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Romanian National Authority of Medicines and Medical Devices
Finasteride Leaflet
Permission number: 9711/2017/01

Leaflet: Information for the Consumer
Finasteride 1 mg film-coated tablets

Read the entire leaflet carefully before you start taking the medicine because it contains important information for you.

- Keep this leaflet. You might need to read it again
- If you have any additional questions ask your doctor or pharmacist
- This medicine is prescribed only to you. Do not recommend it to other people. It might harm them regardless of the similarity of their symptoms to yours.
- If you experience any adverse reactions, inform your doctor or pharmacist. This includes all adverse reactions not described in this leaflet. Check point 4.

What this leaflet contains:

1. What is finasteride 1 mg film-coated tablets and what is it used for
2. What do you have to know before you take finasteride 1 mg film-coated tablets
3. How to take finasteride 1 mg film-coated tablets
4. Possible adverse reactions
5. How to store finasteride 1 mg film-coated tablets
6. Package content and additional information

1. What is finasteride 1 mg film-coated tablets and what is it used for

Finasteride 1 mg film-coated tablets contains finasteride. Finasteride belongs to a group of medicines called 5 α -reductase inhibitors.

Your doctor prescribed you finasteride 1 mg film-coated tablets because you have male pattern baldness (also known as androgenic alopecia). finasteride 1 mg film-coated protects against further hair loss in men. Men with mild to medium, but not full baldness, can benefit by the usage of Finasteride 1 mg film-coated tablets. Finasteride 1 mg film-coated tablets block an important enzyme (type II 5 α -reductase) that participates in the hair follicle regulation.

Finasteride 1 mg film-coated tablets specifically decrease the dihydrotestosterone (DHT) level in the scalp, the main reason for male pattern baldness. In this way finasteride 1 mg film-coated tablets help to stop the baldness process and to prevent further hair loss.

2. What you must know before you take finasteride 1 mg film-coated tablets

Do not take finasteride 1 mg:

- If you are allergic to finasteride or any of the other ingredients in this medicine (they are listed in point 6).
- If you are a child or youth.

If you are a woman (see section below: “Pregnancy, breastfeeding and fertility”).

- During the clinical trials, it was concluded that finasteride 1 mg film-coated tablets is not effective in hair loss treatment (androgenic alopecia) in women.
- If you are already taking finasteride or any other 5 α -reductase inhibitor to treat benign prostatic hyperplasia or any other condition.

Warnings and precautions

- Talk to your doctor or pharmacist before you take finasteride 1 mg film-coated tablets.
- Before starting treatment and during the patients’ therapy with finasteride, determination for the prostate-specific antigen (PSA) in the serum must be performed.
- finasteride may affect male fertility. Patients that are planning to have a child must consider stopping the treatment.

Mood swings and depression

Mood swings such as depressive mood, depression and, rarely, suicide thoughts, have been reported in patients treated with Finasteride 1 mg film-coated tablets. If you have any of these symptoms, stop taking Finasteride 1 mg film-coated tablets and contact your doctor as soon as possible for additional medical help.

Other medicine and Finasteride 1 mg film-coated tablets

Inform your doctor or pharmacist if you take or recently have been taking or if it is possible that you are taking other medicine. Finasteride 1 mg film-coated tablets usually does not interact with other medicines.

There is no available information regarding the simultaneous usage of finasteride 1 mg film-coated tablets and topical minoxidil (applied on the skin) in male pattern baldness. This combination is not recommended.

Finasteride 1 mg film-coated tablets intake with food and beverages.

Finasteride 1 mg can be taken with or without food.

Pregnancy, breastfeeding and fertility

Finasteride 1 mg film-coated tablets are intended only for men. Women, who are pregnant or have the possibility of becoming pregnant, must not touch broken tablets that contains finasteride. If finasteride is absorbed by the skin or is being taken orally by a pregnant woman with a male baby, the baby might be born with deformed genitals.

When the intimate partner of the patient is pregnant or has the possibility of becoming pregnant, it is recommended that the patient reduce her contact to his semen to a minimum (for example, with the use of a condom) or to stop the treatment with finasteride.

Driving and working with machines

There is no data suggesting that finasteride 1 mg film-coated tablets influences the ability to drive or work with machines.

Important information regarding some ingredients of finasteride 1 mg film-coated tablets

This medical product contains lactose. If your doctor has told you that you have intolerance to some sugars, contact them before beginning to take this medicine.

3. How to take finasteride 1 mg film-coated tablets

Always take the medication exactly the way your doctor has told you. If you are unsure about something, ask your doctor or pharmacist.

