

- The effect of long term finasteride use on these types of tumors is not known.

For obtaining information on the tumor grading system or this study, please consult your doctor.

If you notice any side effect not listed in this patient information leaflet, inform your doctor or pharmacist.

Reporting of side effects

Talk with your doctor, pharmacist or nurse if you experience any side effect that is included or not included in this patient information leaflet. Also, report the side effects you have encountered, to Turkish Pharmacovigilance Center (TUFAM) via clicking “Drug Side Effect Report” icon on www.titck.gov.tr or via calling the side effect report line on 0800 314 00 08. By reporting experienced side effects, you will be contributing in obtaining more information regarding the safety of your drug.

5. How to store FINASTIV

FINASTIV is sensitive to humidity. Keep in the original package.

Store FINASTIV by keeping it out of the reach and sight of children in its original package.

Do not put tablets in another container, there is a possibility of mixing with other medicines. Do not remove the tablet from the package until you are ready to take it.

Store at room temperature betweenm 15-30°C.

Use in line with the expiry date.

Do not use FINASTIV after the expiry date which is stated on the packaging.

Do not throw away drugs that have expired or are not being used! Give them to the collection system determined by the Ministry of Environment and Urbanism.

Do not use FINASTIV if you notice any failure / defect in the product and / or packaging.

Distributed by:

BioActiveT Pharma, UNITED KINGDOM.

PATIENT INFORMATION LEAFLET

FINASTIV 1 mg film coated tablet
It is taken orally.

- **Active substance:** Each film coated tablet contains 1 mg finasteride.

- **Excipients:** Lactose monohydrate, pregelatinized starch, sodium starch glycolate, docusate sodium, microcrystalline cellulose, povidone, magnesium stearate, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, titanium dioxide (E171), talc, yellow ferric oxide (E172) and red ferric oxide (E172).

Read this LEAFLET carefully before you start to use the medicine. It contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please consult your doctor or pharmacist.*
- *This medicine is prescribed for you personally. Do not give it to others.*
- *During the use of this medicine, when you visit a doctor or a hospital, tell your doctor that you are using this medicine.*
- *Follow the directives in this leaflet strictly. Do not use **higher or lower** dose of the medicine than the one recommended to you.*

In this patient information leaflet:

- 1. What FINASTIV is and what it is used for**
- 2. What you need to know before you take FINASTIV**
- 3. How to take FINASTIV**
- 4. Possible side effects**
- 5. How to store FINASTIV**

Topics are included.

1. What FINASTIV is and what it is used for

FINASTIV is presented in blister packages containing 30 film coated tablets. FINASTIV is a brown, round, biconvex, film coated tablet. Each film coated tablet contains 1 mg finasteride.

FINASTIV belongs to a group of drugs known as testosterone 5-alpha-reductase inhibitors.

FINASTIV is only used in males for the treatment of mild to moderate male pattern hair loss (also known as androgenic alopecia). FINASTIV increases the growth of hair on the scalp of men and prevents more hair loss. It is not effective on women and on men with complete hair loss. FINASTIV does not have an indication for use on women and on children. **USED ONLY ON MEN.**

How does your hair grow?

Your hair grows approximately 1 cm every month. Hair grows from the hair follicles that are under your skin.

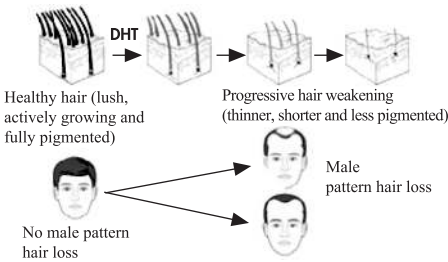
Each hair strand on the scalp grows continuously for 2-4 years (growth phase) and then its growth stops for 2-4 months (resting phase). Afterwards, hair falls out. New healthy hair grows instead of it and this cycle is repeated. Your hair is always on different phases of this cycle; therefore, it is normal for hair to shed every day.

What is male pattern hair loss?

Male pattern hair loss is a common condition in men in which hair is weakened and generally hair line is withdrawn and/or top of the head has gotten bald. It is thought that this condition is due to the combination of genetic factors and a certain hormone (DHT: dihydrotestosterone).

DHT causes the shortening of growth phase of hair and the weakening of hair (see figure). This condition causes male pattern hair loss. These changes can be firstly observed in men in their twenties and they become more common as their age increases. If shedding of hair continues for a long time, loss of hair can be permanent.

MALE PATTERN HAIR LOSS



How does FINASTIV shows its effect?

FINASTIV reduces DHT levels on the hairy scalp. This decrease helps the reversal of balding period. As a result, hair growth increases and more hair loss is prevented.

2. What you need to know before you take

FINASTIV
DO NOT USE FINASTIV in following conditions

If;

- You are allergic (hypersensitive) to finasteride or any ingredients of the drug,
- You are a woman (since this drug is only for men). It is shown in clinical trials that FINASTIV does not have an effect on women with hair loss.
- You are taking finasteride or dutasteride for a prostate condition called benign prostatic hyperplasia (BPH).

Take FINASTIV with special care in the following conditions

If;

- You need to take a blood test for prostate cancer (prostate specific antigen PSA test), tell your doctor that you are taking this drug since FINASTIV can affect the result of the test.

