Package leaflet: Information for the user

Finasteride Aurobindo 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet:

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

1. What Finasteride Aurobindo is and what it is used for

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

The prostate gland is found underneath the bladder (but only in men). It produces the fluid found in semen. A swollen prostate gland can lead to a condition called 'benign prostatic hyperplasia' or BPH.

What is BPH?
If you have BPH it means that your prostate gland is swollen. It can press on the tube that urine passes through, on its way out of your body.
This can lead to problems such as:
- feeling like you need to pass urine more often, especially at night,
- feeling that you must pass urine right away,
- finding it difficult to start passing urine,
- when you pass urine the flow of urine is weak,
- when you pass urine the flow stops and starts,
- feeling that you cannot empty your bladder completely.

In some men, BPH can lead to more serious problems, such as:
- urinary tract infections,
- a sudden inability to pass urine (acute urinary retention),
- the need for surgery.

Finasteride Aurobindo is used in the treatment and control of benign enlargement of the prostate (benign prostatic hyperplasia - BPH). It causes regression of the enlarged prostate, improves urinary flow and symptoms caused by BPH, and reduces the risk of acute urinary retention and the need for surgery.

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

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

Do not take Finasteride Aurobindo
- if you are allergic to finasteride or any of the other ingredients of this medicine (listed in section 6)
- if you are a woman (because this medicine is for men)
- if you are a child.

Warnings and precautions
Talk to your doctor or pharmacist before taking Finasteride Aurobindo.
- if you have a large amount of residual urine and/or severely reduced urinary flow. If this is the case, you should be closely monitored for narrowing of the urinary tract.
- If you have impaired liver function, the level of finasteride in your blood may be increased.
- if you have a PSA test (test used to detect prostate cancer). Tell your doctor that you are taking Finasteride Aurobindo. Finasteride Aurobindo can affect the blood levels of the substance being tested, PSA.
- 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 and may affect the normal development of the baby's sex organs.

Consult your doctor if any of the above applies to you now or in the past.

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

Children
Finasteride Aurobindo is contraindicated in children.

Other medicines and Finasteride Aurobindo
Finasteride Aurobindo does not usually affect other medicines. Tell your doctor or pharmacist if you are taking,have recently taken or might take any other medicines, including medicines obtained without a prescription.

Finasteride Aurobindo with food and drink and alcohol
Finasteride Aurobindo can be taken with or without food.

Pregnancy, breast-feeding and fertility

Finasteride Aurobindo should not be taken by women.
Women who are pregnant or may become pregnant should not handle broken or crushed Finasteride Aurobindo 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. The tablets are film-coated, which prevents contact with finasteride provided the tablets are not broken or crushed.
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 discontinue treatment with Finasteride Aurobindo.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
As far as is known, Finasteride Aurobindo has no influence on the ability to drive or operate machinery.

Finasteride Aurobindo contains 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.

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

3. How to take Finasteride Aurobindo

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

Adults
The recommended dose is one Finasteride Aurobindo 5 mg tablet daily (equivalent to 5 mg finasteride).

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

Although early improvement may be seen, treatment for at least six months may be necessary to assess whether a beneficial response has been achieved.

Your doctor may prescribe Finasteride along with another medicine (called doxazosin) to help control your BPH.

Your doctor will tell you how long you should continue to take Finasteride Aurobindo 5 mg. Do not interrupt treatment early or the symptoms may come back.

Patients with impaired liver function
There is no experience of the use of Finasteride Aurobindo 5 mg in patients with restricted liver function.

Patients with impaired kidney function
No dosage adjustment is required (see "Adults"). The use of Finasteride Aurobindo 5 mg in patients who have to undergo haemodialysis has not been investigated to date.

Elderly patients
No dosage adjustment is required (see "Adults").
Please speak to your doctor or pharmacist if you feel that the effect of Finasteride Aurobindo 5 mg is too strong or too weak.

