Package leaflet: Information for the patient

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

Fintrid is used for men to treat and control:
- **benign prostate enlargement,** which is a non-aggressive prostate growth.

Fintrid belongs to a group of medicines called 5-alpha reductase inhibitors. It reduces the size of the prostate gland, improving urinary flow and other symptoms of prostate enlargement. Fintrid decreases the risk of suddenly being unable to pass urine and needing 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)
- **female** (see also under "Pregnancy and breast-feeding")
- a **child** under 18 years

Warnings and precautions
Talk to your doctor before taking Fintrid.
Inform your doctor if any of the following apply to you:
- **difficulty emptying** your **bladder** completely or a greatly **reduced flow of urine**
  Your doctor will examine you before beginning Fintrid treatment to eliminate the possibility of other urinary tract obstructions.
- need a **blood test** for **"PSA"**, a protein produced in the prostate gland
  Tell your doctor or nurse that you take Fintrid as it may alter the test results.
- reduced **liver function**

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

Fintrid is **not known to influence** or be influenced by other medicines.

Pregnancy and breast-feeding
Fintrid **must not be used by women.**
- If your sexual partner is or may be pregnant:
  Semen can contain traces of Fintrid.
  Therefore **avoid** allowing your **semen** to come into contact **with your partner**, for example by using a condom.
- Women who are pregnant or may become pregnant should **not touch broken or crushed Fintrid** film-coated tablets.
  If Fintrid is absorbed by pregnant women, the male foetus may be born with deformed genital organs. Tablets are therefore film-coated to prevent contact with Fintrid.

Driving and using machines
Fintrid is **not known to likely affect the ability** to drive or use machines.

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.

3 How to take Fintrid

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 once daily**

Route of administration
Swallow the film-coated tablet whole with one glass of water. It may be taken with or without food, however always at the same time.

Duration of treatment
To be **decided** by your attending **doctor**.
Although an improvement is often noticed after a short time, it is necessary to continue the treatment for at least 6 months.

If you take more Fintrid than you should
Contact your doctor or pharmacist immediately.

If you forget to take Fintrid
Do not take a double dose to compensate for the forgotten dose. Just take the next dose when it is due.

If you stop taking Fintrid
Do not alter or stop treatment without your doctor's permission, as this can seriously harm you and reduce the therapy effect.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

continued on the next page >>

4 Possible side effects

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

The most frequent side effects are inability to obtain an erection and reduced sex drive. These side effects occur early in the course of therapy and resolve with continued treatment in the majority of patients.

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

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, tongue, throat and face

Side effects can occur with the following frequencies:
Common, may affect up to 1 in 10 people:
- inability to obtain an erection
- reduced sex drive
- reduced volume of ejected semen

Uncommon, may affect up to 1 in 100 people:
- tenderness and/or enlargement of the breasts
- difficulty discharging semen

Not known, frequency cannot be estimated from available data:
- testicle pain
- inability to obtain an erection that continued after discontinuation of treatment
- reduced sex drive that continued after discontinuation of treatment
- male infertility and/or poor quality of semen
- abnormally rapid or irregular heart beat
- increased level of liver enzymes
- depression

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@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 the 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.

Do not store above 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 Fintrid contains
- The **active substance** is **finasteride**. One film-coated tablet contains 5 mg of finasteride.
- The other ingredients are:

- docusate sodium
- hypromellose
- indigo carmine
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- povidone K30
- propylene glycol
- sodium starch glycolate (type A)
- talc
- titanium dioxide

What Fintrid looks like and contents of the pack
Fintrid film-coated tablets are round, blue, biconvex and approximately 8 mm in diameter.
The film-coated tablets are supplied in blister packs containing 10, 14, 15, 28, 30, 50, 50x1, 56, 60, 100 and 120 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder:
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.
Rowa Pharmaceuticals Ltd., Newtown, Bantry, Co. Cork, Ireland.
LEK S.A., ul. Domaniewska 50C, 02-672 Warsaw, Poland.

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

The Netherlands:	Finasteride Sandoz 5 mg, filmomhulde tabletten
Ireland:	Fintrid 5 mg Film-Coated Tablets
Spain:	Finasterida Sandoz 5 mg comprimidos recubiertos con pelicula EFG

This leaflet was last revised in 10/2014

I.M. L/312a 10-14
Article No