

semen quality has been reported after stopping the medication • Depression • Decrease in sex drive that may continue after stopping the medication • Problems with ejaculation that may continue after stopping the medication These side effects may disappear after a while if you continue taking FINASTIV. If not, they usually resolve after stopping FINASTIV. You should promptly report to your doctor any changes in your breast tissue such as enlargement, lumps, pain or nipple discharge as these may be signs of a serious condition, such as breast cancer. If any of the side effects gets serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist. It will help if you make a note of what happened, when it started and how long it lasted. What else should you know about FINASTIV? FINASTIV (finasteride) is not licensed to treat prostate cancer. Information collected for a clinical trial in men taking finasteride for 7 years showed: • The number of men who developed prostate cancer was lower in men taking finasteride compared with those taking nothing. • The number of men who had a high score in a tumor grading system was higher in some of those taking finasteride compared to those taking nothing. • The effect of long-term use of finasteride on tumors of this kind is not known. • 5 alpha-reductase inhibitors may increase the risk of developing prostate cancer with higher Gleason scores. If you would like to have further information about the tumor grading system, please talk to your doctor. In order to have information about the tumor grading system in this trial, please talk to your doctor. 5. How to store FINASTIV Keep FINASTIV out of the sight and reach of children and in the original package. Store at room temperature below 25°C. Take it in accordance with the expiry date. <i>Do not use FINASTIV after the expiry date which is stated on the pack.</i> Do not use FINASTIV if you notice any defects in the product and/or packaging. Do not throw away any expired or unused medicines! Give them to the collection system determined by the Ministry of Environment and Urbanisation. Distributed by: BioActiveT Pharma, UNITED KINGDOM. <i>This leaflet was approved on 15.10.2018.</i>	PATIENT INFORMATION LEAFLET FINASTIV 5 mg film coated tablets For oral use. •Active substance: Each film coated tablet contains 5 mg of finasteride. •Excipients: Povidone, lactose monohydrate (derived from bovine milk), pregelatinized starch, sodium starch glycolate, dioctyl sodium sulfosuccinate, microcrystalline cellulose, magnesium stearate (E572), hydroxypropyl methyl cellulose (E464), hydroxypropyl cellulose (E463), titanium dioxide (E171), talc (E553b), indigo carmine aluminium lake FD&C Blue No: 2 (E132). Read all of this LEAFLET carefully before you start taking this medicine because it contains important information for you. •<i>Keep this leaflet. You may need to read it again.</i> •<i>If you have any further questions, ask your doctor or pharmacist.</i> •<i>This medicine has been prescribed for you only. Do not pass it on to others.</i> •<i>When you go to a doctor or hospital during the use of this medicine, tell your doctor that you are taking this medicine.</i> •<i>Follow what is stated in this leaflet exactly. Do not take this medicine at a dose higher or lower than recommended to you.</i> In this leaflet: 1. What FINASTIV is and what it is used for 2. What you need to know before you take FINASTIV 3. How to take FINASTIV 4. Possible side effects 5. How to store FINASTIV Topics are included. 1. What FINASTIV is and what it is used for FINASTIV is supplied in blister packs of 30 and 100 film coated tablets. FINASTIV is available as a light blue, round, biconvex, film coated tablet. Each film coated tablet contains 5 mg of finasteride. The tablet contains lactose monohydrate derived from bovine milk. FINASTIV contains a medicine called finasteride. FINASTIV belongs to a group of medicines called 5 alpha-reductase inhibitors. FINASTIV is used in the treatment of benign enlargement of the prostate gland (benign prostatic hyperplasia or BPH). This disease occurs only in men. FINASTIV shrinks prostate gland in men when it is swollen. Your prostate gland is found underneath your urinary bladder. It produces the liquid found in semen. A swollen prostate gland can lead to a condition called “benign prostatic hyperplasia” (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 the body. This can lead to some 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 of urine stops and starts • Feeling that you cannot empty your urinary bladder completely In some men, BPH can lead to very serious conditions. Such as: • Urinary tract infections • A sudden inability to pass urine (acute urinary retention) • 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 may be present at the same time. • Before you start FINASTIV, your doctor will do some simple tests to check whether you have prostate cancer.
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Talk to your doctor if you have any questions about this.

