Patient information leaflet for FINIDE 5 TABLETS

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

FINIDE 5 TABLETS film-coated tablet

Read all of this leaflet carefully before you start taking FINIDE 5 TABLETS.

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

1. WHAT FINIDE 5 TABLETS CONTAINS

The active substance per film coated tablet is 5 mg finasteride.

The other ingredients are docusate sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry Blue [FD&C Blue No. 2/Indigo carmine aluminium lake (colourant), hypromellose, hydroxypropyl cellulose, iron oxide yellow (colourant), talc, titanium dioxide (colourant)], pregelatinised starch, sodium starch glycolate.
Contains sugar (lactose monohydrate).

2. WHAT FINIDE 5 TABLETS IS USED FOR

FINIDE 5 TABLETS is used to shrink the prostate gland in men when it is swollen. A swollen prostate gland can lead to a condition called benign prostatic hyperplasia (BPH). A swollen prostate gland can press on the tube that passes urine out of your body and cause symptoms such as feeling like you need to pass urine more often, especially at night, feeling you must pass urine right away, finding it difficult to start passing urine and feeling that you cannot empty your bladder completely. FINIDE 5 TABLETS is used to improve the flow of urine out of your body.

3. BEFORE YOU TAKE FINIDE 5 TABLETS

Do not take FINIDE 5 TABLETS:

- If you are hypersensitive (allergic) to finasteride or any of the other ingredients of FINIDE 5 TABLETS (see WHAT FINIDE 5 TABLETS CONTAINS).
- If you are pregnant or breastfeeding (see Pregnancy and breastfeeding).
- If you are a woman.
- FINIDE 5 TABLETS should not be given to children.

Take special care with FINIDE 5 TABLETS:

- If your partner is pregnant or planning to become pregnant. You should use a condom or other method of contraception when taking FINIDE 5 TABLETS. Your semen could contain a tiny amount of finasteride, the active ingredient in FINIDE 5 TABLETS and may affect the normal development of a male baby's sex organs.
- Before you start taking FINIDE 5 TABLETS, your doctor will do some tests to check whether you have prostate cancer. You should see your doctor regularly and continue checking for prostate cancer while taking FINIDE 5 TABLETS.
- If you are going to have a blood test called serum prostate specific antigen (S-PSA). Tell your doctor that you are taking FINIDE 5 TABLETS, as it can affect the S-PSA blood test results.
- If you have severe problems with passing urine, your doctor may need to monitor you when you start taking FINIDE 5 TABLETS.

Taking FINIDE 5 TABLETS with food and drink:

FINIDE 5 TABLETS can be taken with or without food.

Pregnancy and breastfeeding:

FINIDE 5 TABLETS should not be taken by women (see Do not take FINIDE 5 TABLETS).

Do not take FINIDE 5 TABLETS if you are pregnant, planning to become pregnant or breastfeeding your baby (see Do not take FINIDE 5 TABLETS).

Do not touch crushed or broken FINIDE 5 TABLETS if you are a woman who is pregnant or planning to become pregnant. The whole tablet is coated to prevent contact with the active ingredient in FINIDE 5 TABLETS during normal handling.

FINIDE 5 TABLETS may affect the normal development of your baby's sex organs. If you are a pregnant woman and had contact with crushed or broken FINIDE 5 TABLETS, speak to your doctor immediately.

Driving and using machinery:

FINIDE 5 TABLETS may cause dizziness and can affect your ability to drive a vehicle and use machines (see POSSIBLE SIDE EFFECTS). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how FINIDE 5 TABLETS affects you.

Important information about some of the ingredients of FINIDE 5 TABLETS:

FINIDE 5 TABLETS contains lactose. Patients with rare hereditary conditions of lactose or galactose intolerance should not take FINIDE 5 TABLETS.

Taking other medicines with FINIDE 5 TABLETS:

Always tell your health care professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE FINIDE 5 TABLETS

Do not share medicines prescribed for you with any other person.

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

Do not crush or break FINIDE 5 TABLETS.

Adults:

Take one tablet every day.

You may have to take FINIDE 5 TABLETS for several months to achieve the best result from the treatment.

Your doctor will tell you how long your treatment with FINIDE 5 TABLETS will last. Do not stop your treatment early.

If you have the impression that the effect of FINIDE 5 TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more FINIDE 5 TABLETS than you should:

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining FINIDE 5 TABLETS with you, so the doctor will know what you have taken.

If you forget to take FINIDE 5 TABLETS:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next scheduled dose, skip the missed dose and take FINIDE 5 TABLETS at the next regularly scheduled time. Do not take a double dose of FINIDE 5 TABLETS to make up for the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

FINIDE 5 TABLETS can have side effects. Not all side effects reported for FINIDE 5 TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FINIDE 5 TABLETS, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking FINIDE 5 TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FINIDE 5 TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequency unknown:

- Breast cancer in men (painless lumps or thickening of your breast tissue, changes to the skin covering your breast, such as dimpling, puckering, redness or scaling, changes to your nipple or a discharge from your nipple).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Impotence (the inability to get or keep an erection).
- Loss of sex drive.
- Decrease in the amount of semen released during sex.

Less frequent:

- Headache, dizziness.
- Stomach pain, diarrhoea.
- Back pain.
- Breast tenderness.
- Pain in your testicles.

Frequency unknown:

- Swelling of your breasts.
- Feeling depressed.
- Male infertility and/or poor quality of semen. Improvement in the quality of the semen has been reported after stopping FINIDE 5 TABLETS.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF FINIDE 5 TABLETS

- Store at or below 25 °C.
- Protect from light and moisture.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the tablets after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF FINIDE 5 TABLETS

Packed in white opaque PVC/PVDC / aluminium foil blister strips of 1 x 14 tablets or 2 x 14 tablets inside an outer cardboard box.

8. IDENTIFICATION OF FINIDE 5 TABLETS

Blue coloured, round, biconvex film coated tablet with a plain surface on both sides. The tablet should be free of all physical defects.

9. REGISTRATION NUMBER

42/21.12/0461

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Zydus Healthcare S.A. (Pty) Ltd

Southdowns Office Park, Building B, Ground Floor

22 Karee Street, Centurion

Pretoria 0157

Tel: 012 748 6400

11. DATE OF PUBLICATION

Date of registration: 18 May 2012

Date of revised patient information leaflet: 25 May 2020