinery:

It is unlikely that **FINCAR 5** will influence your ability to drive or use machines.

Important information about some of the ingredients in FINCAR 5:

FINCAR 5 contains lactose. If you have been diagnosed with hereditary galactose intolerance, glucose-galactose malabsorption, or the Lapp lactase deficiency, you should not take **FINCAR 5**. Please discuss this with your doctor if you are unsure.

Taking FINCAR 5 with other medicines:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of FINCAR 5 with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO TAKE FINCAR 5:

Always take FINCAR 5 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with others.

The recommended dosage is one 5 mg tablet daily. The tablet should be swallowed whole and must not be divided or crushed.

FINCAR 5 may be taken with or without food. In general, daily use for 6 – 12 months may be required to assess whether a beneficial response has been achieved.

Dosage in kidney impairment:

No adjustments in dosage is required.

Dosage in the elderly:

No dose adjustments needed; however, speak to your doctor if you are older than 70 years of age.

If you have the impression that the effect of **FINCAR 5** is too strong or too weak, please discuss this with your doctor or pharmacist.

If you take more FINCAR 5 than you should:

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience side-effects such as listed below (see **"POSSIBLE SIDE-EFFECTS"**).

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

If you forget to take FINCAR 5:

Always take **FINCAR 5** as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule of one tablet once daily (every 24 hours). Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

FINCAR 5 may have side-effects.

Not all side-effects reported for FINCAR 5 are included in this leaflet. Should your general health worsen while taking FINCAR 5, please consult your doctor, pharmacist or other healthcare professional for advice.

The most frequent adverse effects are impotence and reduced libido. These effects usually occur at the beginning of the treatment and in the majority of patients, are of a transient nature on continued treatment.

Serious side-effects that you, or a family member, should report to your doctor as a matter of urgency include:

- Those that occur with unknown frequency:
    - Allergic reactions including hives, itching, and swelling of the face, lips, tongue, or whole body.

Other side-effects that you should report to your doctor as soon as possible:

- Those that occur less frequently:
    - Breast tenderness, breast enlargement, breast secretion, breast nodules (see **"Take special care with FINCAR 5"**).

Side-effects that you should report to your doctor if they continue or become bothersome include:

- Those that occur frequently:
    - Decreased libido.
    - Impotence.
- Those that occur less frequently:
    - Ejaculation disorder.
- Those that occur with unknown frequency:
    - Drowsiness.
    - Palpitations.

- Testicular pain.

Please tell your doctor or pharmacist of any other undesirable effects that you think may be due to taking **FINCAR 5**, especially if not mentioned in this leaflet.

STORAGE AND DISPOSING OF FINCAR 5:

STORE THIS MEDICINE OUT OF REACH AND SIGHT OF CHILDREN.

Store at or below 25 ºC. Protect from light.

Keep blisters in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF FINCAR 5:

PVC/PVDC aluminium foil blister strips of 10 tablets, packed in 30's.

IDENTIFICATION OF FINCAR 5:

Light blue circular, biconvex, film-coated tablets plain on both sides.

REGISTRATION NUMBER:

41/21.12/0422

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

CIPLA MEDPRO (PTY) LTD

Rosen Heights

Pasita Street

Rosen Park

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7530

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