The recommended dose is one tablet of finasteride 1 mg daily (that equals 1 mg finasteride). The film-coated tables can be taken on empty stomach, or with food. The film-coated tablets must be swallowed whole and they must not be divided or broken.

- Finasteride 1 mg film-coated tablets will not have faster or stronger effect if they are taken more than once daily.
- Male pattern baldness is a condition that develops over a long period of time. Most often it is necessary to use daily for 3 to 6 months before noticing any hair growth increase or hair loss decrease.
- Your doctor will help you to evaluate whether finasteride 1 mg film-coated tablets have any effect. It is important to continue taking Finasteride 1 mg film-coated tablets as long as your doctor has prescribed to you.

Patients with impaired liver functions

There is no data for the usage of finasteride 1 mg film-coated tablets in patients with impaired liver function.

Patients with impaired kidney functions

There is no need for dosage change in patients with impaired kidney functions.

If you have taken more than the needed dose of finasteride 1 mg film-coated tablets

If you have taken more than the needed dose of finasteride 1 mg film-coated tablets or anyone else has taken finasteride 1 mg film-coated tablets, immediately contact the emergency ward of your nearest hospital. Show the doctor the rest of the tablets and your medicine package.

If you have missed taking finasteride 1 mg film-coated tablets

If you forget to take a dose from finasteride 1 mg film-coated tablets, just take the next dose as usual. Do not take double dose to compensate for the missed one.

If you have stopped taking finasteride 1 mg film-coated tablets

In order to achieve maximum effect, continued use of finasteride 1 mg film-coated tablets is recommended. If, meanwhile, you stop the treatment, in the next 9 to 12 months you will lose the hair that you have acquired.

If you have any questions regarding the usage of this medicine, ask your doctor or pharmacist.

4. Possible adverse reactions

As with every medicine, this medicine can cause adverse reactions despite the fact that not everyone experiences them. Some of the adverse reactions are temporary during the treatment or disappear when you stop the treatment.

Stop finasteride 1 mg film-coated tablets and immediately contact a doctor if you develop any of the following:

- Allergic reaction symptoms, such as swelling of the lips, face, tongue, throat; experience difficulty in swallowing, rash (hives) and difficulty in breathing
- Depression (feeling of strong sadness and low self-esteem).

You must immediately inform your physician for any change in your breast tissue, such as lumps, breast enlargement, nipple secretion as this could be a sign of a serious disease, such as breast cancer.

Uncommon (can affect between 1 and 100 people)

- lower libido;
- erection difficulties;
- ejaculation problems, such as decrease in the ejected semen during sex
- depression

Unknown frequency

- allergic reaction, such as rash, itching, hives, lips and face swelling;
- breast pain and swelling;
- palpitations;
- testicle pain;
- increased heart rate;
- permanent erectile dysfunction after stopping the treatment;
- permanent decrease in libido after stopping the treatment;
- permanent ejaculation problems after stopping the treatment;
- there is data for infertility in men who have taken finasteride for a continued long period and have also had other risk factors that might have affected fertility. Normalization and improvement in the semen quality was reported after stopping the treatment with finasteride. Long-term clinical trials on finasteride's effect on men's fertility rate have not been done.
- Changes in the liver function that can be detected in blood tests
- Anxiety

Reporting adverse reactions

If you develop any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report adverse reactions directly through the national reporting system, details of which are published on the National Agency for Medicines and Medical Devices website <http://www.anm.ro/>. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Finasteride 1 mg film-coated tablets

- Keep out of reach of children.

- this medicinal product does not require special storage conditions.
- Do not use Finasteride 1 mg film-coated tablets if expired after the date marked on the packaging. The expiration day is the last day of the indicated month.
- These medicines must not be thrown down a drain or into regular trash bins. Ask your pharmacist how to dispose of the medicine that you are no longer using. This measure will help to keep the environment clean.

6. Package content and additional information

What finasteride 1 mg film-coated tablets contain

The active ingredient is finasteride. One film-coated tablet contains 1 mg finasteride.

Other ingredients are:

Tablet's core: lactose monohydrate, microcrystalline cellulose (E460); pregelatinised starch, sodium starch glycolate (type A); lauryl microglycerides, magnesium stearate (E570)

Film coat: Hypromellose (E464), titanium dioxide (E 171), macrogol 6000, red iron oxide (E172), yellow iron oxide (E172)

What do Finasteride 1 mg film-coated tablets look like and what does the package contain:

Film-coated tablet.

Finasteride 1 mg are reddish-brown, round-shaped, with a sign "F1" from one side and without a sign on the other side.

Finasteride 1 mg tablets are packed in blisters aluminum-aluminum, in 28, 30, 84 or 98 package tablets.

Marketing Authorization Holder

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This leaflet was last updated in October 2021.