Package leaflet: Information for the user

Finasterid Stada 5 mg film coated tablet

Finasteride

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

1. What Finasterid Stada is and what it is used for

Finasterid Stada contains the active substance finasteride. Finasteride belongs to a group of medicines called 5-alpha reductase inhibitors. They act by reducing the size of the prostate gland.
Finasterid Stada is used in the treatment and control of benign enlargement of the prostate.

2. What you need to know before you take Finasterid Stada

DO NOT take Finasterid Stada
- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6),
- if you are a woman (see also ‘Pregnancy and breast-feeding’ in this section),
- if you are a child.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Finasterid Stada
- if you have reduced liver function,
- if you have difficulty emptying your bladder completely or a greatly reduced flow of urine, you should be examined by your doctor before you start taking Finasterid Stada to exclude other obstructions in the urinary tract,
- if your sexual partner is or may potentially be pregnant, you should avoid exposing her to your semen (e.g. by use of a condom) which could contain a tiny amount of the drug (see also section 2. “Pregnancy and breast-feeding”).

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.

Before starting treatment and periodically thereafter, your doctor will probably do some simple tests to exclude the possibility of prostate cancer. These may include a digital rectal examination and a blood test to check the level of PSA (prostate specific antigen).
If you need to have a blood test called “PSA”. Make sure you tell your doctor or nurse first since finasteride may alter the results of the test.

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

Other medicines and Finasterid Stada
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Finasterid Stada can normally be taken with other medicines, however, please ask your doctor before you take other medicines at the same time.

Finasterid Stada with food
Finasterid Stada can be taken with or without food.

Pregnancy and breast-feeding
Finasterid Stada is only intended for men and must not be administered to women (see also section 2 "DO NOT take Finasterid Stada").

Women who are pregnant or may become pregnant must not handle crushed or broken finasteride tablets. If finasteride is absorbed through the skin or taken by mouth by a woman pregnant with a male foetus, the child may be born with malformed genital organs.
Finasteride tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed.

If a woman who is pregnant comes into contact with crushed or broken Finasteride Stada tablets, speak to your doctor.
If your sexual partner is or may potentially be pregnant, you should avoid exposing her to your semen (e.g. by use of a condom) which could contain a tiny amount of the drug.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
There are no data to suggest that Finasterid Stada affects the ability to drive or use machines.

Finasterid Stada contains lactose and sodium
Lactose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium: This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Finasterid Stada

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 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 take more Finasterid Stada than you should
If you have taken more Finasterid Stada than you should, or if children have been taking medicine by accident, please contact your doctor or the hospital.

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

If you stop taking Finasterid Stada
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 have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

You should stop taking Finasterid Stada and see your doctor immediately if you experience symptoms of angioedema (frequency not known [frequency cannot be estimated from the available data]), such as
- **swollen face, lips, tongue, or pharynx**
- **difficulty to swallow**
- **hives**
- **difficulties to breath.**

Common (may affect up to 1 in 10 people):
- Inability to obtain an erection (impotence) and reduced sex drive (decreased libido). These side effects generally occur at the beginning of treatment and are for the most part temporary and disappear again if treatment is continued.
- Reduced ejaculatory volume.

Uncommon(may affect up to 1 in 100 people):
- Tenderness and/or enlargement of the breasts
- Difficulty obtaining ejaculation
- Rash

Very rare (may affect up to 1 in 10,000 people):
Excretion of fluid from the breasts, a lump in the breast (breast nodules).

Not known (frequency cannot be estimated from the available data):
- Increased liver enzymes
- Feeling your heartbeat (palpitation).
- Inability to obtain an erection which continue after stopping the medication.
- Male infertility and/or poor seminal quality.
- Depression
- Decrease in sex drive that continue after stopping the medication
- Testicular pain
- Itching (pruritus), hives (urticaria)
- Anxiety
- Suicidal thoughts

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Finasterid Stada

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

Do not use this medicine after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Finasterid Stada contains
- The active substance is finasteride. Each tablet contains 5 mg finasteride.
- The other ingredients are: Tablet core: lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, sodium starch glycolate (type A), sodium laurilsulfate, magnesium stearate. Tablet film coating: microcrystalline cellulose, hypromellose, macrogol (8) stearate (type I).

What Finasterid Stada looks like and contents of the pack
Finasterid Stada is a white, round, biconvex film-coated tablet printed with "F" and "5" on one side. The diameter is 7 mm.
Blister packs containing 10, 15, 20, 28, 30, 50, 50x1, 60, 90, 98, 100, 100x1, 105 and 120 tablets.
Bottles containing 30 and 100 tablets.
Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

[To be completed nationally]

Manufacturer
and
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
and
Eurogenerics NV, Heizel Esplanade b 22, 1020 Brussel, Belgium
and
Haupt Pharma Münster GmbH, Schleebrüggenkamp 15, 48159 Münster, Germany
and
STADA Arzneimittel GesmBH, Muthgasse 36/2, 1190 Wien Austria
and

Siegfried Malta Ltd., HHF070 Hal Far Industrial Estate, Hal Far BBG3000, Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Finasterid STADA 5 mg – Filmtabletten
Belgium:	Finasteride EG 5 mg filmomhulde tabletten
Denmark:	Finasterid ”Stada”
Germany:	Finasterid AL 5 mg Filmtabletten
Iceland:	Finasterid Stada 5 mg filmuhúðuð tafla
Italy:	Finasteride EG 5 mg compresse rivestite con film
Luxembourg:	FINASTERIDE - EG
Sweden:	Finasterid Stada 5 mg filmdragerad tablett

This leaflet was last revised in September 2025.