Proposed Amended Patient Information Leaflet

Information for the Patient about

FINPECIA Tablets

Read all of this leaflet carefully before you start taking FINPECIA:

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

FINPECIA (Tablets)

WHAT FINPECIA TABLETS CONTAIN:

Each film-coated **FINPECIA** tablet contains 1 mg finasteride.

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

Contains lactose.

WHAT FINPECIA IS USED FOR:

FINPECIA belongs to a class of medicines called hormone inhibitors. **FINPECIA** is used to temporarily delay further hair loss and increase hair density in the crown and front mid scalp area in men (between 18 and 41 years) with early signs of androgenetic alopecia (male pattern baldness).

BEFORE YOU USE FINPECIA:

Do NOT take FINPECIA 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.
- Are female or a child under the age of 18 years.
- Are taking finasteride 5 mg, or any other 5α-reductase inhibitors for an enlarged prostate gland (benign prostatic hyperplasia or BPH) or any other condition.

Take special care with FINPECIA:

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

Exposure to **FINPECIA** *(by pregnant women) - Risk to a developing baby boy:*

FINPECIA 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 **FINPECIA** tablets because of the possibility of absorption of **FINPECIA** and the potential risk to a developing male baby.

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

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 **FINPECIA**.

You may experience decreased libido, erectile dysfunction and decreased volume of ejaculate while taking **FINPECIA** (see **"POSSIBLE SIDE-EFFECTS"**). Resolution of these side-effects occurred in men who stopped therapy with **FINPECIA**, and in many who continued therapy.

Persistence of erectile dysfunction after stopping treatment has been reported during post-marketing use of **FINPECIA**. Please discuss this with your treating doctor.

There have been reports of breast cancer in men who took finasteride, as contained in **FINPECIA**. 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"**).

Please inform your doctor that you are taking **FINPECIA** if you and your partner are scheduled for infertility treatment or if you have been diagnosed with poor semen quality. Normalisation or improvement of semen quality has been reported after **FINPECIA** was stopped.

Taking FINPECIA with food and drink:

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

Pregnancy and breastfeeding:

Women must NOT take **FINPECIA** (see **"Do NOT take FINPECIA if you"** and **"Take special care with FINPECIA"**). **FINPECIA** may cause abnormalities of the external genitals of a developing male baby when taken by a pregnant woman.

The safety of **FINPECIA** during breastfeeding has not been established.

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

Driving or using machinery:

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

Important information about some of the ingredients in FINPECIA:

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

Taking FINPECIA with other medicines:

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

There is no information on the combined use of **FINPECIA** and topical minoxidil.

HOW TO TAKE FINPECIA:

Always take FINPECIA 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 1 mg tablet daily.

There is no evidence that an increase in dosage will result in increased hair growth.

Your progress will continuously be assessed by your doctor.

In general, daily use for 3 to 6 months is necessary before increased hair growth and/or prevention of further hair loss is observed. Continued use is recommended to obtain maximum benefit. Withdrawal of treatment leads to reversibility of effect by 6 months and return to the original state by 9 to 12 months.

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

If you take more FINPECIA 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 FINPECIA:

Always take **FINPECIA** 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:

FINPECIA may have side-effects.

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

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 rash, hives, itching, and swelling of the lips and face.

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

- Those that occur with unknown frequency:
    - Breast tenderness, breast enlargement (see **"Take special care with FINPECIA"**).

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

- Those that occur frequently:
    - Impotence.
- Those that occur less frequently:
    - Decreased libido.
    - Ejaculation disorders.
    - Erectile dysfunction.

- Those that occur with unknown frequency:
    - Testicular pain.
    - Palpitations.

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

STORAGE AND DISPOSING OF FINPECIA:

STORE THIS MEDICINE OUT OF REACH OF CHILDREN.

Store at or below 25 °C. Protect from light and moisture.

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 FINPECIA:

FINPECIA tablets are packed as 30's in white coloured, opaque HDPE 60 cc bottles with 38 mm screw caps and in blister packs of 30 tablets.

IDENTIFICATION OF FINPECIA:

Reddish brown coloured, circular, biconvex, film-coated tablets plain on both sides.

REGISTRATION NUMBER:

41/21.12/0221

NAME AND BUSINESS ADDRESS OF THE HOLDER CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

Rosen Heights

Pasita Street

Rosen Park

Bellville

7530

DATE OF PUBLICATION OF THIS PATIENT LEAFLET:

October 2007

Revised: August 2012