

## 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 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 or pharmacist. 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 belongs to a group of medicines called 5-alpha reductase inhibitors. It can be used to treat male pattern hair loss in men.

Your doctor has prescribed Finasteride because you have male pattern hair loss (also known as androgenetic alopecia). Finasteride prevents further hair loss in men. Men with mild to moderate, but not complete hair loss, can benefit from using Finasteride . Finasteride block an important enzyme (Type II 5 $\alpha$ -reductase), which is involved in the regulation of the hair follicle.

In the scalp, finasteride specifically lower the levels of DHT, a major cause of male pattern hair loss. In this way, finasteride help to reverse the balding process and prevent further hair loss.

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

##### **Do not take Finasteride:**

- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6).
- if you are a child or adolescent.
- if you are female (also see ‘Pregnancy and breast-feeding’). Finasteride has been found to be ineffective in the treatment of hair loss (androgenetic alopecia) in women in clinical studies.
- if you are already taking finasteride or any other 5 $\alpha$ -reductase inhibitor (e.g. dutasteride) for an enlargement of the prostate gland (benign prostatic hyperplasia (BPH)) or any other condition.

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Finasteride:  
if you are planning to have a baby (father a child), as this medicine may affect male fertility or sexual activity (see “Fertility” section later in the leaflet).

### **During treatment**

This medicine may affect the results of a blood test used to detect changes in the prostate, including the development of prostate cancer. If you are due to have a blood test, remind your doctor, nurse or hospital staff that you are taking this medicine.

Finasteride has also been reported to increase the risk of changes in the chest (breasts) of men taking this medicine. You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer.

### **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 this medicine and contact your doctor for further medical advice as soon as possible.

### **Children and adolescents**

Do not give this medicine to children and adolescents aged less than 18 years

### **Other medicines and Finasteride**

Finasteride does not usually interfere with other medicines. But tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those obtained without a prescription.

No information is available on the use of finasteride together with topical (applied to the skin) minoxidil in male pattern hair loss. The combination is not recommended.

### **Pregnancy**

Finasteride is only intended for men. If taken by a woman during pregnancy, it can affect the normal development of a male baby’s sex organs. Crushed or broken tablets should not be handled by a pregnant woman because of the risk of finasteride being absorbed in the body.

Finasteride has also been found in the semen of men taking finasteride. If your sexual partner is pregnant or thinks she may be pregnant, you must use a condom to avoid exposing her to your semen, which may contain finasteride. If you have any questions, ask your doctor.

### **Fertility**

If you are planning to have a baby (father a child), talk to your doctor or pharmacist before taking finasteride, as this medicine may affect male fertility or sexual activity. See section 4 “Possible side effects” later in the leaflet for more information on side effects that may affect you.

### **Breast-feeding**

Finasteride is not prescribed for women. It is not known if it can pass into breast milk.

### **Driving and using machines**

Finasteride should not affect your ability to drive or use machines.

### **Finasteride contains lactose monohydrate.**

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

### **Finasteride contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per one 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:

### **Adults**

Swallow one tablet daily, with or without food.

It may take up to six months before some patients notice an improvement. Long-term use is recommended. If treatment is stopped, the beneficial effect starts to disappear after 6 months and completely disappears after 9-12 months.

Taking more than one tablet a day will not make your medicine work better.

### **Patients with liver problems**

There is no experience of the use of finasteride in patients with liver problems.

### **Patients with kidney problems**

No dosage adjustment is required in patients with kidney problems.

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

If you take more Finasteride than you should tell your doctor or go to your nearest hospital emergency department. Take the container and any remaining tablets with you.

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

If you forget to take Finasteride do not take a double dose to make up for a forgotten dose. Take the next dose on time.

## **If you stop taking Finasteride**

If you stop taking Finasteride you are likely to lose the hair you have gained within the following 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. Some of these side effects have usually been temporary with continued treatment or disappeared when treatment is stopped.

The following side effects are important and will require immediate action if you experience them.

**Stop taking this medicine and talk to your doctor immediately or go to the nearest hospital emergency department if you have any of the following symptoms:**

- **swelling of your face, lips, tongue or throat**
- **difficulty swallowing**
- **skin rash, itching, lumps under your skin (hives)**
- **breathing difficulties**

**If you notice any of the following, talk to your doctor straight away:**

- **lumps, pain, enlargement of the breast (chest) tissue or nipple discharge. These may be signs of a serious condition, such as breast cancer.**

The following other side effects have been reported:

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

- decreased sexual drive
- erectile dysfunction
- problems with ejaculation, such as a decreased volume of ejaculation
- depression

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

- pain in the testicles
- blood in semen
- fast heartbeat
- persistent difficulty having an erection after discontinuation of treatment
- 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.
- changes in the way your liver is working, which can be shown by a blood test
- 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). 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.

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

Store in the original package in order to protect from light.

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 1mg of Finasteride
- The other ingredients are docusate sodium, magnesium stearate, microcrystalline cellulose, lactose monohydrate, pregelatinised maize starch, sodium starch glycollate, povidone. The tablet coating contains red and yellow iron oxides (E172), titanium dioxide (E171), hypromellose, talc and hydroxypropylcellulose.

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

Your medicine comes as a brown coated tablet available in blister packs of 7, 14, 28, 30, 60, 84, 90 and 98 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Mylan  
Potters Bar  
Hertfordshire  
EN6 1TL  
United Kingdom

### **Manufacturer**

Gerard Laboratories  
35/36 Baldoyle Industrial Estate  
Grange Road, Dublin 13  
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