

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

1. What Fintrid is and what it is used for

Fintrid belongs to the group of medicines, called 5-alpha reductase inhibitors. It binds to the enzyme 5-alpha reductase, thereby inhibiting the formation of the substance that plays a role in the enlargement of the prostate. As a result of this inhibition, further enlargement of the prostate is prevented. With longer term use, the enlarged prostate becomes smaller in most cases. This medicine is intended for use with men only.

Why has your doctor prescribed Fintrid?

Finasteride is a specific enzyme inhibitor that is used to treat men with benign prostatic enlargement (benign prostatic hyperplasia, BPH). Fintrid reduces the enlarged prostate and relieves urinary tract symptoms. This medicine reduces the risk of suddenly being unable to urinate (acute urinary retention) and having to undergo surgery.

2. What you need to know before you take Fintrid

Do not take Fintrid

- 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.

The condition for which Fintrid is prescribed only affects men. Women who are pregnant or potentially pregnant should not touch broken or crushed tablets (see section "Pregnancy, breastfeeding and fertility").

Warnings and precautions

Talk to your doctor or pharmacist before taking Fintrid.

- 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 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..

- if you have impaired liver function

Breast cancer

Breast cancer has been reported with finasteride. Tell your doctor immediately if you notice any of the symptoms described in section 4.

Effects on the prostate-specific antigen (PSA)

This medicine may affect the results of a blood test called PSA (prostate-specific antigen). This test is used **to detect prostate cancer**. If you have a PSA test, tell your doctor or pharmacist that you are taking this medicine because it lowers the concentration of PSA.

Effects on fertility

Infertility has been reported in men who had used finasteride for a long time and who also had other risk factors that could affect fertility. After stopping finasteride, it was reported that the seed quality became improved or normal. No long-term studies have been conducted into the effect of finasteride on male fertility.

Mood alterations and depression

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

Children

Children must not use this medicine. There are no data demonstrating the efficacy or safety of finasteride in children.

Other medicines and Fintrid

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

Fintrid does not usually affect other medicines.

Fintrid with food and drink and alcohol

Fintrid can be taken with or without food.

Pregnancy, breast-feeding and fertility

Fintrid is only intended for the treatment of benign prostate enlargement in men. For effects on fertility in men, see “Effects on fertility” above.

Women who are pregnant or may become pregnant should not handle broken or crushed Fintrid 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.

If you have any questions, contact your doctor or pharmacist.

Driving and using machines

As far as is known, Fintrid has no influence on the ability to drive or operate machinery.

Fintrid 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.

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

3. How to take Fintrid

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

Dosage:

The recommended dose is one Fintrid 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.

Your doctor may prescribe Fintrid together with another medicine, doxazosin, to help control BPH.

Adults:

Remember that it took years for your prostate to become so large that it caused these complaints. Fintrid only works against these symptoms and your condition if you continue to use it for a long time.

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

Have the effect of treatment checked regularly by your doctor.

Patients with impaired liver function

There is no experience of the use of Fintrid 5 mg in patients with restricted liver function (see also „Take special care with Fintrid 5 mg“)

Patients with impaired kidney function

No dosage adjustment is required (see “Dosage and Adults”). The use of Fintrid 5 mg in patients who have to undergo haemodialysis has not been investigated to date.

Elderly patients

No dosage adjustment is required (see “Dosage and Adults”).

Please speak to your doctor or pharmacist if you feel that the effect of Fintrid 5 mg is too strong or too weak.

If you take more Fintrid than you should

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

If you forget to take Fintrid

If you forget to take a dose of Fintrid 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:

Allergic reactions

If you have an allergic reaction, stop taking it and see your doctor straight away. The signs may include: (the frequency is not known, i.e. it cannot be estimated from the available data)

- Skin rashes, itching, or lumps under your skin (hives)
- Swelling of your lips, tongue, throat and face.

Side effects can occur with the following frequencies:

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 Fintrid. If not, they usually resolve after stopping Fintrid.

Uncommon (may affect up to 1 in 100 people):

- Breast swelling or tenderness
- Rash
- Ejaculation problems

Not known: 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
- Blood in semen
- 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.
- 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.

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 HPRC Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Fintrid

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

This medicine does not require any special storage conditions.

Do not use this medicine if you notice visible signs of deterioration.

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 Fintrid contains

- The active substance is finasteride. Each film-coated tablet contains 5mg of finasteride.
- The other ingredients are: lactose monohydrate, cellulose microcrystalline, sodium starch glycolate (Type A), starch pregelatinised (maize), docusate sodium, magnesium stearate, hydroxypropyl cellulose, hypromellose, titanium dioxide, talc, indigo carmine aluminium lake (E132), iron oxide yellow (E172).

What Fintrid 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.

Fintrid 5 mg tablets are available in PVC/PE/PVdC-aluminium foil blister packs and white opaque HDPE bottle closed with polypropylene closure.

Blister Packs: 10, 14, 15, 20, 28, 30, 45, 50, 60, 90, 98, 100 and 120 film-coated tablets.

HDPE Packs: 30, 50, 60, 90, 98, 100 and 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

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

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

Cyprus	Finasterid Aurobindo 5 mg επικαλυμμένο με λεπτό υμένιο δισκία
Germany	Finasterid Aurobindo 5 mg Filmtabletten
Denmark	Finasterid Aurobindo 5 mg filmovertrukne tabletter
France	FINASTERIDE ARROW LAB 5 mg, comprimé pelliculé
Ireland	Fintrid 5 mg film-coated tablets
The Netherlands	Finasteride Aurobindo 5 mg, filmomhulde tabletten
Poland	ADASTER
Sweden	Finasterid Aurobindo 5 mg filmdragerade tabletter

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