

Package leaflet: information for the user
Finasteride Accord 5 mg Film-coated Tablets
Finasteride

Read the entire 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.
- Do you have any questions? Please contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor, pharmacist, or nurse.

Contents of this leaflet

1. What is Finasteride Accord and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the pack and other information

1. What is Finasteride Accord and what is it used for?

Finasteride belongs to a group of medicines called 5-alpha-reductase inhibitors. These reduce the size of the prostate in men.

This medicine reduces the prostate size in men when it is swollen. This medicine is used in the treatment and control of benign enlargement (not cancer) of the prostate (benign prostatic hyperplasia, BPH). The prostate is located below the bladder (only in men). The prostate produces the fluid in the semen. A swollen prostate gland can lead to a condition called 'benign prostatic hyperplasia' (BPH). This medicine reduces the enlarged prostate, improves urinary flow and symptoms of BPH, and reduces the risk of suddenly being unable to urinate (acute urinary retention) and the need for surgical intervention.

What is BPH?

If you have BPH, it means your prostate is swollen. It can press on the tube through which urine flows as it leaves your body.

This can lead to problems such as

- Feeling the need to urinate more often, especially at night
- Feeling the need to urinate immediately
- Difficulty urinating
- A weak urine stream when you urinate
- A urine stream that stops and starts when you urinate
- Feeling that you cannot completely empty your bladder

In some men, BPH can have more serious consequences, such as:

- Urinary tract infections

- Sudden inability to urinate
- The need for surgery

2. When should you not use this medicine or be extra careful?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- If you are a woman (because this medicine is intended for men)
- If you are a child.

Do not use Finasteride Accord 5 mg if any of the above apply to you. Contact your doctor or pharmacist if you are not sure.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

- If you have a large residual urine volume in your bladder and/or a severely reduced urine flow. If this is the case, you should be carefully monitored for narrowing of the urinary tract
- If you have impaired liver function. The concentration of finasteride in your blood may then increase
- If your partner is pregnant or possibly pregnant, you should prevent her from being exposed to your semen, which may contain a small amount of the medicine
- If you are undergoing a blood test called a PSA test (a test to detect prostate cancer). Tell your doctor that you are using finasteride. Finasteride can affect the concentration of the substance in the blood being tested (PSA)

Mood swings and depression

Mood swings such as depressed mood, depression, and, less often, suicidal thoughts have been reported in patients treated with Finasteride Accord 5 mg. Contact your doctor as soon as possible for medical advice if you experience any of these symptoms.

Children

This medicine should not be used for children.

Are you taking any other medicines?

Are you taking any other medicines besides Finasteride Accord, have you recently done so, or is there a possibility that you will take other medicines in the near future? Then tell your doctor or pharmacist.

This also applies to medicines for which you do not need a prescription.

Finasteride Accord generally does not interact with other medicines.

No significant interactions with other medicines have been identified.

What should you pay attention to with food?

This medicine can be taken with or without food.

Pregnancy, breastfeeding, and fertility

This medicine is intended for use by men only. This medicine should not be used by women. Women who are pregnant or may become pregnant should not handle this medicine, especially if the tablets are broken or crushed. When finasteride is absorbed through the skin or ingested orally by a woman who is pregnant with a boy, the child may be born with malformed genitalia. If a pregnant woman comes into contact with crushed or broken tablets of this medicine, then immediately contact your doctor. If the patient's partner is pregnant or can become pregnant, the patient should prevent his partner from being exposed to his semen (for example, by using a condom) or discontinue treatment with finasteride. staken.

There are no known data that this medicine affects the ability to drive and operate machines. Finasteride Accord 5 mg contains lactose affects.

contact your doctor before taking this medicine.

Finasteride Accord 5 mg contains sodium This medicine contains less than 1 mmol (23 mg) sodium per dose and is therefore essentially 'sodium-free'.

3. How to use this medicine? Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use?

Then contact your doctor or pharmacist.

The recommended dosage is one tablet per day (equivalent to 5 mg finasteride per day). The film-coated tablet can be taken on an empty stomach or with food. This medicine must be taken orally, swallowed whole, and must not be broken or crushed. Your doctor

The film-coated tablet can be taken on an empty stomach or with food. This medication must be administered through the are to be taken orally, swallowed whole, and must not be broken or crushed. Your doctor can you prescribe another medicine (called doxazosin) to help control your BPH. Although improvement may occur early, treatment for at least six months may be needed to assess whether a favorable response has occurred.

Your doctor will tell you how long to use Finasteride Accord 5 mg. Do not stop the treatment prematurely, otherwise the symptoms may return.

Patients with impaired liver function There is no experience with the use of this medicine in patients with limited liver function (see also

- 'When should you be extra careful with this medicine?')
- Patients with impaired kidney function No dose adjustment is necessary. The use of this medicine in patients who need to undergo hemodialysis
- has not been studied to date.
- No dose adjustment is necessary. The use of this drug in patients undergoing hemodialysis, No dose adjustment is necessary.
- Elderly
- Have you taken too much of this medicine
- If you have taken too many tablets or if someone else has taken this medicine, contact

the emergency department of the nearest hospital. Take the rest of the tablets or the empty box with you. contact the emergency department of the nearest hospital. Take the remaining tablets or the empty box with you so that the medicine can be more easily recognized.

