- The number of men who developed prostate cancer was lower in men taking finasteride compared with those taking nothing.
- The number of men who had a high score in a tumour grading system was higher in some of those taking finasteride compared to those taking nothing.
- The effect of long-term use of finasteride on tumours of this kind is unknown.
- If you would like further information about the tumour grading system or this trial, please talk to your doctor.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Finasteride Tablets

Keep this medicine out of the sight and reach of children.
Do not use Finasteride Tablets after the expiry date which is stated on the blister, carton or bottle. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.

Do not put the tablets into another container, they might get mixed up. Do not remove the tablet from the pack until you are ready to take it.
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 Tablets contain
The active substance is finasteride 1 mg.
The other ingredients are:
Tablet core: Lactose monohydrate, microcrystalline cellulose, pregelatinised starch, lauroyl macrogolglycerides, sodium starch gycolate (Type A) and magnesium stearate.
Tablet coating: Hypromellose, titanium dioxide (E171), yellow and red iron oxide (E172) and macrogol 6000.

What Finasteride Tablets look like and contents of the pack
Finasteride Tablets are round, biconvex reddish-brown tablets, with the markings 'F1'.

They are supplied in:
Blister packs containing 28 and 84 tablets.
Plastic bottles containing 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Relonchem Limited, Cheshire House, Gorsey Lane, Widnes, Cheshire, WA8 0RP, UK.

Product Licence Number: PL 20395/0068

POM

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PHARMACODE

Finasteride 1mg film-coated tablets

Finasteride

RelonChem

PACKAGE LEAFLET: INFORMATION FOR THE USER

The product name is Finasteride 1mg film-coated tablets which is referred to as Finasteride Tablets in this leaflet.
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may want to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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 Tablets are and what they are used for
2. What you need to know before you take Finasteride Tablets
3. How to take Finasteride Tablets
4. Possible side effects
5. How to store Finasteride Tablets
6. Contents of the pack and other information

1. What Finasteride Tablets are and what they are used for

Finasteride Tablets contain a medicine called finasteride. This belongs to a group of medicines called Type II '5-alpha reductase inhibitors'.

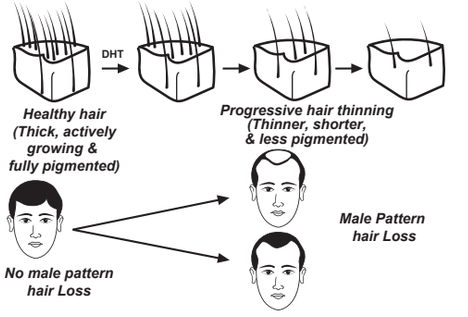
Finasteride Tablets are used for the treatment of male pattern hair loss (also known as androgenetic alopecia). Finasteride Tablets increase hair growth on the scalp and prevent further hair loss in men. Men with mild to moderate, but not complete hair loss, can benefit from using Finasteride Tablets.

How does the hair on your head grow?
On average your hair grows about 1 centimetre (half an inch) each month. Hair grows from hair follicles, which are located under your skin.
A single scalp hair grows continuously for 2-4 years (growth phase) and then stops growing for 2-4 months (rest phase).
After this the hair falls out. In its place a new healthy hair begins to grow, and the cycle is repeated. The hairs on your scalp are always in different stages of this cycle so it is normal to lose scalp hair every day.

What is male pattern hair loss?
Male pattern hair loss is a common condition in which men experience thinning of the hair on the scalp, often resulting in a receding hairline and/or balding on the top of the head. This condition is thought to be caused by a combination of genetic factors and a particular hormone, DHT (dihydrotestosterone).

DHT causes a decrease in the growth phase and thinning of the hair (see picture). This leads to male pattern hair loss. These changes can start to occur in some men in their 20s and become more common with age. Once hair loss has occurred over a long period of time, the hair may be permanently lost.

MALE PATTERN HAIR LOSS



How do Finasteride Tablets work?
Finasteride Tablets lower the levels of DHT in the scalp. This helps to reverse the balding process, leading to an increased hair growth and prevention of further hair loss.

