

Package leaflet: Information for the user
Finasteride Aristo 5 mg film-coated tablets
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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Finasteride Aristo is and what it is used for
2. What you need to know before you take Finasteride Aristo
3. How to take Finasteride Aristo
4. Possible side effects
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1. What Finasteride Aristo is and what it is used for

Finasteride belongs to the group of medicines called 5-alpha reductase inhibitors. They act by reducing the size of the prostate gland in men.

Finasteride Aristo is used in the treatment and control of benign (i. e., non-cancerous) enlargement of the prostate (benign prostatic hyperplasia - BPH). It reduces the risk of you developing a sudden inability to pass urine (known as acute urinary retention) and the need for surgery.

2. What you need to know before you take Finasteride Aristo

Do not take Finasteride Aristo

- if you are pregnant or may become pregnant (see also under ‘Pregnancy and breast-feeding’);
- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6).

Finasteride must not be used by women or children.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Finasteride Aristo.

Tell your doctor:

- If you have or have had a large amount of residual urine in your bladder after urinating and/or severely reduced urinary flow, you should be closely monitored for narrowing of the urinary tract.
- If you have or have had impaired liver function, the level of finasteride in your blood may be increased.
- If your sexual partner is or may potentially be pregnant, you should avoid exposing her to your semen which could contain a tiny amount of the drug.
- If you have or have had a PSA test (test used to detect prostate cancer), tell your doctor that you are taking finasteride. Finasteride can affect the blood levels of the substance being tested, PSA.

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.

Mood alterations and depression

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

Use in children

Finasteride Aristo must not be used in children. Safety and efficacy in children have not yet been established.

Other medicines and Finasteride Aristo

Finasteride does not usually interfere with other medicines. No significant drug interactions have been identified.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Finasteride Aristo with food and drink

Finasteride Aristo can be taken with or without food.

Pregnancy, breast-feeding and fertility

Finasteride Aristo must not be taken by women.

Women who are or may potentially be pregnant must not handle Finasteride Aristo tablets especially if broken or crushed. If finasteride is absorbed through the skin or taken by mouth by women pregnant with a male foetus, the child may be born with malformed genital organs. If a woman who is pregnant comes into contact with finasteride, a doctor should be consulted.

When the patient's sexual partner is or may become pregnant, the patient should either avoid exposure of his partner to semen (e. g. by use of a condom) or talk to his doctor about continuing the treatment.

Driving and using machines

There is no information to suggest that finasteride affects the ability to drive and use machines.

Finasteride Aristo contains lactose

If you have been told by your doctor that you have intolerance to some sugars contact your doctor before taking this medicinal product.

Finasteride Aristo contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Finasteride Aristo

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 tablet daily (equivalent to 5 mg finasteride).

The film-coated tablets can either be taken on an empty stomach or with a meal. The tablet should be swallowed whole and must not be divided or crushed.

Your doctor will tell you how long you should continue to take Finasteride Aristo. Do not interrupt treatment early or the symptoms may come back.

Combination therapy with doxazosin

Finasteride Aristo can be administered alone or in combination with the alpha blocker doxazosin. Your doctor will determine the dosage of doxazosin.

Patients with impaired liver function

There is no experience of the use of finasteride in patients with impaired liver function (see also 'Warnings and precautions').

Patients with impaired kidney function

No dosage adjustment is required. The use of Finasteride in patients who have to undergo haemodialysis has not been investigated yet.

Elderly patients

No dosage adjustment is required.

Please speak to your doctor or pharmacist if you feel that the effects of Finasteride Aristo is too strong or too weak.

If you take more Finasteride Aristo than you should

If you have taken more tablets than you were told to, or if someone else has taken any tablets, contact and consult your doctor immediately.

If you forget to take Finasteride Aristo

If you forget to take a dose of Finasteride Aristo, you can take it as soon as you remember unless it is time for the next dose, in which case you should continue with your medication as prescribed. Do not take a double dose to make up for a forgotten dose.

If you stop taking Finasteride Aristo

Do not stop taking Finasteride Aristo unless your doctor tells you to.

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. These effects normally occur at the start of the treatment but do not usually last long in the majority of patients if treatment continues.

Common: may affect up to 1 in 10 people

- Impotence
- libido decreased
- decreased volume of ejaculate

Uncommon: may affect up to 1 in 100 people

- rash
- ejaculation disorder
- breast tenderness
- breast enlargement
- Isolated cases of nipple discharge have been reported and lumps in the breast as part of gynecomastia have been reported, which has been surgically removed in individual patients.

Unknown: frequency cannot be estimated from the available data

- Depression
- Anxiety
- Palpitation
- Pruritus
- Urticaria
- hypersensitivity reactions such as angioedema (including swelling of lips, tongue, throat and face)
- hepatic enzymes increased

- testicular pain
 - sexual dysfunction (libido decreased, erectile dysfunction and ejaculation disorders) that continued after discontinuation of treatment
 - infertility male and/or poor sperm quality
- A normalization or improvement in sperm quality was reported after discontinuation of finasteride.

Finasteride may affect the result of PSA-laboratory test.

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 Finasteride Aristo

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton or 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 Finasteride Aristo contains

- The active substance is Finasteride. Each film-coated tablet contains 5 mg of finasteride.
- The other ingredients are:
Tablet core: lactose monohydrate, microcrystalline cellulose (PH 102), maize starch pregelatinized (1500), sodium starch glycolate (type A), docusate sodium, magnesium stearate.
Film coating: hypromellose type 2910 6cP (E464), titanium dioxide (E171), indigo carmine aluminium lake (E132), talc (E553b), iron oxide yellow (E172).

What Finasteride Aristo looks like and contents of the pack

Film-coated tablet.

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

Finasteride tablets are available in PVC/PE/PVdC-Aluminium blister packs containing 15, 28, 30, 50, 56, 60 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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