

Package leaflet: Information for the user

Finasterid Actavis 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 Finasterid Actavis is and what it is used for
2. What you need to know before you take Finasterid Actavis
3. How to take Finasterid Actavis
4. Possible side effects
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1. What Finasterid Actavis is and what it is used for

Finasterid Actavis contains the active substance finasteride which belongs to a group of medicines called ‘5-alpha reductase inhibitors’. They act by reducing the size of the prostate gland in men.

Finasterid Actavis is used in the treatment and control of benign (not cancerous) enlargement of the prostate.

2. What you need to know before you take Finasterid Actavis

Do not take Finasterid Actavis:

- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman or a child (see also ‘Pregnancy, breast-feeding and fertility’ in this section).

Warnings and precautions

Talk to your doctor or pharmacist before taking Finasterid Actavis

- if you have reduced liver function.
- if you have difficulty emptying your bladder completely or a greatly reduced flow of urine, your doctor should examine you thoroughly before you start taking Finasterid Actavis to exclude other obstructions in the urinary tract.

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.

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 (see also ‘Pregnancy, breast-feeding and fertility’ in this section).

If you need to have a blood test called “PSA”, make sure you tell your doctor or nurse first since finasteride may alter the results of the test.

Mood alterations and depression

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

Other medicines and Finasterid Actavis

Finasterid Actavis tablets can normally be taken with other medicines. Please ask your doctor before you take other medicines at the same time.

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

Finasterid Actavis with food and drink

Finasterid Actavis can be taken with or without food.

Pregnancy, breast-feeding and fertility

Finasterid Actavis is only intended for men.

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.

Women who are pregnant or may become pregnant should not handle broken or crushed Finasterid Actavis tablets. If finasteride is absorbed through the skin or taken by mouth by a woman pregnant with a male fetus, 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.

Infertility and poor semen quality has been reported in men treated with finasteride. In some of these reports, the men had other risk factors that may affect fertility. Normalisation or improvement in semen quality has been reported after discontinuation of finasteride.

Driving and using machines

There is no evidence to suggest that Finasterid Actavis affects the ability to drive or use machines.

Finasterid Actavis contains lactose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Finasterid Actavis

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.

The tablet should be swallowed whole and must not be broken or crushed. It may be taken with or without food.

If you take more Finasterid Actavis than you should

Immediately contact a doctor, the nearest hospital casualty department or the centre for poison information for advice.

If you forget to take Finasterid Actavis

Do not take a double dose to make up for a forgotten tablet. Just take the next one when it is due.

If you stop taking Finasterid Actavis

Although an improvement is often noticed after a short time, it may be necessary to continue the treatment for at least 6 months. Do not alter the dose or stop treatment without asking your doctor.

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.

Stop using Finasterid Actavis and immediately contact your doctor if you experience any of the following symptoms (angioedema): Swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties. These symptoms can be signs of an allergic reaction, which is reported as not known (frequency cannot be estimated from the available data).

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

Inability to obtain an erection, reduced sex drive, reduced ejaculatory volume.

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

Tenderness of the breasts, skin rash, breast enlargement, difficulty obtaining ejaculation.

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

Depression, testicular pain, blood in semen, inability to obtain an erection even after stopping treatment with Finasterid Actavis, ejaculatory dysfunction that continued after stopping treatment, reduced sex drive that continued after stopping treatment, male infertility and/or poor quality of semen (improvement in semen quality has been reported after discontinuation), itching, urticaria (hives), irregular, hard, or rapid heartbeat, increase in liver enzymes, anxiety.

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.

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 Finasterid Actavis

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 label and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Finasterid Actavis 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), lauroyl macroglycerides, sodium starch glycolate, magnesium

stearate. The tablet coating contains hypromellose, macrogol, titanium dioxide (E171) and indigo carmine aluminium lake (E132).

What Finasterid Actavis looks like and contents of the pack

Finasterid Actavis is a blue, round, biconvex tablet marked "F5". The diameter is 7 mm.

Blister packs containing 7, 10, 14, 15, 20, 28, 30, 49, 50, 60, 98, 100 or 300 tablets.

Plastic bottles containing 10, 30, 50, 100 or 300 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

Austria	Finasterid Actavis 5 mg Filmtabletten
Norway	Finasterid Actavis
Sweden	Finasterid Actavis

This leaflet was last revised in 2024-02-22