

## Package leaflet: Information for the user

### Finasteride 1 mg film-coated tablets finasteride

**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, pharmacist or nurse.
- 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 contains the active substance finasteride.

##### **Finasteride 1 mg is for use in men only.**

Finasteride 1mg 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 1mg specifically lowers the 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 1mg. In most of the men treated with Finasteride 1 mg for 5 years, the progression of hair loss was temporarily 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 take Finasteride**

- if you are a woman (because this medicine is for men only, see pregnancy). It has been shown in clinical trials that finasteride 1 mg does not work in women with hair loss.
- if you are allergic (hypersensitive) 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 1 mg.

##### **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 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 1mg. If you experience any of these symptoms stop taking Finasteride 1 mg and contact your doctor for further medical advice as soon as possible.

### **Children and adolescents**

Finasteride 1mg 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 1 mg 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 1mg 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 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 Finasteride, a doctor should be consulted.
- Finasteride tablets are coated and will prevent contact with the active ingredient during normal use.

If you have questions, ask your doctor.

### **Driving and using machines**

There are no data indicating that Finasteride 1 mg affects your ability to drive or operate machinery.

### **Finasteride contains lactose**

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

### **Finasteride contains sodium**

This medicine contains less than 1 mmol sodium (23mg) per film-coated tablet, that is so 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 to determine if Finasteride is working for you. It is important to take Finasteride for as long as your doctor prescribes Finasteride 1mg. Finasteride 1 mg can only work over the 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 forgot to take Finasteride**

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

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

It may take three to six months for the full effect to develop. It is important to keep taking Finasteride 1mg as long as your doctor tells you. If you stop taking Finasteride, you are likely to lose the hair you have gained within the next 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 and disappeared when treatment is stopped.

Stop taking Finasteride and talk to your doctor immediately 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.

You should promptly report to your doctor any changes in the breast tissue such as lumps, pain, enlargement of the breast 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:**

- difficulty having an erection
- less desire to have sex
- 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 sperm
- 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

#### **Reporting of side effects**

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

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 the sight and reach of children.

This medicinal product does not require any special storage conditions.

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

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. One film-coated tablet contains 1 mg of finasteride.
- The other ingredients are:  
Tablet core: lactose monohydrate, microcrystalline cellulose, starch pregelatinized, sodium starch glycolate, docusate sodium, magnesium stearate.  
Film coating: hypromellose (E464), titanium dioxide (E171), talc, iron oxide yellow (E172), iron oxide red (E172).

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

Film-coated tablet.

Brown coloured, round film coated tablets, debossed with 'H' on one side and '36' on the other side.

Finasteride tablets are available in blister packs containing 28, 84 or 98 film-coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder

Amarox Limited  
Congress House  
14 Lyon Road  
Harrow, Middlesex HA1  
2EN United Kingdom

#### Manufacturer

Pharmadox Healthcare Ltd.  
KW20A Kordin Industrial Park, Paola, PLA 3000  
Malta

or

Amarox Limited  
Congress House  
14 Lyon Road Harrow,  
Middlesex HA1 2EN  
United Kingdom

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Germany: Finasterid Amarox 1 mg Filmtabletten  
France: Finasteride Amarox 1 mg comprimé pelliculé  
Spain: Finasterida Tarbis 1 mg comprimidos recubiertos con película EFG  
Italy: Finasterida Amarox  
Portugal: Finasterida Amarox  
United Kingdom: Finasteride 1 mg film-coated tablets

**This leaflet was last revised in 09/2021.**