

PACKAGE LEAFLET: INFORMATION FOR THE USER

Finasteride 5mg Tablets

Read all this leaflet carefully before you start taking this medicine:

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:



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1. What Are Finasteride 5mg Tablets And What They Are Used For

The name of this medicine is Finasteride 5mg Tablets (also referred to as finasteride in this leaflet). Finasteride is a type of medicine called a 5-alpha-reductase inhibitor. It is used to shrink an enlarged prostate in men. Your doctor has prescribed Finasteride 5mg Tablets for you because your prostate is bigger than normal (a condition known as Benign Prostatic Hyperplasia; BPH) which is making it more difficult for you to pass urine. Finasteride 5mg Tablets will help to reduce the risk of developing a sudden inability to pass urine, known as acute urinary retention. They will also reduce the need for prostatic surgery.

2. Before You Take Finasteride 5mg Tablets

Do not take Finasteride 5mg Tablets

- if you are allergic to any of the ingredients in these tablets, listed in Section 6.
- if you are a woman or a child
- if a woman carrying a male baby comes into contact with the active ingredient, finasteride, the normal development of the baby's sex organs may be affected.

Take special care with Finasteride 5mg Tablets

- If you have a lot of difficulty passing urine (water).
- If you suffer from liver problems
- Finasteride can affect a blood test called PSA. If you need a PSA test, you should tell the doctor that you are taking finasteride.
- Women who are pregnant or who might become pregnant should not come into contact with finasteride.
- If you have been told by your doctor that you have an intolerance to certain sugars – see below under 'Important information about some of the ingredients of Finasteride 5mg Tablets'.

If any of the above apply, you should inform your doctor before beginning treatment with Finasteride 5mg Tablets.

Taking other medicines

Finasteride 5mg Tablets do not usually interfere with other medicines, however, you should make sure you have told your doctor or pharmacist about any other medicines that you are taking, including any you have bought without a prescription.

Taking Finasteride 5mg Tablets with food and drink

Finasteride 5mg Tablets can be taken with or without food. The effectiveness of your medicine is not altered by food.

Pregnancy

Women **MUST NOT** use Finasteride Tablets. Women who are pregnant, or think they may be pregnant, should avoid any contact with finasteride, particularly if the tablets are crushed or broken.

If your sexual partner is, or could be, pregnant, you must avoid exposing her to your semen which could contain a small amount of finasteride – for example by using a condom during sexual activity. If a pregnant woman comes into contact with finasteride, a doctor should be consulted.

Driving and using machines

Driving and using of machinery is not known to be affected by this medicine.

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

This medicine contains lactose, so patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Those patients on a sodium controlled diet should be aware that each tablet contains 6.6mg of sodium.

3. How To Take Finasteride 5mg Tablets

Finasteride 5mg Tablets are for oral use and are for men only.

Always take your medicine exactly as your doctor has told you and according to the instructions printed on the label of the pack. You should check with your doctor or pharmacist if you are not sure.

Adults: The usual dose is one tablet every day with or without food. The tablets should be swallowed whole and must not be crushed or divided. Finasteride 5mg Tablets may be taken on their own or with another medicine called doxazosin, which will not affect the effectiveness of your medicine. You may experience more side effects if you also take doxazosin.

Children: Finasteride 5mg Tablets MUST NOT be used in children.

Elderly patients or those with kidney disorders: Usually no adjustment to the dose is necessary and the same dose as for adults should be used.

If you take more Finasteride 5mg Tablets than you should

If you take more than the recommended number of tablets, contact your doctor or pharmacist for advice straight away. No side effects have been reported under these circumstances.

If you forget to take Finasteride 5mg Tablets

Take the forgotten tablet when you remember then take your next tablet as usual the following day. Do not take a double dose to make up for the missed dose.

If you stop taking Finasteride 5mg Tablets

If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, Finasteride 5mg Tablets can cause side effects, although not everybody gets them.

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.

Common side-effects include: impotence (inability to maintain an erection); a reduced desire to have sex; producing a reduced amount of semen

Uncommon side-effects include: Swelling and/or tenderness of the breasts; problems with ejaculation; skin rashes

Rare side-effects include: Allergic reactions including itching, hives or swelling of the face and lips; pain in the testicles and a rapid and irregular heart beat

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store your Finasteride 5mg Tablets

Keep your Finasteride 5mg Tablets in a safe place out of the reach and sight of children. Do not store above 30°C and keep the blister strips in the box. Do not take this medicine after the expiry date which is stated on the blister. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Finasteride 5mg Tablets contains

The active substance in your medicine is finasteride. Your medicine also contains lactose monohydrate, cellulose microcrystalline (E460), starch pregelatinised, sodium starch glycolate (Type A), magnesium stearate (E470b), docusate sodium. The coating of these tablets contains hypromellose (E464), titanium dioxide (E171), macrogol and indigo carmine (E132). The sodium content of each tablet is 6.6mg.

What Finasteride 5mg Tablets looks like and contents of the pack

Finasteride 5mg Tablets are blue, oval, film-coated tablets with the following markings: 'FIN' on one side and '5' on the other side. The tablets are presented in blister strips containing 28, 30, 50 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer (also EU batch release site)

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This medicine is authorised in Member States of the EEA under the following names:

UK: Finasteride 5mg Tablets (PL 08553/0261)

Spain: Finasterida 5mg Aphar Comprimidos Recubiertos EFG

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