

Dutasteride 0.1% Minoxidil 5% topical hair loss foam

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.
- This product is for EXTERNAL USE only.

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1. What Dutasteride 0.1% Minoxidil 5% topical hair loss foam is, and what is it used for?

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

Dutasteride 0.1% Minoxidil 5% topical hair loss foam contains the active ingredient finasteride. Dutasteride belongs to a group of medicines known as type 1 and 2, 5-alpha reductase inhibitors. It is intended for use in men only.

Dutasteride 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.

Dutasteride works by lowering the levels of DHT in the scalp. This reduction helps to reverse the balding process, promote increased hair growth, and prevent 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.
- Dutasteride 0.1% Minoxidil 5% topical hair loss foam 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 below).
- Gradual onset and progression.
- Family history of hair loss.
- No other symptoms are present with your hair loss.

How Does Hair Grow?

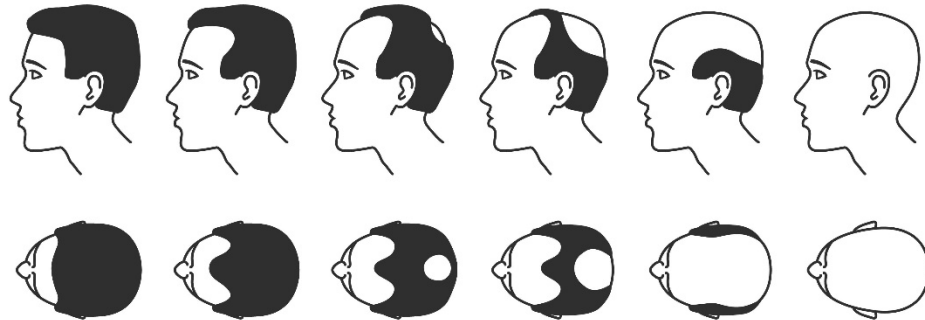
Your hair grows about 1 centimetre (half an inch) each month. Hair grows from hair follicles located under your skin. A single scalp hair grows continuously for 2-4 years (growth phase) and then stops growing for 2-4 months (rest phase). After this, the hair falls out, and new, healthy hair grows, repeating 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 do you need to know before you take Dutasteride 0.1% Minoxidil 5% topical hair loss foam

Do not apply Dutasteride 0.1% Minoxidil 5% topical hair loss foam 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 dutasteride or finasteride for a prostate problem called benign prostatic hyperplasia (BPH).
- You have severe liver disease.
- You have breast cancer.
- 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.

- You have severe mental health issues, such as depression.

Do not take Dutasteride 0.1% Minoxidil 5% topical hair loss foam if any of the above apply to you. If you are unsure, consult your doctor or pharmacist.

Warnings and Precautions

Consult your doctor or pharmacist before taking Dutasteride:

- Inform your doctor if you have liver problems. If you have a history of liver disease, additional check-ups may be required while taking Dutasteride.
- Women, children, and adolescents should not handle leaking Dutasteride 0.1% Minoxidil 5% hair loss foam, as the active ingredient can be absorbed through the skin. If contact occurs, wash the area immediately with soap and water.
- Use a condom during sexual intercourse. Dutasteride 0.1% Minoxidil 5% hair loss foam can be present in semen and may affect the normal development of a male baby if your partner is pregnant or may become pregnant.
- Dutasteride has been shown to decrease sperm count, semen volume, and sperm motility, potentially reducing fertility.
- Dutasteride can affect PSA (prostate-specific antigen) blood tests used to detect prostate cancer. Inform your doctor that you are taking dutasteride if you are undergoing a PSA test. Regular PSA testing is recommended for men taking dutasteride.
- In clinical studies, men at increased risk of prostate cancer who took dutasteride experienced a serious form of prostate cancer more often than those who did not take dutasteride. The impact of dutasteride on this serious form of cancer is not clear.
- Dutasteride may cause breast enlargement and tenderness. If you experience these symptoms, or if you notice breast lumps or nipple discharge, contact your doctor as these may indicate a serious condition such as breast cancer.

Food and Drink

Dutasteride can be taken with or without food.

Pregnancy, Breast-Feeding, and Fertility

If your partner is pregnant, breastfeeding, or planning to become pregnant, consult your doctor or pharmacist before taking this medicine. Pregnant women must not handle leaking Dutasteride 0.1% Minoxidil 5% hair loss foam, as the active ingredient can be absorbed through the skin and affect the development of a male baby, especially in the first 16 weeks of pregnancy. Use a condom during sexual intercourse to avoid exposing your partner to dutasteride through semen.

Dutasteride has been shown to reduce sperm count, semen volume, and sperm movement, which may reduce male fertility.

Mood Alterations and Depression

Mood changes such as depressed mood, depression, and, less frequently, suicidal thoughts have been reported in patients treated with dutasteride. If you experience any of these symptoms, stop taking Dutasteride 0.1% Minoxidil 5% hair loss foam and contact your doctor immediately for further advice.

Children and Adolescents

Dutasteride 0.1% Minoxidil 5% hair loss foam should not be used in children.

