

Finasteride 5 mg Film-coated Tablets

Package leaflet: Information for the user

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 effect 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 belongs to a group of medicines called 5-alpha reductase inhibitors. They act by reducing the size of the prostate gland in men.

Finasteride is used in the treatment and control of benign enlargement of the prostate (benign prostatic hyperplasia – BPH). It causes regression of the enlarged prostate, improves urinary flow and symptoms caused by BPH, and reduces the risk of acute urinary retention and the need for surgery.

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)
- are a woman (see also under "Pregnancy and breast-feeding")
- are a child.

Warnings and precautions

Talk to your doctor or pharmacist before taking Finasteride:

- If you have a large amount of residual urine and/or severely reduced urinary flow. If this is the case, you should be closely monitored for narrowing of the urinary tract.
- If you have a reduced liver function. The finasteride plasma level may be increased in these patients.

Speak to your doctor if any of the above applies to you now or in the past.

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.

A clinical examination (including digital rectal examination) and a determination of prostate-specific-antigen (PSA) in serum should be carried out prior initiating therapy with finasteride and during treatment.

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 contact your doctor for further medical advice as soon as possible.

Other medicines and Finasteride

No significant drug interactions have been identified.

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

Pregnancy and breast-feeding

Finasteride is only intended for men.

Women who are pregnant or may become pregnant should not handle broken or crushed Finasteride tablets. If finasteride is absorbed through the skin or taken by mouth by a woman pregnant with a male foetus, the child may be born with malformed genital organs. The tablets are film-coated, which prevents contact with finasteride provided the tablets are not broken or crushed.

Driving and using machines

There are no data which suggest that Finasteride affects the ability to drive or use machines.

Important information about some of the ingredients of Finasteride

Finasteride contains lactose

This medicine contains **lactose**. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Please consult your doctor before taking Finasteride 5 mg if you know that you suffer from a sugar intolerance.

Information about ingredient of Finasteride

This medicine contains less than 1 mmol sodium (23 mg) per dose, 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 1 tablet daily (equivalent to 5 mg finasteride).

The film-coated tablets can either be taken on an empty stomach or with a meal. The film-coated tablets should be swallowed whole and should not be divided or crushed. Although early improvement may be seen, treatment for at least six months may be necessary to assess whether a beneficial response has been achieved.

Your doctor will tell you how long you should continue to take Finasteride 5 mg. Do not interrupt treatment early or the symptoms may come back.

Patients with hepatic impairment

There is no experience of the use of Finasteride 5 mg in patients with restricted liver function (see also "Take special care with Finasteride 5 mg").

Patients with renal impairment

No dosage adjustment is required. The use of Finasteride 5 mg in patients who have to undergo haemodialysis has not been investigated to date.

Older people

No dosage adjustment is required.

Please speak to your doctor or pharmacist if you feel that the effect of Finasteride 5 mg is too strong or too weak.

If you take more Finasteride than you should

If you take more Finasteride 5 mg than you should or if children have been taking medicine by accident please notify your doctor immediately.

If you forget to take Finasteride

If you forget to take a dose of Finasteride 5 mg, you can take it as soon as you remember unless it is almost time for the next dose, in which case you should continue with your medication as prescribed. Do not take a double dose to make up for a forgotten dose.

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.

Allergic reactions (frequency cannot be estimated from the available data)

Stop using Finasteride and immediately contact a doctor if you experience allergic reactions and any of the following symptoms (angioedema): swelling of face, tongue or throat; difficulty swallowing; lumps under the skin (hives) and breathing difficulties.

Other possible side effects during treatment:

Common: may affect up to 1 in 10 people

- you may be unable to have an erection (impotence)
- you may have less desire to have sex.

These side effects above may disappear after a while if you continue taking Finasteride. If not, they usually resolve after stopping Finasteride.

- you may have a decrease in the amount of semen released during sex. This decrease in the amount of semen does not appear to affect normal sexual function.

Uncommon: may affect up to 1 in 100 people

- skin rashes and itching
- breast swelling or tenderness
- problems with ejaculation.

Not known: frequency cannot be estimated from the available data

- palpitations (feeling your heartbeat)
- changes in the way your liver is working, which can be shown by a blood test
- pain in your testicles
- blood in semen
- male infertility and/or poor quality of semen. Improvement in the quality of the semen has been reported after stopping medication
- depression
- decrease in sex drive that may continue after stopping the medication
- anxiety
- problems with erection that may continue after stopping the medication.

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.

Finasteride may affect the result of PSA-laboratory test.

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 the Yellow Card Scheme at: 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.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the container and the outer packaging 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 5 mg finasteride.
- The other ingredients in the tablet core are lactose monohydrate, microcrystalline cellulose, pregelatinised starch (maize), povidone K30, sodium starch glycolate (type A), magnesium stearate, sodium laurilsulfate. The tablet coating Opadry 03G20795 Blue contains hypromellose, (E464), titanium dioxide (E171), macrogol 6000, macrogol 400, indigo carmine lake (E132).

What Finasteride looks like and contents of the pack

Finasteride 5 mg Film-coated Tablets are blue, capsule shaped tablets, with the inscription "FNT5" on one side and plain on the other.

Blister packs PVC/PVDC/Aluminium: 10, 14, 15, 20, 28, 30, 50, 50x1, 56, 60, 98, 100, 100x1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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