

# Finasteride 5mg tablets

## Read all of 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:

1. What Finasteride tablets are and what they are used for
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## 1. What Finasteride tablets are and what they are used for

Finasteride belongs to a group of medicines called 5-alpha reductase inhibitors. They act by reducing the size of the prostate gland in men.

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

## 2. Before you take Finasteride tablets

### Do not take Finasteride tablets if you

- are **allergic** (hypersensitive) to finasteride or any other ingredients in Finasteride tablets (see section 6)
- are a **woman** who is pregnant, or who may potentially be pregnant

## Check with your doctor or pharmacist before taking Finasteride tablets if you

- have **difficulty emptying your bladder completely** or a greatly **reduced flow of urine**. Your doctor should examine you before you start taking Finasteride tablets to exclude other obstructions in the urinary tract.

Finasteride tablets are not recommended for use in women or children.

## Mood alterations and depression

Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been

reported in patients treated with Finasteride tablets. If you experience any of these symptoms contact your doctor for further medical advice as soon as possible.

## Taking other medicines

Finasteride tablets can normally be taken with other medicines. However, please ask your doctor or pharmacist before you take other medicines at the same time or if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

## Special precautions

### Pregnancy and breast-feeding

- Finasteride tablets are not recommended for use in women.
- Women who are pregnant or may become pregnant should not handle broken or crushed Finasteride tablets. If finasteride is absorbed through the skin or taken by mouth by a woman pregnant with a male baby, 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.
- If your sexual partner is or may possibly be pregnant, you must avoid exposing her to your semen, which could contain a small amount of the drug. The use of a condom is recommended. If you think a pregnant woman has come into contact with finasteride, you should consult a doctor.
- It is not known whether finasteride is excreted in human milk.

## Driving and using machines

There is no evidence to suggest that Finasteride tablets affect the ability to drive or use machines.

## Sugar intolerance

Finasteride tablets contain lactose monohydrate. If you do not tolerate some types of sugar, contact your doctor before you take this medicine.

## Blood tests

Finasteride tablets can affect a blood test called PSA. If you have a PSA test done, tell your doctor you are taking Finasteride tablets.

## Children

Finasteride tablets are not recommended for use in children.

### 3. How to take Finasteride tablets

Always take Finasteride tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

The usual dose is 1 tablet daily.

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

#### If you stop taking Finasteride tablets

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 take more Finasteride tablets than you should

If you (or someone else) swallow a lot of the tablets at the same time, or you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

#### If you forget to take Finasteride tablets

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

### 4. Possible side effects

Like all medicines, Finasteride tablets can cause side effects, although not everybody gets them.

The following side effects may happen with this medicine:

#### Allergic reactions

**Stop taking Finasteride tablets and immediately contact a doctor if you experience any of the following symptoms of an allergic reaction:**

- Skin rashes, itching, or lumps under your skin (hives)
- Swelling of your lips, face, tongue or throat; difficulty swallowing; breathing difficulties (angioedema).

**Common** (occurs in less than 1 of 10, but more than 1 of 100 patients treated)

- Inability to obtain an erection (impotence)
- Reduced sex drive (libido)
- A decrease in the amount of semen released during sex. Impotence and reduced libido may occur soon after starting treatment but usually resolve with continued treatment.

**Uncommon** (less than 1 of 100, but more than 1 of 1000 patients treated)

- Skin rash
- Ejaculation disorders
- Breast tenderness
- Breast enlargement

#### Other side effects reported in men are:

- Palpitations
- Itching
- Lumps under your skin (hives)
- Change in liver function
- Testicular pain
- Sexual dysfunction – erectile and ejaculation problems that may continue after stopping the medication
- Male breast cancer
- Male infertility and/or poor seminal quality – normalization or improvement in seminal quality has been reported after stopping this medication
- depression, decreased libido that continued after discontinuation of treatment

### 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, 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 at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

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

### 5. How to store Finasteride tablets

Keep out of the reach and sight of children. There are no special storage precautions. Use before the expiry date which is stated on the package. The expiry date refers to the last day of that month.

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 tablets contain

- The active substance (the ingredient which makes the medicine work) is finasteride 5 mg
- The other ingredients are lactose monohydrate, cellulose microcrystalline, pregelatinised starch, lauroyl macrogolglycerides, sodium starch glycolate (type A), magnesium stearate. The film coating contains hypromellose, macrogol 6000, titanium dioxide (E171) and indigocarmine lake (E132).

#### What Finasteride tablets look like and contents of the pack

The tablets are film-coated, blue, round, biconvex. They are supplied in:  
Blister packs containing 12, 28 or 30 or 56 tablets.  
Plastic bottles containing 50, 75 or 100 tablets.

Not all pack sizes may be available.

#### Marketing Authorisation Holder

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