Pregnancy, Breast-Feeding, and Fertility

- Dutasteride 0.1% Minoxidil 5% hair loss foam is intended for the treatment of male pattern hair loss in men only.
- Dutasteride 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 Dutasteride 0.1% Minoxidil 5% hair loss foam if you are a woman who is pregnant or planning to become pregnant.
- If a pregnant woman comes into contact with the Dutasteride 0.1% Minoxidil 5% hair loss foam, 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

Dutasteride 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.

Other Medicines and Dutasteride 0.1% Minoxidil 5% topical hair loss foam

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

Do not take Dutasteride 0.1% Minoxidil 5% topical hair loss foam if you are already taking dutasteride or dutasteride for a prostate problem called benign prostatic hyperplasia (BPH).

When using the Dutasteride 0.1% Minoxidil 5% topical hair loss foam, it's important to be aware of potential drug interactions that may affect the efficacy or safety of the treatment. Here are some key points to consider:

Oral Finasteride or dutasteride:

If you are already taking oral dutasteride or finasteride for hair loss or benign prostatic hyperplasia (BPH), using a topical solution containing dutasteride might increase the risk of systemic side effects, including decreased libido, erectile dysfunction, and other hormonal imbalances. It is essential to inform your healthcare provider if you are using both forms of finasteride.

Antihypertensive Medications:

Minoxidil is a vasodilator and can lower blood pressure. If you are taking antihypertensive medications (blood pressure-lowering drugs), using a minoxidil-containing solution may enhance the blood pressure-lowering effects, potentially leading to hypotension (abnormally low blood pressure). Regular monitoring of blood pressure is recommended.

Topical Corticosteroids or Other Dermatological Treatments:

The concurrent use of other topical medications, especially corticosteroids, retinoids, or other dermatological treatments on the scalp, may increase the risk of skin irritation or alter the absorption of minoxidil and finasteride. Consult your healthcare provider before combining these treatments.

Oral Minoxidil:

If you are taking oral minoxidil for severe hypertension, adding a topical minoxidil solution may increase the risk of systemic side effects such as tachycardia (rapid heart rate) and fluid retention. Ensure your healthcare provider is aware of all forms of minoxidil you are using.

Other Hair Loss Treatments:

Combining dutasteride and minoxidil with other hair loss treatments like dutasteride, spironolactone, or hair growth supplements may lead to compounded effects or unexpected interactions. Always discuss with your healthcare provider before starting any additional treatments.

Anticoagulants and Antiplatelet Drugs:

While there are no specific known interactions, patients using anticoagulants (blood thinners) or antiplatelet drugs should be cautious as minoxidil's vasodilatory effects might theoretically impact clotting. Close monitoring and consultation with a healthcare provider are advised.

It's crucial to discuss all current medications, supplements, and medical conditions with your healthcare provider before starting the Dutasteride 0.1% Minoxidil 5% hair loss foam to avoid potential interactions and ensure safe and effective use of the product.

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

3. How to apply Dutasteride 0.1% and Minoxidil 5% Hair Loss Foam

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 Dutasteride 0.1% Minoxidil 5% topical hair loss foam

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

If You Stop Taking Dutasteride 0.1% Minoxidil 5% topical hair loss foam

- **Treatment Duration:** It may take 3 to 6 months to see the full effect of Dutasteride 0.1% Minoxidil 5% topical hair loss foam. It is crucial to continue taking the medication as prescribed by your doctor.
- **Discontinuation:** If you stop taking Dutasteride 0.1% Minoxidil 5% topical hair loss foam, 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

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

Signs of an allergic reaction can include:

- Itchy skin rash
- Hives (similar to nettle rash)
- Swelling of the eyelids, face, lips, arms, or legs

If you experience any of these symptoms, stop using Dutasteride 0.1% Minoxidil 5% hair loss foam and contact your doctor immediately.

Serious side effects

- Stop taking the Dutasteride 0.1% Minoxidil 5% hair loss foam 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 (May Affect Up to 1 in 10 Men)

- Impotence or erectile dysfunction (difficulty achieving or maintaining an erection), which may persist after stopping Dutasteride 0.1% Minoxidil 5% hair loss liquid.
- Decreased sex drive (libido), which may persist after stopping Dutasteride 0.1% Minoxidil 5% hair loss foam.
- Ejaculation issues, such as reduced semen volume during sex, which may persist after stopping Dutasteride 0.1% Minoxidil 5% hair loss foam.
- Breast enlargement or tenderness (gynecomastia)
- Dizziness when taken with tamsulosin

Uncommon Side Effects (May Affect Up to 1 in 100 Men)

- Heart failure (reduced efficiency in pumping blood, symptoms may include shortness of breath, extreme fatigue, and swelling in the ankles and legs)
- Hair loss (typically from the body) or unusual hair growth
- Nausea

Unknown Frequency (Cannot Be Estimated from Available Data)

- Depression
- Pain and swelling in the testicles

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 above or in the product information leaflet, please inform your doctor or pharmacist. Keeping a note of what happened, when it started, and how long it lasted can be helpful.

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 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 Dutasteride 0.1% Minoxidil 5% topical hair loss foam

- 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

Lactic acid, ethanol, glycerin, sodium metabisulfite

7. Company Contact Details

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