

# Finasteride 0.1% Minoxidil 5% Hair Loss Solution

## Important Information - Please Read Carefully

Before you start taking this medicine, please read this leaflet thoroughly as it contains essential information for you.

- Keep this leaflet: You might need to reread it.
- If you have further questions, please consult your doctor or pharmacist.
- This medicine has been prescribed specifically for you. Do not share it with others, even if they have similar symptoms, as it may harm them.
- If you experience any side effects, please inform your doctor or pharmacist. This includes any side effects not listed in this leaflet.
- This medicine is used to treat hereditary hair loss in men.
- This product is for men only and should NOT be used by women.
- Do not apply to other areas of the body besides the scalp. If accidentally applied, rinse thoroughly with plenty of water.
- Follow the instructions on how to use this product carefully.
- This medicine is for external use only and should only be applied to your scalp.
- This product is highly flammable and should be used and disposed of carefully.

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## 1. What Finasteride 0.1% Minoxidil 5% Hair Loss Solution is, and what is it used for?

Finasteride 0.1% Minoxidil 5% Hair Loss Solution treats hereditary hair loss in men by preventing further hair loss and aiding hair regrowth. It contains finasteride and minoxidil, which prevent the excess production of dihydrotestosterone (DHT) and improve blood flow to the hair follicles on the scalp.

Finasteride 0.1% Minoxidil 5% Hair Loss Solution contains the active ingredient finasteride. Finasteride belongs to a group of medicines known as Type II 5-alpha reductase inhibitors. It is intended for use in men only.

Finasteride is prescribed for treating male-pattern hair loss, also known as androgenetic alopecia. It helps increase hair growth on the scalp and prevents further hair loss. Men with mild to moderate hair loss can benefit from using finasteride.

Finasteride works by lowering the levels of DHT in the scalp. This reduction helps to reverse the balding process, promoting increased hair growth and preventing further hair loss.

- It works best in men with hair loss or thinning at the top of the scalp.
- Younger men, those who have been losing hair for a short period, or those with a small area of baldness are likely to experience the best results.
- Finasteride 0.1% Minoxidil 5% Hair Loss Solution is unlikely to benefit men who have been bald for many years or have a large area of hair loss.

Hereditary hair loss is recognisable by:

- The pattern of hair loss (see diagrams above).
- Gradual onset and progression.
- Family history of hair loss.
- No other symptoms are present with your hair loss.

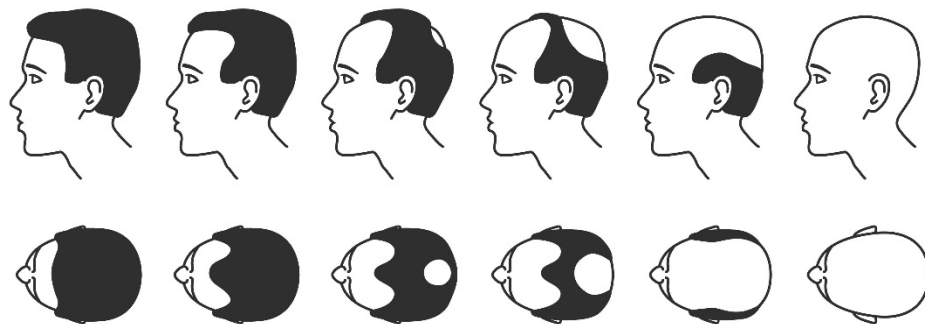
### How does hair grow?

Your hair grows about 1 centimetre (half an inch) each month. Hair grows from hair follicles 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, and new, healthy hair grows, repeating the cycle. The hairs on your scalp are always at different stages of this cycle, so you are expected to lose some scalp hair every day.

## What is male pattern hair loss?

Male-pattern hair loss is a common condition in which men experience thinning hair on the scalp, often leading to a receding hairline and balding on the top of the head. This condition is believed to result from a combination of genetic factors and the hormone dihydrotestosterone (DHT).

DHT shortens the growth phase of hair and causes it to thin, leading to male-pattern hair loss. These changes can begin in some men as early as their 20s and tend to become more prevalent with age. Prolonged hair loss over time may result in permanent hair loss.