If you take more Finasteride Aurobindo than you should
If you take more Finasteride Aurobindo than you should or if children have been taken medicine by accident please notify your doctor or pharmacist immediately.

If you forget to take Finasteride Aurobindo
If you forget to take a dose of Finasteride Aurobindo 5 mg, you can take it as soon as you remember unless it is almost 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 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.
The following side effects may happen with this medicine:

Common (may affect up to 1 in 10 people):
- You may be unable to have an erection (impotence)
- You may have less desire to have sex
- You may have problems with ejaculation, for example a decrease in the amount of semen released during sex. This decrease in the amount of semen does not appear to affect normal sexual function.

These side effects above may disappear after a while if you continue taking Finasteride Aurobindo. If not, they usually resolve after stopping Finasteride Aurobindo.

Uncommon (may affect up to 1 in 100 people):
- Breast swelling or tenderness
- Rash
- Ejaculation problems

Unknown (frequency cannot be estimated from the available data):
- Palpitations (feeling your heartbeat)
- Changes in the way your liver is working, which can be shown by a blood test
- Pain in your testicles
- **Allergic reactions**
  If you have an allergic reaction, stop taking it and see your doctor straight away. The signs may include:
- Skin rashes, itching, or lumps under your skin (hives)
- Swelling of your lips, toungue, throat and face.
- Difficulty swallowing and breathing.
- depression, decreased libido that continued after discontinuation of treatment
- erectile dysfunction that continued after discontinuation of treatment
- Male infertility and/or poor seminal quality.Infertility has been reported in men who took finasteride for long time and had other risk factors that may affect fertility. Normalisation or improvement of seminal quality, has been reported after discontinuation of finasteride.
- Blood in semen
- in rare cases, male breast cancer
- Anxiety
- Suicidal thoughts

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

If you get any side effects , talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. It will help if you make a note of what happened, when it started and how long it lasted.

Combination treatment with doxazosin
The following side effects have been reported more frequently when Finasteride Aurobindo was used together with doxazosin, an alpha-receptor blocker: exhaustion 16.8% (placebo 7.1%), blood pressure

decrease upon standing 17.8% (placebo 8.0%), dizziness 23.2% (placebo 8.1%) and impaired ejaculation 14.1% (placebo 2.3%).

Laboratory parameters
When measuring the level of prostate-specific antigen (PSA), it must be taken into account that the PSA value is reduced in patients on Finasteride Aurobindo.

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 a ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Finasteride Aurobindo

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 carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

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 Aurobindo contains
- The active substance is finasteride. Each film-coated tablet contains 5 mg of finasteride.

The other ingredients are:
Core: lactose monohydrate, cellulose microcrystalline (grade-101), sodium starch glycolate (Type A), starch pregelatinised (maize), docusate sodium, magnesium stearate,
Film-coating: hydroxypropyl cellulose, hypromellose (6 cP), titanium dioxide (E171), talc, indigo carmine aluminium lake (E132), iron oxide yellow (E172).

What Finasteride Aurobindo looks like and contents of the pack
Film coated tablet.

Blue coloured, circular, biconvex, beveled edged film-coated tablet debossed with'E' on one side and '61' on the other side.

Finasteride Aurobindo 5 mg film-coated tablets are available in blister pack.

Pack sizes : 10, 20, 28, 30, 50, 60 and 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authourisation Holder

Aurobindo Pharma (Malta) Limited
Vault 14, Level 2, Valletta Waterfront
Floriana FRN 1913
Malta

Manufacturer

APL Swift Services (Malta) Limited
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HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

This medicine is authorised in the Member States of the European Economic Area under the following names:

Germany:	Finasterid PUREN 5 mg Filmtabletten
Malta:	Finasteride Aurobindo 5 mg film-coated tablets
Spain:	Finasterida Aurovitas 5 mg comprimidos recubiertos con película EFG
Portugal:	Finasterida Ritisca

This leaflet was last revised in 07/2025