Please consult your doctor if these cautions apply to you even for any time in the past.

Taking FINASTIV with food and drinks
FINASTIV can be taken with or without food.

Pregnancy
Please consult your doctor or pharmacist before using the medicine.

FINASTIV is only intended for men and for male pattern hair loss.

- FINASTIV should not be used on women.
- FINASTIV should not be used on children.
- Women who are or may potentially be pregnant should not handle FINASTIV tablets especially if broken or crushed (tablets are coated to prevent contact with the drug during normal use); because it is possible for the drug to affect the genital organs of the baby.
- If a pregnant woman touches to broken or crushed FINASTIV tablets, she should talk to her doctor.

Breast-feeding
Consult your doctor or pharmacist before using this medicine.

FINASTIV is only used on men.

Driving and using machines
For FINASTIV, it is a low possibility affect the ability to drive and to use tools and machines.

Important information about some of the ingredients of FINASTIV
Each tablet contains 110.4 mg of lactose monohydrate. If you have been told by a doctor previously that you have intolerance to some sugars or you cannot digest some sugars (intolerance), contact your doctor before taking this drug.

Taking with other medicines
No information is available on the use of FINASTIV together with topical (applied to the skin) minoxidil in male pattern hair loss.

If you are taking medicines such as finasteride or dutasteride for a prostate condition called benign prostatic hyperplasia (BPH), do not use FINASTIV.

Please tell your doctor or pharmacist if you are using or have recently used any prescribed or non-prescribed medicine.

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

Instructions for proper use and dose/dosing intervals:

- The recommended dose is one FINASTIV 1 mg tablet daily.
- It will not work faster or better if you take them more than once a day.

Administration route and method:

- FINASTIV is taken only for oral use.
- It can be taken on empty or full stomach.
- Take tablets with sufficient amount of water without chewing (e.g., with a glass of water).

Different age groups:
Use in children:
FINASTIV should not be used on children. There is no study showing efficacy or safety in children under 18 years of age.

Use in the elderly:
There is no need for dose adjustment on the elderly.

Special Conditions:
Renal failure, liver failure:
There is no need for a special dose adjustment in patients with renal failure. Care should be taken upon FINASTIV administration on patients with

hepatic failure.

If you have any impression that the effect of FINASTIV is too strong or too weak, consult your doctor or pharmacist.

If you took more FINASTIV than you should
If you have any impression that the effect of FINASTIV is too strong or too weak, consult your doctor or pharmacist.

If you forget to take FINASTIV
Please try to use FINASTIV in the way your doctor has prescribed.
If you forget to take a dose, just carry on with the next one as usual.
Do not take a double dose to make up for a forgotten dose.

Possible effects when treatment with FINASTIV is terminated:
It can take 3-6 months for the drug to show its full effect. It is important for you to carry on taking FINASTIV as long as the period that your doctor prescribed for you.

If you stop taking FINASTIV, you are likely to lose the hair you have gained, within the next 9 to 12 months.

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

4. Possible side effects
Like all medicines, FINASTIV can cause side effects, although not everybody gets them.

Allergic reactions that occur suddenly.

If the symptoms of an allergic reaction occurs, stop taking FINASTIV and consult your doctor immediately.

- Blisters under your skin (urticaria)
- Swelling on face, lips, tongue or throat
- Difficulty in swallowing
- Difficulty in breathing

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

- Difficulty having an erection(ejaculation) (impotence)
- Less desire to have sex
- Ejaculation problems (e.g., decrease in the amount of sperm secreted during sex). Decrease in the amount of semen does not affect normal sexual function.

Side effects mentioned above can disappear while FINASTIV administration is continued. Even they continue, side effects are generally disappeared when FINASTIV treatment is terminated.

- Side effects of which frequency is unknown are:
- Sensitivity or swelling on breasts
 - Palpitation (feeling your heartbeat)
 - Changes in liver function (can be understood with a blood test)
 - Pain in testicles
 - Having permanent difficulties in achieving erection after the termination of treatment
 - Continuation of less desire to have sex after stopping the treatment
 - Continuation of ejaculation problems after stopping the treatment
 - Infertility and /or low semen quality in men
 - Depressive mood

If you observe any change in breast tissue (mass, pain, growth in breast or discharge from nipples), you should inform your doctor immediately since these can be symptoms of a serious condition such as breast cancer.

If you encounter any side effect that is not included in this leaflet or any of the side effects becomes serious, please inform your doctor or pharmacist. It will be helpful to note down when these effects are started, for how long they continued and what you experienced.

Does FINASTIV administration affect hair on other parts of the body?
FINASTIV does not affect hair on other parts of the body.

What more do I need to know about FINASTIV?
Finasteride can also be used for a type of prostate condition called "benign prostatic hyperplasia" (BPH). Information obtained from a clinical trial performed on men using finasteride 5 mg (5 times of the dose FINASTIV contains) has shown that:

- Number of men who have developed prostate cancer is less for men using finasteride compared to men who does not use any drugs.
- Number of men who have gotten a high score on tumor grading system is higher in some of men using finasteride compared to men who does not use any drugs.