

## **Package leaflet: Information for the user**

### **Finasteride 1mg film-coated tablets**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Finasteride is and what it is used for
2. What you need to know before you take Finasteride
3. How to take Finasteride
4. Possible side effects
5. How to store Finasteride
6. Contents of the pack and other information

#### **1. What Finasteride is and what it is used for**

Finasteride 1mg film-coated tablets contain the active substance finasteride.

Finasteride 1mg film-coated tablets are for use in men only.

Finasteride is used for the treatment of male pattern hair loss (also known as androgenetic alopecia) in men aged 18-41. If after reading this leaflet, you have any questions about male pattern hair loss, ask your doctor.

Male pattern hair loss is a common condition thought to be caused by a combination of genetic factors and a particular hormone called dihydrotestosterone (DHT). DHT contributes to shortening of the growth phase of the hair and to thinning of the hair.

In the scalp, Finasteride specifically lowers levels of DHT by blocking an enzyme (Type II 5-alpha reductase) that converts testosterone to DHT. Only men with mild to moderate, but not complete hair loss, can expect to benefit from the use of Finasteride. In most of the men treated with finasteride for 5 years, the progression of hair loss was slowed, and at least half of these men also had some kind of improved hair growth.

#### **2. What you need to know before you take Finasteride**

##### **Do not use Finasteride if you:**

- Are a woman (because this medicine is for men, see section ‘Pregnancy, breast-feeding and fertility’). It has been shown in clinical trials that finasteride does not work in women with hair loss.
- Are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6).

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Finasteride

#### Effects on Prostate Specific Antigen (PSA)

Finasteride can affect a blood test called PSA (Prostate-Specific Antigen) for the screening of prostate cancer. If you have a PSA test done, you should tell your doctor or pharmacist that you are taking Finasteride because Finasteride decreases PSA levels.

#### Effects on fertility

Infertility has been reported in men who took finasteride for a long time and had other risk factors that may affect fertility. Normalisation or improvement of seminal quality has been reported after discontinuation of finasteride. Long-term clinical studies about the effect of finasteride on fertility in men have not been conducted.

#### Breast cancer

See section 4.

#### Mood alterations and depression

Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with Finasteride. If you experience any of these symptoms stop taking Finasteride and contact your doctor for further medical advice as soon as possible.

Impaired sexual function that may contribute to mood alterations, including suicidal thoughts, has been reported in some patients. If you experience symptoms of impaired sexual function, contact your doctor for further medical advice. Your doctor may consider stopping the treatment (see section 4 below for more information about these side effects).

A patient card reminding of the above is provided with the package of Finasteride 1mg film-coated tablets.

#### **Children and adolescents**

Finasteride should not be used in children. There are no data demonstrating efficacy or safety of finasteride in children under the age of 18.

#### **Other medicines and Finasteride**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

#### **Pregnancy, breast-feeding and fertility**

Finasteride is for the treatment of male pattern hair loss in men only. For effects on fertility in men see section 2.

- **Women must not use Finasteride due to the risk in pregnancy**
- **Do not touch crushed or broken tablets of Finasteride if you are a woman who is pregnant or may potentially be pregnant.**
- If the active substance in Finasteride is absorbed after oral use or through the skin by a woman who is pregnant with a male baby, this may cause the male baby to be born with abnormalities of the sex organs.
- If a woman who is pregnant comes into contact with the active substance in Finasteride, a doctor should be consulted.
- Finasteride tablets are coated and will prevent contact with the active substance during normal use

If you have any questions, ask your doctor.

#### **Driving and using machines**

There are no data indicating that Finasteride affects your ability to drive or operate machinery.

#### **Finasteride contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

#### **Sodium content**

This medicine contains less than 1 mmol sodium (23mg) per film-coated tablet, that is to say essentially

'sodium-free'.

### 3. How to take Finasteride

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet each day. The tablet can be taken with or without food.

Your doctor will help you determine if Finasteride is working for you. It is important to take Finasteride for as long as your doctor prescribes it. Finasteride can only work over long term if you continue taking it.

#### **If you take more Finasteride than you should**

If you take too many tablets by mistake, talk to your doctor promptly. Finasteride will not work faster or better if you take it more than once a day.

#### **If you forget to take Finasteride**

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

#### **If you stop taking Finasteride**

It may take 3 to 6 months for the full effect to develop. It is important to keep taking Finasteride for as long as your doctor tells you. If you stop taking Finasteride, you are likely to lose the hair you have gained within 9 to 12 months.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects have usually been temporary with continued treatment or disappeared when treatment is stopped.

#### **Stop taking Finasteride and talk to your doctor if you have any of the following symptoms:**

- Swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties.
- Suicidal thoughts.

You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement or nipple discharge as these may be signs of a serious condition, such as breast cancer.

#### **Uncommon** (may affect up to 1 in 100 people):

- Less desire to have sex
- Difficulty having an erection
- Problems with ejaculation such as a decrease in the amount of semen released
- depression

#### **Not known** (frequency cannot be estimated from the available data):

- allergic reactions such as rash and itching
- breast swelling or tenderness
- pain in the testicles
- blood in the semen
- fast heartbeat
- persistent difficulty having an erection after discontinuation of treatment
- persistent decrease in sex drive after discontinuation of treatment
- persistent problems with ejaculation after discontinuation of treatment
- male infertility and/or poor quality of semen
- elevated liver enzymes

- anxiety
- suicidal thoughts

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Finasteride**

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Finasteride contains**

The active substance is finasteride. Each film-coated tablet contains 1mg finasteride.

The other ingredients are:

- Tablet core: lactose monohydrate, maize starch pregelatinised, docusate sodium, iron oxide yellow (E172), sodium starch glycolate (type A), cellulose microcrystalline, silica colloidal anhydrous, magnesium stearate, water purified.
- Tablet coating: hydroxypropyl cellulose, Hypromellose, talc, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172).

#### **What Finasteride looks like and contents of the pack**

Finasteride tablets are round biconvex red film-coated tablets with a 6.5 mm nominal diameter.

Finasteride film-coated tablets are available in white PVC/PE/PVDC/Aluminium and/or Aluminium blisters. The blisters are packed in cardboard boxes containing 14, 20, 28, 30, 50, 60 or 100 film-coated tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

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#### **Manufacturer**

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