

Package leaflet: information for the user  
FINASTERIDE ACCORD 1 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 further questions? Please ask your doctor or pharmacist.

Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects not listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

### 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 Accord contains finasteride. Finasteride belongs to a group of medicines called 5-alpha reductase inhibitors.

Your doctor has prescribed this medicine because you suffer from male pattern baldness (also known as androgenetic alopecia). This medicine prevents further hair loss in men. Men with mild to moderate, but not complete hair loss, can expect to benefit from using this medicine. This medicine inhibits an important enzyme (5 $\alpha$ -reductase type 2), which is involved in the regulation of hair follicles. In the scalp, this medicine particularly lowers the concentration of DHT, a substance that significantly contributes to hair loss in men. In this way, this medicine helps to reverse the balding process and prevent further hair loss.

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

#### When should you not use this medicine?

You are a woman (because this medicine is only to be used by men, see the section 'Pregnancy'). Clinical studies have shown that this medicine does not work for hair loss in women.

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.

#### When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

## Effects on prostate-specific antigen (PSA)

This medicine can affect the results of a blood test called PSA (prostate-specific antigen). This test is used in investigations for prostate cancer. If you are having a PSA test, tell your doctor or pharmacist that you are using this medicine, as it lowers the PSA concentration.

## Effects on fertility

Infertility has been reported in men who had used finasteride long-term and who also had other risk factors that could affect fertility. After stopping finasteride, it has been reported that semen quality improved or returned to normal. No long-term studies have been conducted on the effect of finasteride on fertility in men.

## Breast cancer

See section 4.

## Mood changes and depression

Mood changes such as depressed mood, depression, and, less frequently, suicidal thoughts have been reported in patients treated with Finasteride Accord. Stop using Finasteride Accord 1 mg if you experience any of these symptoms and contact your doctor as soon as possible for medical advice.

Reduced sexual function has been reported in some patients. This may contribute to mood changes, including suicidal thoughts. If you experience symptoms of reduced sexual function, contact your doctor for further medical advice. Your doctor may consider discontinuing treatment (see section 4 below for more information on these side effects).

A patient card reminding you of the above is included with the packaging of Finasteride Accord 1 mg tablets.

## Children and adolescents under 18 years

This medicine should not be used by children. There is no data demonstrating the efficacy or safety of finasteride in children under 18 years of age.

## Are you using any other medicines?

Are you using any other medicines besides Finasteride Accord, have you done so recently, or is there a possibility that you will use 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.

## What should you pay attention to with food?

This medicine can be taken with or without food.

## Pregnancy, breastfeeding, and fertility

Finasteride Accord 1 mg is intended only for the treatment of hair loss in men. For effects on fertility, see section 2.

Women should not use Finasteride Accord 1 mg due to risk during pregnancy.

Do not touch crushed or broken Finasteride Accord 1 mg tablets if you are a woman and are pregnant or may potentially be pregnant.

If the active substance in this medicine is ingested or absorbed through the skin by a woman who is pregnant with a male baby, it may cause the boy to be born with abnormalities of the sex organs.

If a pregnant woman comes into contact with crushed or broken Finasteride Accord 1 mg tablets, consult your doctor.

The film coating of the tablets will prevent contact with the active substance during normal use, provided the tablets are not broken or crushed.

### Driving and using machines

There are no known data indicating that this medicine affects the ability to drive and use machines.

### Finasteride Accord contains lactose

This medicine contains lactose. If your doctor has told you that you are intolerant to certain sugars, contact your doctor before taking this medicine.

### Finasteride Accord contains sodium

This medicine contains less than 1 mmol (23 mg) of 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. If you are unsure about the correct use, contact your doctor or pharmacist.

The recommended dosage is one tablet of this medicine per day (equivalent to 1 mg finasteride). The film-coated tablet can be taken on an empty stomach or with food. The film-coated tablets should be swallowed whole and must not be broken or crushed.

This medicine does not work faster or better if you take it more than once a day.

Hair loss in men is a condition that develops over a long period of time. Generally, it may be necessary to use this medicine daily for 3 to 6 months before you notice an increase in hair density or a decrease in hair loss.

