

Package leaflet: Information for the user

Finasteride 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, 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 of the 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

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1. What Finasteride 5 mg Tablets is and what it is used for

Finasteride belongs to the group of medicines called 5-alpha reductase inhibitors.

They act by reducing the size of the prostate gland in men.

Finasteride shrinks the prostate gland in men when it is swollen. Finasteride is used in the treatment and control of benign (i.e., non-cancerous) enlargement of the prostate (benign prostatic hyperplasia - BPH). The prostate gland is found underneath the bladder (but only in man). It produces the fluid found in semen. A swollen prostate gland can lead to a condition called 'benign prostatic hyperplasia' (BPH). Finasteride causes shrinkage of the enlarged prostate, improves urinary flow and symptoms caused by BPH, and reduces the risk of you developing a sudden inability to pass urine (known as acute urinary retention) and the need for surgery.

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 pass 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

2. What you need to know before you take Finasteride 5 mg Tablets

Do not take Finasteride 5 mg Tablets:

- If you are allergic to finasteride or any of the other ingredients of Finasteride 5 mg Tablets.
- If you are a woman (because this medicine is for men)
- If you are a child

Do not take finasteride if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Finasteride 5 mg Tablets

- If you have a large amount of residual urine in your bladder after urinating 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 impaired liver function. The level of finasteride in your blood may be increased if so
- If your sexual partner is or may potentially be pregnant, you should avoid exposing her to your semen which could contain a tiny amount of the drug.
- If you have a blood test called PSA (test used to detect prostate cancer). Tell your doctor that you are taking finasteride. Finasteride can affect the blood levels of the substance being tested, PSA.

Children

Finasteride should not be used in children.

Other medicines and Finasteride 5mg Tablets:

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. No significant drug interactions have been identified. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Finasteride 5 mg Tablets with food and drink:

Finasteride can be taken with or without food.

Pregnancy, breast-feeding and fertility:

Finasteride 5 mg Tablets are only intended for men.

Finasteride should not be taken by women. Women who are or may potentially be pregnant should not handle Finasteride 5 mg Tablets especially if broken or crushed. If finasteride is absorbed through the skin or taken by mouth by women pregnant with a male foetus, the child may be born with malformed genital organs. If a women who is pregnant comes into contact with crushed or broken Finasteride tablets, speak to you doctor.

When the patient's sexual partner is or may become pregnant, the patient should either avoid exposure of his partner to semen (e.g. by use of a condom) or discontinue treatment with finasteride.

Driving and using machines:

There is no information to suggest that Finasteride affects the ability to drive and use machines.

Important information about some of the ingredients of Finasteride 5 mg Tablets:

This medicinal product 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.

Mood alterations and depression

Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with Finasteride 5 mg Tablets. If you experience any of these symptoms contact your doctor for further medical advice as soon as possible.

3. How to take Finasteride 5 mg Tablets

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet daily (equivalent to 5 mg finasteride).

The film-coated tablets can either be taken on an empty stomach or with a meal. This medicine should be taken by mouth, swallowed whole and should not be divided or crushed. Your doctor may prescribe finasteride along with another medicine (called doxazosin) to help control your BPH.

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 Tablets. Do not interrupt treatment early or the symptoms may come back.

• Patients with impaired liver function

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

• Patients with impaired kidney function

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

• Elderly patients

No dosage adjustment is required.

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

If you take more Finasteride 5 mg Tablets 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 Finasteride 5 mg Tablets:

If you forget to take a dose of Finasteride 5 mg Tablets, you can take it as soon as you remember unless it is 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 stop taking Finasteride 5 mg Tablets:

Your condition may show an early improvement after taking Finasteride. However, it may take at least six months for the full effect to develop. It is important to keep taking Finasteride 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, Finasteride 5 mg Tablets can cause side effects, although not everybody gets them.

Stop taking finasteride and immediately contact a doctor if you experience any of the following symptoms (angioedema):

- swelling of face, tongue or throat
- difficulty swallowing
- hives and breathing difficulties

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.



Common: (may affect up to 1 in 10 people)

- You may have problems with ejaculation, for example 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.
- You may be unable to have an erection (impotence)
- You may have less desire to have sex

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

- rash
- Problems with ejaculation that may continue after stopping the medication
- Breast swelling or tenderness

Unknown:

- pruritus, urticaria
- palpitations (feeling your heartbeat)
- Swelling of face, lips, tongue or throat, difficulty swallowing and breathing difficulties (angioedema)
- changes in the way your liver is working, which can be shown by a blood test
- pain in your testicles
- an inability to obtain an erection which may continue after stopping the medication
- male infertility and/or poor seminal 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

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.

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. By reporting side effects you can help provide more information on the safety of this medicine.

For UK - 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

For Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

For Ireland
HPRA Pharmacovigilance Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie

5. How to store Finasteride 5 mg Tablets

- Keep out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Do not use Finasteride 5 mg Tablets 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 to protect the environment.

6. Contents of the pack and other information

What Finasteride 5 mg Tablets contain:

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

The other ingredients are –
Tablet core- lactose monohydrate, cellulose microcrystalline (E460), starch pregelatinized (maize), sodium starch glycolate (type-A), lauryl macroglycerides, and magnesium stearate (E572).

Film coating- Hypromellose (E464), titanium dioxide (E 171), indigo carmine (E132), macrogol 6000

What Finasteride 5 mg Tablets look like and content of the pack:

Film-coated Tablet.
Finasteride 5 mg Tablets are blue, round, biconvex, film-coated tablets, marked 'F5' on one side and plain on other side
Finasteride 5 mg Tablets are packed in opaque white PVC/PVdC – Alu blisters in pack of 7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 or 120 tablets.

Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder
United Kingdom
Accord Healthcare Limited
Sage House, 319 Pinner Road
North Harrow, Middlesex, HA1 4HF
United Kingdom

Ireland/Malta

Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer

Accord Healthcare Limited
Sage House, 319 Pinner Road
North Harrow, Middlesex, HA1 4HF
United Kingdom

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomska 50, 95-200 Pabianice, Poland

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

Name of the member state	Name of the medicinal product
Estonia	Finasteride Accord 5 mg õhukese polümeerikattega tabletid
France	Finasteride Accord 5 mg comprimé pelliculé
Ireland	Finasteride 5 mg Film-coated Tablets
Italy	Finasteride AHCL 5 mg compresse rivestite con film
Latvia	Finasteride Accord 5 mg apvalkotās tabletes
Malta	Finasteride 5 mg Film-coated Tablets
Spain	Finasterida Norman 5 mg comprimidos recubiertos con película EFG
The Netherlands	Finasteride Accord 5 mg Filmomhulde Tabletten
UK	Finasteride 5 mg Film-coated Tablets
Bulgaria	Finasteride Accord 5 mg Film-coated Tablets
Cyprus	Finasteride Accord 5 mg επικαλυμμένα με λεπτό υμένιο δισκία
Lithuania	Finasteride Accord 5 mg plevele dengtos tabletės
Poland	Finahit, 5 mg, tabletki powlekane
Sweden	Finasteride Accord 5 mg filmdragerade tabletter
Slovakia	Finasteride Accord 5 mg Filmom obalené tablety

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