Did you forget to take this medicine?

If you forgot to take a dose of this medicine, you can still do so as soon as you remember, unless it is almost time for your next dose. In this case, follow the regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine

Your condition may improve quickly after using this medicine. However, it may take at least six months before the full effect is achieved. It is important that you continue to use this medicine as long as your doctor advises, even if you do not experience immediate benefits.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. Stop using this medicine and contact a doctor immediately if you experience any of the following symptoms (angioedema):

- swelling of the face, tongue, or throat
- difficulty swallowing
- skin rash with severe itching and bumps (hives, urticaria) and breathing problems

The most common side effects are impotence (erectile dysfunction) and decreased libido. These side effects usually occur at the beginning of the treatment, but persist in most patients usually not long if the treatment is continued.

Common: (occur in less than 1 in 10 users)

- you may experience ejaculation problems, such as a reduction in the amount of semen released during sex. The reduction in the amount of released semen does not seem to affect normal sexual functions.
- you may be unable to get an erection (impotence)
- you may have a decreased libido

Uncommon: (occur in less than 1 in 100 users)

- rash
- ejaculation problems that persist after you stop using this medication
- swelling or tenderness of the breasts Not known (cannot be determined from the available data):
- itching, rash with severe itching and welts (hives, urticaria)
- palpitations (you feel your heart beating)
- swelling of the face, lips, tongue or throat, difficulty swallowing, breathing difficulties (angioedema)
- changes in the way your liver functions, which can be shown by means of a blood test
- pain in your testicles
- the inability to achieve an erection, which may persist after you stop using this medicine
- infertility in men and/or poor semen quality. After stopping the use of this medicine, improvement in semen quality has been reported
- depression
- reduced libido, which may persist after you stop using this medicine
- anxiety

Report changes in breast tissue such as lumps, pain, enlargement of breast tissue, or nipple discharge to your doctor immediately, as these may be signs of a serious condition, such as breast cancer.

Reporting side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

- Keep out of the sight and reach of children.
- There are no special storage conditions for this medicine.
- Do not use this medicine after the expiry date. It can be found on the box after EXP. There states a month and a year. The last day of that month is the expiration date
- Do not flush medicines down the sink or toilet and do not throw them in the trash.
- Ask your pharmacist what to do with medicines you no longer use. They will then be disposed of responsibly and will not end up in the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is finasteride. One film-coated tablet contains 5 mg finasteride.

The other substances in this medicine are:

Tablet core: lactose monohydrate, microcrystalline cellulose (E460), pregelatinized starch (maize), sodium starch glycolate (type A), lauroyl macroglycerides, and magnesium stearate (E572).

Film coating: Hypromellose (E464), titanium dioxide (E171), indigotine (E132), macrogol 6000

What does Finasteride Accord 5 mg look like and what is in a package?

Film-coated tablets.

Finasteride Accord 5 mg are blue, round, biconvex, film-coated tablets with the imprint 'F5' on one side and no imprint on the other side.

Finasteride Accord 5 mg tablets are packed in opaque, white PVC/PVdC/Alu blister packaging with 7, 10, 14, 15, 20, 28, 30, 50, 60, 84, 90, 98, 100, or 120 tablets.

Not all mentioned pack sizes are marketed.

Registered under: RVG 100578

Marketing authorization holder

Accord Healthcare B.V.,

Winthontlaan 200,

3526 KV Utrecht,

Netherlands

Manufacturer

Laboratorios Normon S.A.,
Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid, Spain
Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
Netherlands

Accord Healthcare Single Member S.A.
64th Km National Road Athens, Lamia, 32009, Greece

This medicine is registered in EEA member states under the following names:

Name of the member state

Name of the medicine

Estonia Finasteride Accord 5 mg film-coated tablets

France Finasteride Accord 5 mg film-coated tablet

Ireland Finasteride 5 mg Film-coated Tablets

Italy Finasteride AHCL 5mg film-coated tablets

Latvia Finasteride Accord 5 mg film-coated tablets

Malta Finasteride 5mg Film-coated Tablets

Portugal Finasteride Accord 5mg film-coated tablets

Spain Finasteride Normon 5 mg film-coated tablets

Netherlands Finasteride Accord 5mg Film-coated Tablets

United Kingdom Finasteride 5 mg Film-coated Tablets

Bulgaria Finasteride Accord 5 mg Film-coated Tablets

Cyprus Finasteride Accord 5 mg film-coated tablets

Lithuania Finasteride Accord 5 mg film-coated tablets

Poland Finahit, 5 mg, film-coated tablets

Sweden Finasteride Accord 5 mg film-coated tablets

Slovakia Finasteride Accord 5 mg film-coated tablets

This leaflet was last approved in December 2024.