210 mm

296 mm

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

Do not take Finasteride Tablets if:
- You are a woman (because this medicine is for men). It has been shown in clinical trials that Finasteride Tablets do not work in women with hair loss.
- You are allergic (hypersensitive) to finasteride or any of the other ingredients of this medicine (listed in section 6)
- You are already taking finasteride or dutasteride used for a prostate problem called benign prostatic hyperplasia (BPH).

Do not take Finasteride Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking Finasteride Tablets if:
- You are going to have a blood test for prostate cancer called PSA (prostate -specific antigen). This is because Finasteride Tablets can affect the result of this test.

Effects on fertility
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. Long-term clinical studies about the effects of finasteride on fertility in men have not been conducted.

Breast Cancer
See section 4.

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

Impaired sexual function that may contribute to mood alterations, including suicidal thoughts, has been reported in some patients. If you experience symptoms of impaired sexual function, contact your doctor for further medical advice. Your doctor may consider stopping the treatment (see section 4 below for more information about these side effects).

Impaired sexual function has also been reported without mood alterations or suicidal thoughts. A patient card reminding of the above is provided with the package of Finasteride.

Children and adolescents
Finasteride Tablets should not be used in children. There are no data demonstrating efficacy or safety of finasteride in children under the age of 18.

Other medicines and Finasteride Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Finasteride Tablets do not usually affect other medicines.
- Do not take Finasteride Tablets if you are already taking finasteride or dustasteride, used for a prostate problem called benign prostatic hyperplasia (BPH).
- No information is available about the use of Finasteride Tablets with minoxidil, another type of medicine for male pattern hair loss which is applied to the head.

Pregnancy, breast-feeding and fertility
Finasteride Tablets are for the treatment of male pattern hair loss in men only. For effects on fertility see section 2.

- Finasteride Tablets should not be taken by women.
- Do not touch crushed or broken Finasteride Tablets if you are a woman who is pregnant or planning to become pregnant (whole tablets are coated to stop contact with the medicine during normal use). This is because this medicine may affect the baby's sex organs.
- If a woman who is pregnant comes into contact with crushed or broken Finasteride Tablets, speak to your doctor.

Driving and using machines
Finasteride Tablets are not likely to affect you being able to drive, use tools or machines.

Finasteride Tablets contain 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.

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

3. How to take Finasteride Tablets

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

- The recommended dose is one tablet each day. The tablet can be taken with or without food.

If you take more Finasteride Tablets than you should
If you take too many tablets by mistake, contact your doctor immediately. Finasteride Tablets will not work faster or better if you take them more than once a day.

If you forget to take Finasteride Tablets
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Finasteride Tablets
It may take 3 to 6 months for the full effect to develop. It is important to keep taking Finasteride Tablets for as long as your doctor tells you. If you stop taking Finasteride Tablets, you are likely to lose the hair you have gained within 9 to 12 months.

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. Some of the side effects are temporary with continued treatment or disappear when treatment is stopped.

Stop taking Finasteride Tablets and talk to your doctor immediately if you have any of the following:
- Symptoms of an allergic reaction: swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties
- Depression (feelings of severe sadness and unworthiness)
- 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.

Uncommon: may affect up to 1 in 100 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.
- Depression.

Not known: frequency cannot be estimated from the available data
- Breast swelling or tenderness
- Palpitations (feeling your heartbeat)
- Changes in the way your liver is working, which can be shown by a blood test
- Pain in the testicles
- Blood in semen
- Persistent difficulty having an erection after discontinuation of treatment
- Persistent decrease in sex drive after discontinuation of treatment
- Persistent problems with ejaculation after discontinuation of treatment
- Male infertility and/or poor quality of semen
- Anxiety
- Suicidal thoughts.

If any of these side effects gets serious, or if you notice any side effects not listed on this leaflet please tell your doctor or pharmacist. It will help if you make a note of what happened, when it started and how long it lasted.
Will the use of Finasteride Tablets affect the hair on other parts of your body?
Finasteride Tablets do not affect hair on other parts of the body.

What else should you know about Finasteride Tablets?
Finasteride can also be used for a type of prostate problem called 'benign prostatic hyperplasia' or BPH. Information collected from a clinical trial in men taking finasteride 5 mg (a dose 5 times higher than Finasteride Tablets) for 7 years showed:

210 mm
296 mm