## 2. What you need to know before you take Finasteride 0.1% Minoxidil 5% Hair Loss Solution

### Do not take Finasteride 0.1% Minoxidil 5% Hair Loss Solution if:

- You are female.
- You are under 18.
- You have reacted badly to finasteride, minoxidil, or other ingredients.
- If you are allergic (hypersensitive) to finasteride, minoxidil, or any other ingredients in this medicine.
- If you are already taking finasteride or dutasteride for a prostate problem called benign prostatic hyperplasia (BPH).
- Your hair loss is caused by drug treatment.
- You have total baldness or complete loss of all body hair.
- The cause of your hair loss is unknown, sudden, or unexpected.
- You have high blood pressure, treated or untreated.
- You have any scalp condition, including sunburn and psoriasis.
- You have a shaved scalp.

- You are using creams, ointments, or lotions for scalp conditions, such as dithranol, tretinoin, corticosteroids, or petrolatum.
- You have any kind of dressing or bandage on your scalp.
- Your scalp is not normal and healthy.

Do not take Finasteride 0.1% Minoxidil 5% Hair Loss Solution if any of the above apply to you. If you are unsure, consult your doctor or pharmacist.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Finasteride 0.1% Minoxidil 5% Hair Loss Solution if:

- You are going to have a blood test for prostate cancer called PSA (prostate-specific antigen), as Finasteride can affect the results of this test.
- You have breast cancer.

### Mood Alterations and Depression

Mood changes such as depressed mood, depression, and, less frequently, suicidal thoughts have been reported in patients treated with Finasteride. If you experience these symptoms, stop taking Finasteride 0.1% Minoxidil 5% Hair Loss Solution and immediately contact your doctor for further advice.

### Effects on Fertility

Infertility has been reported in men taking finasteride for an extended period who also had other risk factors affecting fertility. Normalisation or improvement of seminal quality was observed after discontinuing finasteride. Long-term clinical studies on the effects of finasteride on male fertility have not been conducted.

### Children and Adolescents

Finasteride 0.1% Minoxidil 5% Hair Loss Solution should not be used in children.

### Other medicines and Finasteride 0.1% Minoxidil 5% Hair Loss Solution

Inform your doctor or pharmacist if you are taking, have recently taken, or might take other medicines.

- **Do not take Finasteride 0.1% Minoxidil 5% Hair Loss Solution if you are already taking finasteride or dutasteride for a prostate problem called benign prostatic hyperplasia (BPH).**

### Pregnancy, breast-feeding, and fertility

Finasteride 0.1% Minoxidil 5% Hair Loss Solution is intended for treating male pattern hair loss in men only.

- **Finasteride should not be taken by women.**
- **This product is for men only and should NOT be used by women, especially if pregnant or breastfeeding.**
- **Do not touch the Finasteride 0.1% Minoxidil 5% solution if you are a woman who is pregnant or planning to become pregnant.**
- **If a pregnant woman comes into contact with the Finasteride 0.1% Minoxidil 5% Hair Loss Solution, she should speak to a doctor.**

### Consult your doctor or pharmacist if:

- You are unsure whether your scalp is normal and healthy.
- You suffer from heart disease, abnormal heart rhythms, chest pains, or circulation disorders.
- You are taking or using other medicines, especially certain blood pressure medicines called 'vasodilators', e.g., hydralazine, as minoxidil may interact with these medications.

### Driving and using machines

Finasteride is not likely to affect your ability to drive, use tools, or operate machines. However, minoxidil may cause dizziness or low blood pressure. If you experience these side effects, do not drive or operate machinery.

## 3. How to use Finasteride 0.1% and Minoxidil 5% Hair Loss Solution

### 1. Preparation:

- Ensure your scalp and hair are clean and dry before applying the solution.

- Wash your hands thoroughly before and after application.

## 2. Application:

- Apply the recommended dose (as prescribed by your doctor) directly to the affected areas of the scalp.
- Gently massage the solution into the scalp using your fingertips to ensure even distribution.
- Avoid contact with your eyes, mouth, and other mucous membranes. If contact occurs, rinse thoroughly with water.

## 3. Frequency:

- Apply the solution once daily as directed by your healthcare provider.
- It is important to use the solution consistently for the best results.

### **If you forget to take Finasteride 0.1% Minoxidil 5% Hair Loss Solution**

- **Missed Dose:** Do not take an extra dose to compensate for a missed dose. Continue with your next scheduled dose.

