

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

ProAvenir film-coated tablets 1 mg

For use in men only

Active ingredient

Each tablet contains: finasteride 1 mg

For a list of the inactive ingredients, see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

- **This medicine is intended for use in men only and should not be used by women or children.**

ProAvenir contains the active ingredient finasteride, which belongs to a group of medicines called type II 5 α -reductase inhibitors. Men with partial, but not complete, baldness may benefit from use of this medicine.

The hair grows on the scalp in cycles - continuous growth for 2-4 years (growth stage), followed by a 2-4 month break (rest phase), after which the hair falls out and in its place renewed growth begins. The hair on the scalp is always in different stages of the growth cycle and, therefore, daily hair loss is natural.

Male hair loss pattern is manifested by thinning of the hair, which often causes recession of the hair line and/or balding at the front of the head. This results from a combination of genetic factors and the DHT (dihydrotestosterone) hormone.

The DHT hormone leads to decreased growth phase and to thinning of the hair, an effect which can already begin in certain men in their twenties. Hair loss that is left untreated for a long time may become permanent.

ProAvenir lowers the DHT hormone levels, thereby facilitating termination of the balding process and increased hair growth.

1. What is this medicine intended for?

ProAvenir is indicated for the treatment of men with male pattern hair loss (androgenetic alopecia) to increase hair growth and prevent further hair loss.

ProAvenir is intended for use in men only and should not be used by women or children.

Therapeutic group

5 α -reductase inhibitor.

2. Before using the medicine

2.1 Do not use this medicine if:

- You are a woman (because this medicine is for men). It has been shown in clinical trials that the medicine does not work in women with hair loss.
- You are sensitive (allergic) to finasteride or to any of the other ingredients of this medicine (for a list of inactive ingredients, see section 6).
- You are already taking finasteride or dutasteride used for a prostate problem called benign prostatic hyperplasia (BPH).

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

2.2 Special warnings about using this medicine

Before using ProAvenir, tell your doctor if:

- You suffer or have previously suffered from impaired function of the liver or if you suffer or have previously suffered from allergies.
- You are going to have a blood test for prostate cancer called PSA (prostate-specific antigen). This is because the medicine can affect the result of this test.

Breast cancer

See section 4 'Side effects'.

Mood alterations and depression

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

Children and adolescents

ProAvenir should not be used in children.

There is no information demonstrating efficacy or safety of finasteride in children under the age of 18.

2.3 Drug interactions

If you are taking or recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist in order to prevent hazards or lack of efficacy arising from drug interactions.

ProAvenir does not usually affect other medicines.

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

2.4 Using this medicine and food

ProAvenir can be taken with or without food.

2.5 Pregnancy, breastfeeding and fertility

ProAvenir is for the treatment of male pattern hair loss in men only.

- **ProAvenir should not be taken by women.**
- **Women who are or may potentially be pregnant must not use ProAvenir.**

Do not touch crushed or broken ProAvenir 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 ProAvenir tablets, she should speak to her doctor.

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.

2.6 Driving and using machines

ProAvenir is not likely to affect you being able to drive, use tools or dangerous machines or activity requiring alertness.

2.7 Important information about some of this medicine's ingredients:

ProAvenir contains lactose, which is a disaccharide composed of glucose and galactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

- **The recommended dosage is usually** one tablet by mouth, each day.

Do not exceed the recommended dose.

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

- **How to use** - Take the medicine with a small amount of water. With/without food. No information is available regarding crushing/splitting/chewing of the tablets.

- **Length of treatment** - it may take 3-6 months to obtain the full effect of the medicine. It is important to continue the treatment according to the doctor's instructions. ProAvenir can only work over the long term if you continue taking it. If the medicine has not affected you within 12 months, further treatment is unlikely to be of benefit.

ProAvenir is not effective in the treatment of hair loss (androgenetic alopecia) in postmenopausal women.

If you take more ProAvenir than you should

If you have taken an overdose or if a child has accidentally swallowed some medicine, go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, skip this tablet and take the next tablet at the usual time. Do not take a double dose to make up for the forgotten tablet.

How can you contribute to the success of the treatment?

Complete the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

You will likely lose the hair that has grown within 9-12 months of stopping treatment. You should discuss this with your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines using ProAvenir may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Stop treatment with ProAvenir and contact your doctor immediately if you experience:

- Symptoms of an allergic reaction: swelling of your lips, face, tongue and throat; difficulty swallowing; lumps under your skin (hives) and breathing difficulties. Stop taking **ProAvenir** and talk to your doctor immediately.
- Depression (feeling of severe sadness and unworthiness).

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 side effects: 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

Side effects of unknown frequency:

- 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

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Will the use of this medicine affect the hair on other parts of your body?

Clinical studies have shown that the medicine does not affect hair on other parts of the body.

What should you know when you take ProAvenir?

ProAvenir can also affect a blood test called PSA (prostate specific antigen) used to test for prostate cancer. If you are undergoing a PSA test, inform your doctor(s) that you are taking ProAvenir, since ProAvenir causes a decrease in PSA levels. Changes in PSA levels must be assessed by your doctor(s). When monitoring PSA levels, any rise from their lowest values may indicate presence of prostate cancer and must be assessed, even if the test results are within the normal range for men who are not taking ProAvenir. In addition, inform your doctor if you are not taking ProAvenir as prescribed, since this can impact the PSA test results. For further information, refer to your doctor.

There may be an increased risk of more severe prostate cancer in men taking finasteride at a dose 5 times higher than ProAvenir.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the (exp. date) which is stated on the carton and label. The expiry date refers to the last day of that month.
- **Storage conditions:**
Store below 25°C.
Store in the original package.

6. Additional information

- 6.1 What ProAvenir contains?
- **In addition to the active ingredient, this medicine also contains** -
Lactose monohydrate, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate, magnesium stearate, lauroyl macrogolglycerides, opadry 03F34739 Pink.
- 6.2 **What the medicine looks like and contents of the pack**
ProAvenir contains film-coated, red-brown, biconvex tablets, with "F1" embossed on one side and the other side smooth. The medicine is provided in packs of 28, 30 and 98 tablets in blister packs.
- **Registration holder and importer**
BioAvenir Ltd.
1 David Hamelech, Herzeliya Pituach 4666101.
- **Manufacturer**
Intas Pharmaceuticals Ltd., Ahmedabad, India.
- Revised in March 2021 according to MOH guidelines.
- Registration number of the medicine in the Ministry of Health's National Drug Registry: 150 83 33638.