

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

**- 1986**

This medicine is dispensed with a doctor's prescription only

**ProAvenir**  
**film-coated tablets**

Each film-coated tablet contains:  
finasteride 1 mg

For a list of the inactive ingredients, see section 6 'What ProAvenir contains?'. See also section 2.6 'Important information about some of this medicine's ingredients'.

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

- This leaflet contains concise information about **ProAvenir**. 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.**

**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.

**Therapeutic group:** 5 $\alpha$ -reductase inhibitor.

**2. Before using the medicine**

**2.1 Do not use this medicine if:**

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| <ul style="list-style-type: none"><li>- You are a woman (because this medicine is for men). It has been shown in clinical trials that <b>ProAvenir</b> does not work in women with hair loss.</li><li>- 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).</li><li>- You are already taking finasteride or dutasteride used for a prostate problem called benign prostatic hyperplasia (BPH).</li></ul> |
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Do not take **ProAvenir** 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 ProAvenir**

Before using **ProAvenir**, tell your doctor if:

You are going to have a blood test for prostate cancer called PSA (prostate-specific antigen). This is because **ProAvenir** 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 **ProAvenir**. 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 have 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 for application 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 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 prevent 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 Important information about some of this medicine's ingredients

**ProAvenir** contains 95.6 mg lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**ProAvenir contains sodium.**

This medicine contains less than 1 mmol sodium (7.5 mg) per tablet, that is to say essentially 'sodium-free'.

### 2.7 Driving and using machines

**ProAvenir** is not likely to affect your ability to drive, use tools or machines.

## 3. How to use this medicine?

Always use **ProAvenir** 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.

Swallow the medicine with a small amount of water, with or without food.

No information is available regarding crushing/splitting/chewing the tablets.

See also section 2.5 'Pregnancy, breastfeeding and fertility'.

**Do not exceed the recommended dose.**

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

You may need to take **ProAvenir** daily for three months or more before you see a benefit from taking **ProAvenir**. **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 have accidentally taken a higher dose of ProAvenir**

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

**If you forget to take ProAvenir**

If you forget to take **ProAvenir**, do not take an extra tablet. Take the next tablet as usual.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

**If you stop taking ProAvenir**

If you stop taking **ProAvenir**, you will likely lose the hair that has grown within 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 taking ProAvenir and talk to your doctor 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: 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.

### **Unknown frequency:**

- Breast swelling or tenderness.
- Palpitations (feeling your heartbeat).
- Changes in the way your liver is working, which can be shown by blood tests.
- 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 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 ProAvenir affect the hair on other parts of your body?**

**ProAvenir** does not affect hair on other parts of the body.

### **What else should you know about ProAvenir?**

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 that in **ProAvenir**) 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 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](http://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 ProAvenir?**

- 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 the doctor.
- Do not use **ProAvenir** after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store this medicine in its original package. Store this medicine below 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer used. These measures will help protect the environment.

## **6. Additional information**

### **• 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 macroglycerides, opadry 03F34739 Pink.

- **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 marketed in packs of 28, 30 and 98 tablets in blister packs.

Not all pack sizes may be marketed.

- **Name and address of registration holder and importer:** BioAvenir Ltd., 1 David Hamelech St., Herzeliya Pituach 4666101.

- **Manufacturer:** Intas Pharmaceuticals Ltd., Ahmedabad, India.

- Revised in March 2024.

- Registration number of the medicine in the Ministry of Health National Drug Registry: 150-83-33638-00/01.