### **If you stop taking Finasteride 0.1% Minoxidil 5% Hair Loss Solution**

- **Treatment Duration:** It may take 3 to 6 months to see the full effect of Finasteride 0.1% Minoxidil 5% Hair Loss Solution. It is crucial to continue taking the medication as prescribed by your doctor.
- **Discontinuation:** If you stop taking Finasteride 0.1% Minoxidil 5% Hair Loss Solution, the hair you have gained may be lost within 9 to 12 months.

### **Further information**

- **Questions:** If you have any additional questions about using this medication, consult your doctor or pharmacist.

## 4. Possible side effects

Like all medications, this medicine can cause side effects, although not everyone experiences them. Some side effects may be temporary and improve with continued treatment or upon stopping the medication.

## Serious Side Effects

Stop taking the Finasteride 0.1% Minoxidil 5% Hair Loss Solution and seek immediate medical attention if you experience any of the following:

- **Allergic Reaction:** Symptoms such as swelling of the lips, face, tongue, or throat; difficulty swallowing; hives (lumps under the skin); and breathing difficulties.
- **Depression:** Feelings of severe sadness and worthlessness.
- **Breast Changes:** Any changes in breast tissue, such as lumps, pain, enlargement, or nipple discharge, as these may indicate a serious condition like breast cancer.
- **Chest pain**

**Stop using and consult your doctor if you experience:**

- Low blood pressure, fast heartbeat, palpitations.
- Faintness or dizziness, swollen hands or feet, shortness of breath.
- Sudden unexplained weight gain, persistent local redness or rash.

## Common side-effects:

- Headache, itching or dermatitis, unwanted non-scalp hair growth.

## Uncommon Side Effects (May Affect up to 1 in 100 People)

- **Erectile Dysfunction:** Difficulty in achieving or maintaining an erection (impotence).
- **Reduced Libido:** Decreased desire for sexual activity.
- **Ejaculation Issues:** Problems with ejaculation, such as a decrease in the amount of semen released during sex, which typically does not affect normal sexual function.
- **Nausea**

If you experience any side effects or if you have any concerns about your symptoms, promptly contact your doctor or pharmacist.

### Frequency not known

- Breast swelling or tenderness
- Testicular pain
- Blood in semen
- Palpitations (feeling your heartbeat)
- Persistent difficulty in maintaining 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
- Changes in liver function, detectable by blood tests
- Anxiety
- Suicidal thoughts

### Rare side-effects:

- Change in hair texture.

### Other possible side-effects:

- Depressed mood, eye irritation, vomiting, scalp irritation, acne-like rash, temporary hair loss, and change in hair colour.

If any of these side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist. It can be helpful to note what happened, when it started, and how long it lasted.

### Will Finasteride 0.1% Minoxidil 5% Hair Loss Solution affect hair on other parts of your body?

Finasteride 0.1% Minoxidil 5% Hair Loss Solution does not affect hair on other parts of the body.

### Additional information about Finasteride 0.1% Minoxidil 5% Hair Loss Solution



Finasteride is also used for treating a prostate condition called ‘benign prostatic hyperplasia’ (BPH). Data from a clinical trial in men taking 5 mg of finasteride (a dose five times higher than for hair loss) for seven years showed:

- A lower number of men developed prostate cancer compared to those not taking finasteride.
- A higher number of men taking finasteride had a high score in a tumour grading system compared to those not taking the medication.
- The long-term effects of finasteride on these types of tumours are unknown.

Please consult your doctor if you would like more information about the tumour grading system or the clinical trial.

### Reporting of side effects

If you experience 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 at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. Reporting side effects can help provide more information on the safety of this medicine.

### Overuse:

- Seek immediate medical advice if anyone uses too much.

## 5. How to store Finasteride 0.1% Minoxidil 5% Hair Loss Solution

- Keep this medicine out of the sight and reach of children.
- This medicine does not require any special storage conditions.
- Do not use this medicine after the expiry date stated on the label.
- 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.
- Do not store above 25°C.
- Extremely flammable aerosol. Protect from sunlight and do not expose to temperatures exceeding 50°C.

## 6. Contents of the pack and other information

Benzoyl alcohol, propylene glycol, dimethyl sulfoxide, acetic acid

## 7. Company Contact Details

APC Labs Limited

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