

**1.5.3 Patient Information Leaflet (PIL) or Package Insert****BINFIN 5 (Finasteride Tablets 5 mg)****PACKAGE LEAFLET: INFORMATION FOR THE USER**

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, please 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 get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

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

1.WHAT FINASTERIDE 5 MG IS AND WHAT IT IS USED FOR

Finasteride 5 mg contains the active substance finasteride. This belongs to a group of medicines called ‘5-alpha reductase inhibitors’.

Finasteride 5 mg 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 Finasteride 5 mg, 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 5 MG

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- The usual dose is one tablet each day.
- Take this medicine by mouth.
- Your doctor may prescribe Finasteride 5 mg along with another medicine (called doxazosin) to help control your BPH.

If you take more Finasteride 5 mg than you should

If you take too many tablets by mistake, contact your doctor immediately.

If you forget to take Finasteride 5 mg

- 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.

If you stop taking Finasteride 5 mg



Your condition may show an early improvement after taking Finasteride 5 mg. However, it may take at least six months for the full effect to develop. It is important to keep taking Finasteride 5 mg 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.

3. HOW TO TAKE FINASTERIDE 5 MG

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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**



If you have an allergic reaction, stop taking it and see your doctor straight away. The signs may include:

- Skin rashes, itching, or lumps under your skin (hives)
- Swelling of your lips, tongue, throat and face.

Other side effects may include:

- You may be unable to have an erection (impotence)
- You may have less desire to have sex
- You may have problems with ejaculation, for example a decrease in the amount of semen released during sex. This decrease in the amount of semen does not appear to affect normal sexual function.

These side effects above may disappear after a while if you continue taking Finasteride 5 mg. If not, they usually resolve after stopping Finasteride 5 mg. Other side effects reported in some men are:

- Breast swelling or tenderness
- Palpitations (feeling your heartbeat)
- Changes in the way your liver is working, which can be shown by a blood test
- Pain in your 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 quality of the semen has been reported after stopping medication
- Depression
- Decrease in sex drive that may continue after stopping the medication
- Problems with ejaculation that may continue after stopping the medication

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.

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 5 mg?

Finasteride 5 mg (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.

5. HOW TO STORE FINASTERIDE 5 MG

Keep this medicine out of the sight and reach of children.

Store below 30°C and protect from moisture.

If you have been given a calendar pack, do not remove the tablets from the blister until you are ready to take the medicine.

Do not use Finasteride 5 mg after the expiry date which is stated on the carton after the letters 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What BINFIN 5 (Finasteride Tablets 5 mg) contains

The active substance is Finasteride.

Each film coated tablet contains 5 mg of Finasteride Ph.Eur.

- The other ingredients are:
- Lactose monohydrate (Pharmatose 200M), Cellulose Microcrystalline (Avicel PH 102), Starch Pregelatinized (Starch 1500), Sodium starch glycolate (Primojel), Docusate sodium, Purified water, Magnesium Stearate and Opadry Blue 03A80928

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

Blue colour, round film coated tablets, debossed with 'H' on one side and '37' on other side.

BINFIN 5 (Finasteride Tablets 5 mg) are available in:



Blister pack: 15's pack

Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder:

Name: Hetero Labs Limited

Business Address: 7-2-A2, Hetero Corporate,
Industrial Estates,
Sanath Nagar,
Hyderabad-500 018
Andhra Pradesh.

Country: INDIA

Manufacturer:

Name: Hetero Labs Limited (Unit-III)

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Hyderabad-500 055
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Additional Manufacturer Name and Address :

(Company) Name : Hetero Labs Limited (Unit-V)

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Telephone : +91 08542-238400

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E-Mail : drkepi@heterodrugs.com; formulations@heterodrugs.com

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