**2. What you need to know before you take FINASTIV
DO NOT TAKE FINASTIV:**

If:

- you are a woman (because this medicine is only for men),
- you are allergic (hypersensitive) to finasteride or any of the other ingredients of the medicine,

Take special care with FINASTIV:

- If your wife (partner) is pregnant or planning to become pregnant, you should use a condom or other barrier methods of contraception when taking FINASTIV. This is because your semen could contain a tiny amount of the drug and may affect the normal development of your male baby’s sex organs.
- If you are going to have a blood test called PSA, tell your doctor that you are taking this medicine. This is because FINASTIV can affect the results of this test.
- FINASTIV can increase the risk of developing a very serious type of prostate cancer.
- You should promptly report to your doctor any changes in your breast tissue such as enlargement, lumps, pain or nipple discharge as these may be signs of a serious condition, such as breast cancer.

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.

Please consult your doctor, even if these warnings were applicable to you at any time in the past.

Taking FINASTIV with food and drink

FINASTIV can be taken with or without food.

Pregnancy

Ask your doctor or pharmacist for advice before taking the medicine.

FINASTIV should not be taken by women.

Do not touch crushed or broken FINASTIV tablets if you are pregnant or planning to become pregnant. This is because this medicine may affect the development of your male baby’s sex organs (whole tablets are coated to stop contact with the medicine during normal use). If you come into contact with crushed or broken FINASTIV tablets when you are pregnant, speak to your doctor immediately.

If you notice that you are pregnant during the treatment, consult your doctor or pharmacist immediately.

Breastfeeding

Ask your doctor or pharmacist for advice before taking the medicine.

FINASTIV should not be taken by women.

Driving and using machines

FINASTIV is not likely to affect you being able to drive, use tools or machines.

Important information about some of the excipients of FINASTIV

Each tablet contains 97.583 mg of lactose monohydrate. If your doctor has previously told you that you have intolerance to certain sugars, talk to your doctor before taking FINASTIV.

Concomitant use with other medicines

FINASTIV does not usually affect other medicines.

Please tell your doctor or pharmacist if you are currently taking or have recently taken any prescription or non-prescription medicine.

3. How to take FINASTIV

Instructions for appropriate use and dosing/administration frequency:

- Always take FINASTIV exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- The recommended dose of FINASTIV is 5 mg once a day (1 tablet).
- Your doctor may prescribe FINASTIV along with another medicine called doxazosin to help control your BPH.

Route and method of administration:

- FINASTIV is taken only by mouth.
- It can be taken on an empty stomach or with food.

Various age groups:

Use in children:

FINASTIV should not be used in children.

Use in elderly patients:

No dosage adjustment is necessary in elderly.

Special uses:

Renal/Hepatic insufficiency:

No specific dosage adjustment is necessary in patients with renal sufficiency. Caution should be used in the administration of FINASTIV in patients with hepatic failure.

If you feel that the effects of FINASTIV is too strong or too weak, talk to your doctor or pharmacist.

If you take more FINASTIV than you should:

If you take more FINASTIV than you should, contact a doctor or pharmacist.

If you forget to take FINASTIV:

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.

The effects that may occur if you stop taking FINASTIV

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

The frequencies of the possible side effects are as follows:

Very common: May be observed at least one in 10 patients.

Common: May be observed in less than one in 10 patients, but more than one in 100 patients.

Uncommon: May be observed less than one in 100 patients, but more than one in 1000 patients. Rare: May be observed less than one in 1000 patients, but more than one in 10000 patients.

Very rare: May be observed in less than one in 10000 patients.

Not known: Cannot be estimated from the available data.

Stop using FINASTIV and IMMEDIATELY contact your doctor or go to the emergency department of your nearest hospital if you experience any of the following symptoms:

- Skin rashes
- Itching or lumps under your skin (urticaria)
- Swelling of face, tongue, throat or lips

These are all very serious side effects.

If you experience any of these side effects, it means that you are seriously allergic to FINASTIV. Emergency medical attention or hospitalization may be required.

These very serious side effects all occur very rarely.

Other side effects may include:

Common:

- You may have less desire to have sex.

Uncommon:

- You may be unable to have an erection (impotence).
- Breast swelling, tenderness or enlargement

Not known:

- You may have problems with ejaculation, for example a decrease in the amount of semen released during sex. This decrease does not appear to affect normal sexual function.
- Palpitations (feeling your heartbeat)
- Changes in the way your liver is working (which can be shown by a blood test)
- Pain in testicles
- An inability to have an erection which may continue after stopping the medication
- Male infertility and/or poor quality of semen. Improvement in the