

problem called 'benign prostatic hyperplasia' or BPH. Information collected from a clinical trial in men taking finasteride 5 mg (a dose 5 times higher) for 7 years showed:

- 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 Website: 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.
- This medicinal product does not require any special temperature storage conditions
- 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 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 contains

- The active substance is finasteride. Each film-coated tablet contains 1 mg of finasteride.

- The other ingredients are lactose monohydrate, maize starch pregelatinised, docusate sodium, iron oxide yellow (E172), sodium starch glycollate, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, opadry pink (consists of hypromellose, hydroxypropyl cellulose, talc, titanium dioxide (E171), iron oxide red and yellow (E172))

What Finasteride Tablets looks like and contents of the pack

- Finasteride Tablets are red, round, biconvex film-coated tablets, marked with 'BL1' on one side and plain on the other side
- Finasteride Tablets is available in packs of 7, 28, 30, 84 or 98 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Finasteride 1 mg film-coated tablets; PL 17907/0497

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To request a copy of this leaflet in Braille, large font or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.

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Package leaflet: Information for the patient

Finasteride 1 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, 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 contains a medicine called finasteride. This belongs to a group of medicines called Type II '5-alpha reductase inhibitors'.

Your doctor has prescribed Finasteride because you have male pattern hair loss (also known as androgenetic alopecia). Finasteride increases hair growth on the scalp and prevents further hair loss in men. Men with mild to moderate, but not complete hair loss, can benefit from using Finasteride.

How does the hair on your head grows?

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. 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.

How does Finasteride Tablets work?

This medicine lowers 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.

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

Do not take Finasteride Tablets if:

- you are allergic (hypersensitive) to finasteride or any of the other ingredients (listed in Section 6)
- you are a woman (because this medicine is for men). It has been shown in clinical trials that this medicine does not work in women with hair loss

- you are a child or adolescent.
- If you are already taking finasteride 5mg or dutasteride used for a prostate problem called benign prostatic hyperplasia (BPH).

Do not take finasteride tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor, pharmacist or nurse 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 can affect the result of this test.
- **Mood alterations and depression:** Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with Finasteride 1mg. If you experience any of these symptoms stop taking Finasteride 1mg and contact your doctor for further medical advice as soon as possible.
- **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.
- **Children and adolescents:** Finasteride 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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This medicine does not usually affect other medicines.

- Do not take this medicine if you are already taking finasteride or dutasteride, used for a prostate problem called benign prostatic hyperplasia (BPH).
- No information is available about the use of this medicine with minoxidil, another type of medicine for male pattern hair loss which is applied to the head.

Finasteride Tablets with food, drink and alcohol

This medicine can be taken with or without food.

Pregnancy, breast-feeding and fertility

This medicine is for the treatment of male pattern hair loss in men only. For effects on fertility see section 2.

- This medicine should not be taken by women.
- Do not touch crushed or broken 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 tablets, speak to your doctor.
- If your sexual partner is or could be pregnant, you must avoid exposing her to your semen, which could contain a small amount of finasteride – for example by using a condom during sexual activity.

Driving and using machines

Driving and using machinery is not known to be affected by this medicine.

Finasteride Tablets contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.

Adults: The recommended dose is one tablet each day with or without food.

The tablets should be **swallowed whole** and **must not be crushed or divided**.

- Finasteride 1 mg Tablets will not work faster or better if you take them more than once a day.
- Male pattern hair loss is a condition that develops over a long period of time. In general,

daily use for three to six months may be necessary before you notice any increase in the hair density or reduction in hair loss.

- Your doctor will help you to assess if Finasteride 1 mg Tablets are working. It is important to continue taking Finasteride 1 mg Tablets for as long as your doctor prescribes them.

Patients with renal or hepatic impairment:

Usually no dose adjustment is needed and the same dose as for other adults should be used.

If you take more Finasteride Tablets than you should

If you take more of this medicine than you should, talk to a doctor straight away.

This medicine will not work faster or better if you take it more than once a day.

If you forget to take Finasteride Tablets

If you forget to take a dose, just take your next dose as normal. **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 this medicine for as long as your doctor tells you. If you stop taking this medicine, 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.

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.

Stop taking this medicine, and see your doctor straightaway, if you notice any symptoms of allergic reaction which may include:

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

- difficulty swallowing
- breathing difficulties
- Depression (feeling of severe sadness and unworthiness)

The side effects have usually been temporary with continued treatment or disappeared when treatment is stopped.

Uncommon (may affect up to 1 in 100 people)

- less desire to have sex
- difficulty having an erection (impotence)
- problems with ejaculation such as 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

Frequency unknown (cannot be estimated from the available data)

- hypersensitivity reactions, including swelling of the lips, tongue, throat and face
- breast swelling or tenderness
- pain in the testicles
- fast heart beat (palpitations)
- 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.
- change in the way your liver is working, which can be shown by a blood test (elevated liver enzymes)
- 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 1mg tablets affect the hair on other parts of your body?

Finasteride 1mg tablets does not affect hair on other parts of the body.

What else should you know about Finasteride 1mg Tablets?

Finasteride can also be used for a type of prostate xxx