

finasteride on fertility in men have not been conducted.

- Changes in the way your liver is working, which can be shown by a blood test (elevated liver enzymes)
- Anxiety
- Suicidal thoughts

If any of the side effects get serious, or if you notice any side effects 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 finasteride?

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 tumour grading system was higher in some of those taking finasteride compared to those taking nothing.
- The effect of long-term use of finasteride on tumours of this kind is not known.

If you would like further information about the tumour grading system or this trial, please talk to your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or 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 Website: 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 Tablets

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special temperature storage conditions.
- Do not use this medicine 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 protect the environment.

6. Contents of the pack and other information

What Finasteride Tablets medicine contains

- The active substance is finasteride. Each film coated tablet contains 5 mg of finasteride.
- The other ingredients are lactose monohydrate, maize starch pregelatinised, docusate sodium, iron oxide yellow (E172), sodium starch glycollate, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, opadry blue (consists of hypromellose, hydroxypropylcellulose, titanium dioxide (E171), indigotine, indigo carmine (E132), sunset yellow FCF (E110), quinolone yellow (E104))

What Finasteride Tablets looks like and contents of the pack

- Finasteride Tablets are light blue, round, biconvex film-coated tablets, marked with "BL5" on one side and plain on the other side.
- Finasteride Tablets is available in packs of 7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 or 120 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Finasteride 5 mg film-coated tablets;
PL 17907/0498

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Package leaflet: Information for the patient

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 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:

1. What Finasteride Tablets are and what they are used for
2. What you need to know before you take Finasteride Tablets
3. How to take Finasteride Tablets
4. Possible side effects
5. How to store Finasteride Tablets
6. Contents of the pack and other information

1. What Finasteride Tablets are and what they are used for

Finasteride 5mg contains a medicine called finasteride. This belongs to a group of medicines called '5-alpha reductase inhibitors'.

This medicine shrinks the prostate gland in men when it is swollen. The prostate gland is found underneath the bladder (but only in men). It produces the fluid found in semen. A swollen prostate gland can lead to a condition called benign prostatic hyperplasia' or 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 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 start passing 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

What else should you know about BPH?

- BPH is not cancer and does not lead to cancer, but the two conditions can be present at the same time.
- Before you start this medicine, your doctor will do some simple tests to check whether you have prostate cancer.

Talk to your doctor if you have any questions about this.

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

Do not take Finasteride Tablets:

- if you are allergic (hypersensitive) to finasteride or any of the other ingredients of this medicine (listed in Section 6)
- if you are a woman (because this medicine is for men)
- if you are a child.

Do not take this medicine 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, pharmacist or nurse before taking Finasteride Tablets:

- your partner is pregnant or planning to become pregnant. You should use a condom or other barrier method of contraception when taking this medicine. This is because your semen could contain a tiny amount of the drug and may affect the normal development of the baby's sex organs.

• you are going to have a blood test called PSA. This is because this medicine can affect the results of this test.

If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Tell 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.

Mood alterations and depression

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

Children

Finasteride 5mg should not be used in children.

Other medicines and Finasteride Tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This medicine does not usually affect other medicines.

Finasteride Tablets with food, drink and alcohol

This medicine can be taken with or without food.

**Pregnancy, breast-feeding and fertility
Finasteride is only intended for men.**

This medicine should not be taken by women.

- Do not touch crushed or broken this medicine if you are woman who is pregnant or planning to become pregnant (whole tablets are coated

to stop contact with the medicine during normal use). This is because this medicine may affect the normal development of the baby's sex organs. If a woman who is pregnant comes into contact with crushed or broken this medicine, speak to your doctor.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

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

Finasteride Tablets contains lactose and sunset yellow

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

Sunset yellow (E110): may cause allergic reactions, possibly delayed.

Information on sodium content

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

3. How to take Finasteride Tablets

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 one 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 may prescribe Finasteride along with another medicine (called doxazosin) to help control your BPH.
- Your doctor will tell you how long you should continue to take this medicine. 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 'Warnings and precautions').

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 this medicine is too strong or too weak.

If you take more Finasteride 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 Tablets

If you forget to take a dose of this medicine, 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 Tablets

Your condition may show an early improvement after taking this medicine. However, it may take at least six months for the full effect to develop. It is important to keep taking this medicine for as long as your doctor tells you, even if you do not feel any benefit straight away.

Do not stop taking this medicine unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Allergic reactions

Stop taking this medicine, and immediately contact

a doctor if you experience any of the following symptoms:

- Skin rashes, itching, or lumps under your skin (hives)
- Swelling of lips, face, tongue or throat
- Difficulty in swallowing
- Breathing difficulties (angioedema)

The side effects have usually been temporary with continued treatment or disappeared when treatment is stopped.

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.

Common (may affect up to 1 in 10 people)

- impotence (an inability to have an erection)
- less desire to have sex
- problems with ejaculation, for example 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)

- rash
- breast swelling or tenderness
- problems with ejaculation

Frequency unknown (cannot be estimated from the available data)

- hypersensitivity reactions, including swelling of the lips, tongue, throat and face
- pain in your testicles
- fast heart beat (palpitations)
- blood in semen
- depression
- an inability to have an erection which may continue after stopping the treatment
- decrease in sex drive that may continue after discontinuation of treatment.
- problems with ejaculation that may continue after discontinuation of treatment.
- infertility has been reported in men who took finasteride for long time and had other risk factors that may affect fertility. Normalisation or improvement of seminal quality has been reported after discontinuation of finasteride. Long-term clinical studies about the effect of