Your doctor will help you determine if this medicine works for you. It is important that you continue to use this medicine for as long as your doctor prescribes it.

### Patients with impaired liver function

There is no experience with the use of this medicine in patients with impaired liver function (see also 'When to be extra careful with this medicine').

### Patients with impaired kidney function

No dose adjustment is necessary for patients with impaired kidney function.

Have you taken too much of this medicine

If you have taken too much of this medicine 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 so that the medicine can be easily identified.

Have you forgotten to take this medicine?

If you have forgotten to take this medicine, you can skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine

It is recommended to continue using this medicine to achieve the maximum effect. If you stop the treatment in between, it is likely that you will lose the regained hair growth within 9 to 12 months.

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. Some of the side effects are temporary and disappear during the course of treatment or after stopping the treatment.

Stop using this medicine and contact a doctor immediately if you experience any of the following:

Symptoms of an allergic reaction: swelling of the lips, face, tongue, or throat; difficulty swallowing; hives under your skin and breathing problems.

Suicidal thoughts

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.

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

decreased libido

erectile dysfunction

ejaculation problems, including a decrease in the amount of semen during sex  
depression

Not known (frequency cannot be determined from the available data):

allergic reactions such as rash, itching, skin rash with severe itching and hives (urticaria) and swelling of lips and face

painful or swollen breasts  
testicular pain  
blood in semen  
rapid heartbeat  
persistent erectile dysfunction after discontinuation of treatment  
persistent decreased libido after discontinuation of treatment  
persistent ejaculation problems after discontinuation of treatment  
infertility has been reported in men who had used finasteride for a long time and had other risk factors that could affect fertility. After discontinuation of finasteride treatment, it has been reported that semen quality improved or became normal. No long-term studies have been conducted on the effect of finasteride on male fertility.  
changes in liver function, which can be determined by a blood test  
anxiety  
Suicidal thoughts

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. 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](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

#### 5. How should you 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. It includes a month and a year. The last day of that month is the expiry 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 destroyed in a responsible manner and will not enter the environment.

#### 6. Contents of the packaging and other information

##### What substances are in this medicine?

The active substance in this medicine is finasteride. One film-coated tablet contains 1 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 macrogolglycerides; magnesium stearate (E572).

Film coating: Hypromellose (E464); titanium dioxide (E171); macrogol 6000; red iron oxide (E172); yellow iron oxide (E172).

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

Film-coated tablet.

Finasteride Accord 1 mg film-coated tablets are reddish-brown, round, biconvex, film-coated tablets with the imprint 'F1' on one side and no imprint on the other side.

Finasteride Accord 1 mg film-coated tablets are packed in aluminum/aluminum blister packs in packages of 28, 30, 84, and 98 tablets.

Not all mentioned pack sizes are marketed.

Registered under: RVG 100577

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

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

Laboratorios Normon S.A.,  
Ronda de Valdecarrizo 6, 28760 Tres Cantos, Madrid, Spain

Accord Healthcare Polska Sp.z o.o.,  
ul. Lutomiarska 50,95-200 Pabianice, Poland

Accord Healthcare Single Member S.A.  
64th Km National Road Athens  
Lamia, Schimatari, 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 1 mg film-coated tablets
Italy	Finasteride AHCL 1 mg film-coated tablets
Latvia	Finasteride Accord 1 mg film-coated tablets
Netherlands	Finasteride Accord 1 mg film-coated tablets
Malta	Finasteride 1 mg Film-coated Tablets
Portugal	FINOX 1 mg film-coated tablets
Spain	Finasterida Normon 1 mg film-coated tablets EFG
United Kingdom	Finasteride 1 mg Film-coated Tablets
Bulgaria	Finasteride Accord 1 mg Film-coated Tablets
Cyprus	Finasteride Accord 1 mg film-coated tablets
Poland	Finahit, 1 mg, film-coated tablets
Sweden	Finasteride Accord 1 mg film-coated tablets

This leaflet was last approved in September 2025.

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