

## Package leaflet: Information for the user

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

### 1. What /.../ is and what it is used for

/.../ contains a medicine called finasteride. This belongs to a group of medicines called ‘5-alpha reductase inhibitors’.

/.../ shrinks the prostate gland in men when it is swollen.

The prostate gland is found underneath the bladder (but only in men). It produces the fluid found in semen.

A swollen prostate gland can lead to a condition called ‘benign prostatic hyperplasia’ or BPH.

### What is BPH?

If you have BPH it means that your prostate gland is swollen. It can press on the tube that urine passes through, on its way out of your body.

This can lead to problems such as:

- feeling like you need to pass urine more often, especially at night
- feeling that you must pass urine right away
- finding it difficult to start passing urine
- when you pass urine the flow of urine is weak
- when you pass urine the flow stops and starts
- feeling that you cannot empty your bladder completely

In some men, BPH can lead to more serious problems, such as:

- urinary tract infections
- a sudden inability to pass urine
- the need for surgery

### **What else should you know about BPH?**

- BPH is not cancer and does not lead to cancer, but the two conditions can be present at the same time.
- Before you start /.../, your doctor will do some simple tests to check whether you have prostate cancer.

Talk to your doctor if you have any questions about this.

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

### **Do not take /.../:**

- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman (because this medicine is for men)).

### **Warnings and precautions**

Talk to your doctor or pharmacist se before taking /.../.

- If your partner is pregnant or planning to become pregnant. You should use a condom or other barrier method of contraception when taking /.../. This is because your semen could contain a tiny amount of the drug and may affect the normal development of the baby's sex organs.
- If you are going to have a blood test called PSA. This is because /.../ can affect the results of this test.

### **Mood alterations and depression**

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

If you are not sure, talk to your doctor or pharmacist before taking /.../.

### **Children**

/.../ should not be used in children.

### **Other medicines and /.../**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. /.../ (finasteride) does not usually interfere with other medicines.

### **/.../ with food and drink**

/.../ can be taken with or without food.

### **Pregnancy and breast-feeding**

/.../ should not be taken by women.

- Do not touch crushed or broken /.../ tablets if you are a woman who is pregnant or planning to become pregnant (whole tablets are coated to stop contact with the medicine during normal use). This is because this medicine may affect the normal development of the baby's sex organs.
- If a woman who is pregnant comes into contact with crushed or broken /.../ tablets, speak to your doctor.

### **Driving and using machines**

/.../ is not likely to affect you being able to drive, use tools or machine.

### **/.../ 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.

### 3. How to take /.../

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

#### Taking this medicine

- The recommended dose is one tablet daily.
- The tablets can be taken with or without food. The tablets should be swallowed whole and should not be divided or crushed.

#### If you take more /.../ than you should

If you have taken more tablets than you were told to, or if someone else has taken any tablets, contact accident and emergency department of your nearest hospital. Take any left over tablets or empty box with you for easier identification.

#### If you forget to take /.../

- If you forget to take a tablet, skip the missed dose.
- Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

#### If you stop taking /.../

Your condition may show an early improvement after taking /.../. However, it may take at least six months for the full effect to develop. It is important to keep taking /.../ for as long as your doctor tells you, even if you do not feel any benefit straight away.

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.

For the assessment of side effects, the following descriptions of frequency have been used:

Very common – occur in more than 1 in 10 patients

Common – occur in more than 1 in 100 patients, but in less than 1 in 10 patients

Uncommon – occur in less than 1 in 100 patients, but in more than 1 in 1000 patients

Rare – occur in less than 1 in 1000 patients, but in more than 1 in 10000 patients

Very rare – occur in less than 1 in 10000 patients, including isolated reports

The most common side effects are impotence and decreased sexual drive. These effects normally occur at the start of the treatment but do not usually last long in the majority of patients if treatment continues.

Finasteride may affect the result of PSA-laboratory test.

Type of disorder	Frequency	Side effect
Investigations	common	decreased volume of ejaculate
Cardiac disorder	unknown	palpitation
Skin and subcutaneous tissues disorders	uncommon	rash
	unknown	pruritus, urticaria
Immune system disorders	unknown	hypersensitivity reactions including swelling of the lips and face

Hepatobiliary disorders	unknown	increased hepatic enzymes
Reproductive system and breast disorders	common	impotence
	uncommon	ejaculation disorder, breast tenderness, breast enlargement
	unknown	testicular pain, erectile dysfunction which may continue after discontinuation of treatment; male infertility and/or poor seminal quality. Normalization or improvement of seminal quality has been reported after discontinuation of finasteride.
Psychiatric disorders	common	decreased libido
	unknown	depression, 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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store /.../

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 /.../ contains

The active substance is finasteride. One film-coated tablet contains 5 mg of finasteride.

The other ingredients are:

Tablet core: lactose monohydrate, microcrystalline cellulose, starch pregelatinized (maize), sodium starch glycolate (type A), docusate sodium, magnesium stearate.

Film coating: hypromellose (E464), titanium dioxide (E171), indigo carmine aluminum lake (E132), talc, iron oxide yellow (E172).

#### What /.../ looks like and contents of the pack

Blue colour, round film coated tablets, debossed with 'H' on one side and '37' on the other side packed in Al/Al blisters.

Pack sizes: 7, 10, 14, 15, 20, 28, 30, 49, 50, 56, 60, 84, 90, 98, 100, 112, 120, 250, 300, 500 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

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

<To be completed nationally>

**This leaflet was last revised in MM/YYYY.**