

Package Leaflet: Information for the user

Finxta, 5 mg, film-coated tablets

Finasteride

THIS MEDICINE IS FOR USE IN MEN ONLY

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Finxta is and what it is used for

Finasteride, an active substance of Finxta, is an inhibitor of enzyme called 5-alpha reductase, which converts testosterone (male sex hormone) to the more potent dihydrotestosterone (DHT). Finxta acts by reducing the size of the prostate gland.

Finxta is used in the treatment of benign enlargement of the prostate (benign prostatic hyperplasia - BPH). The prostate gland located around the bladder has increased, causing difficulty in urinating.

Finxta is indicated in the treatment of benign prostatic hyperplasia to:

- relieve symptoms,
- reduce the risk of acute urinary retention,
- reduce the risk of surgery including transurethral resection of the prostate (TURP) and prostatectomy (surgical removal of the prostate).

2. What you need to know before you take Finxta

What you should know before and during Finxta taking

If your sexual partner is or may be pregnant, you should avoid exposing her to your semen, which may contain a tiny amount of the medicine.

Do not take Finxta

- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6)
- if you are a woman who is pregnant or may potentially be pregnant.

Finxta is not indicated for use by women.

Warnings and precautions

Talk to your doctor before taking Finxta.

Tell your doctor about all the diseases that occur now or in the past as well as allergies.

Benign prostatic hyperplasia is a disease developing for a long time. In some patients relief of symptoms occurs shortly after start of therapy. However, it may take at least 6 months for the full effect to develop. Whatever the symptoms will be relieved or not, Finxta can reduce the risk of acute urinary retention and the need for surgical treatment. In order to control the progression of the treatment the patient should be under constant medical care.

Benign prostatic hyperplasia is not a cancer and does not lead to cancer, but this two conditions can be present at the same time. Only physician can properly assess symptoms and their probable cause.

Finxta can affect the result of PSA (prostate specific antigen) test. Therefore, before performing this test, tell your doctor that you are taking Finxta.

Finxta is indicated only for men to treat benign prostatic hyperplasia.

Mood alterations and depression

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

Children

Symasteride should not be used in children.

Other medicines and Finxta

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

Pregnancy and breast-feeding

Pregnancy

Women who are pregnant and woman with childbearing potential cannot use Finxta. They also should not touch broken or crushed Finxta tablets. If active substance is absorbed (taken by mouth or through the skin) by a pregnant woman with a male foetus, the child may be born with malformed genital organs. If a woman who is pregnant comes into contact with finasteride, speak to your doctor. The tablets are film-coated, what prevents from contact with active substance provided the tablets are not broken or crushed.

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

Breast-feeding

Finxta is not indicated for use by women.

It is not known, whether finasteride is excreted in human milk.

Driving and using machines

There are no data suggesting that Finxta affects the ability to drive or use machines.

Finxta contains lactose

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Finxta

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

The recommended dose is one 5 mg tablet daily, regardless of food intake.

Take this medicine by mouth. The film-coated tablets should be swallowed whole and should not be divided or crushed.

Keep in mind that benign prostatic hyperplasia is a process lasting many years before symptoms are noticed. Finxta may alleviate symptoms and control the disease, if it is taken regularly for a long time.

Patients with renal impairment and (or) hepatic impairment

No dosage adjustment is required in patient with varying degrees of renal and/or hepatic insufficiency.

Elderly patients

No dosage adjustment is required in elderly.

Please speak to your doctor or pharmacist if you feel that the effect of Finxta is too strong or too weak.

If you take more Finxta than you should

If you take more tablets than recommended, than you should contact your doctor immediately.

If you forget to take Finxta

You should take Finxta exactly as your doctor has told you. However, if you forget to take a tablet, skip the missed dose. The next day, return to the dosing regimen recommended by your doctor. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (may occur in 1 to 10 users in 100)

- decreased libido,
- impotence (inability to obtain erection),
- decreased volume of ejaculate (the amount of semen). This does not affect normal sexual function.

In some cases, these side effects may disappear after a while if you continue treatment. However, if side effects persist, talk to your doctor, who may decide to stop taking Finxta.

Uncommon side effects (may occur in 1 to 10 users in 1 000)

- rash,
- ejaculation disorder,
- breast enlargement and (or) tenderness.

Unknown (cannot be estimated from the available data)

You should stop taking Finxta and contact your doctor immediately if you experience any of the following symptoms (angioedema): swelling of the face, tongue or throat, difficulty in swallowing, hives and difficulty in breathing.

- allergic reactions; swelling of the lips, tongue, throat, face,
- depression,

- persistence of diminished libido after discontinuation of treatment,
- blood in semen,
- palpitation,
- changes in liver function, which can be seen in blood tests,
- itching, urticarial,
- testicular pain,
- an inability to have an erection which may continue after stopping medicine,
- abnormal ejaculation persisting after discontinuation of the drug,
- male infertility and/or poor quality of semen (improvement in the quality of semen has been reported after stopping medication),
- in rare cases, the development of breast cancer,
- anxiety.

You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, breast enlargement or nipple discharge as these may be signs of a serious conditions, such as breast cancer.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

Al. Jerozolimskie 181C, 02-222 Warszawa, tel.: + 48 22 49 21 301, faks: + 48 22 49 21 309,
strona internetowa: <https://smz.ezdrowie.gov.pl>.

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

5. How to store Finxta

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the outer package and on the blister 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 Finxta contains

- The active substance is finasteride. One film-coated tablet contains 5 mg finasteride.
- The other ingredients in the tablet core are lactose monohydrate, microcrystalline cellulose, pregelatinised starch (maize), sodium starch glycolate (type A), magnesium stearate, sodium laurilsulfate.

The tablet coating contains hypromellose, microcrystalline cellulose, macrogol 8 stearate (type I).

What Finxta looks like and contents of the pack

Finxta are white, round, biconvex, film-coated tablets with a diameter of 7 mm and they are embossed with “F” and “5” on one side.

Blister packs (PVC/PVDC/Aluminium): 15, 28, 30, 50, 98, 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Recordati Polska sp. z o.o.
ul. Królewska 16
00-103 Warszawa

Manufacturer

Haupt Pharma Münster GmbH
Schleebrüggenkamp 15
48159 Münster
Germany

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HHF070 Hal Far Industrial Estate
Hal Far BBG3000
Malta

This leaflet was last revised in: 06/2022