

# **Dutasteride 0.02% / Azelaic Acid 5% Topical Spray**

Patient Information Leaflet



**PharmaBee**

Read this leaflet carefully and keep it in case you need to refer to it again. This medicine has been prescribed to you only. Sharing medicines with others, even if they have the same symptoms as you, is dangerous. If you experience any side effects, listed or not, or if you have any questions, seek medical advice from a pharmacist, the prescriber, or your doctor. Keep all medicines out of the reach and sight of children.

## 1. What this medicine is and what it is used for

This is a prescription-only compounded topical medicine used to treat male pattern hair loss (androgenetic alopecia) in adult men. This higher-strength formulation is typically used when standard treatments have not provided a sufficient response. It contains two active ingredients:

- Dutasteride 0.02%: Reduces dihydrotestosterone (DHT), the hormone responsible for follicle miniaturisation. By lowering DHT levels directly at the scalp, it helps to reverse the shrinking of hair follicles.
- Azelaic Acid 5%: Supports scalp health and may reduce local scalp inflammation. It works by inhibiting the action of the enzyme 5-alpha-reductase, which converts testosterone into DHT

In combination, these active ingredients work to nourish and strengthen the scalp and hair follicles. They help to widen blood vessels to improve the flow of oxygen and nutrients, leading to an increase in hair density and a prolongation of the growth (anagen) phase. This medicine is an unlicensed "special" supplied following clinical assessment by a UK-registered prescriber.

## 2. Before you take this medicine

### Do NOT use if:

- You are female.
- You are pregnant or planning a pregnancy.
- You are under 18 years of age.

- You have sudden or patchy hair loss.
- You have infected or broken scalp skin.
- You are allergic to Dutasteride, Azelaic Acid, or any other ingredients.

### **Special Warnings:**

**Pregnancy:** Pregnant women must not handle the product or leaking containers. Dutasteride can be absorbed through the skin and may affect male foetal development.

**Medical Conditions:** Speak to your prescriber if you have heart disease, arrhythmia, severe uncontrolled cardiovascular disease, low blood pressure, or liver impairment.

**PSA Tests:** Dutasteride lowers Prostate Specific Antigen (PSA) levels by approximately 50%. Let your doctor know you are using this if you need to have PSA blood tests for prostate cancer screening.

## **3. How to take this medicine**

Apply 1ml once daily at the same time each day to a clean, dry scalp. Continuous use is required for benefit to be maintained. If treatment is stopped, hair loss is likely to resume within a few months.

### **Application Steps:**

- Part the hair to expose the thinning areas of the scalp.
- Spray the solution directly onto the scalp.
- Spread the liquid gently with your fingers if needed to ensure even coverage.
- Wash hands thoroughly after use to avoid accidental absorption or contact with others.
- Allow the solution to dry fully before sleeping or applying styling products.
- Do not wash your hair for at least 4 hours after application.

## **4. Possible side effects**

While systemic absorption is lower with topical preparations, side effects can still occur. Most improve with time, but some may last longer or continue after stopping treatment.

- **Common:** Mild scalp irritation, redness, dryness, headache, or increased local hair growth

- **Uncommon:** Dizziness, postural hypotension (feeling faint when standing), fatigue, and testicular discomfort.
- **Sexual/Hormonal:** Reduced libido, erectile dysfunction, decreased semen volume, or breast tenderness/enlargement.
- **Rare but Serious:** : Chest pain, rapid heartbeat, shortness of breath, severe swelling of the hands or feet, or severe allergic reactions.
- **Mental Health:** Rare reports of severe depression or suicidal thoughts.

Seek urgent medical attention if any serious symptoms occur. Stop use and consult your doctor if you experience chest pain or fainting.

## 5. Storage

- Store below 25°C in the original packaging.
- Keep the bottle tightly closed and out of direct sunlight.
- Keep out of the reach and sight of children at all times.
- Do not use after the expiry date shown on the label.
- Do not throw unused or expired medicines away with household waste or via wastewater.
- Any unwanted medicines should be returned to a pharmacy for safe disposal.

## Reporting side effects

You can report side effects via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Reporting helps provide more information on the safety of this medicine.

## Medicine Information for Dutasteride 0.02% / Azelaic Acid 5% Topical Spray

At PharmaBee, we are proud to be able to provide you with UK medicines prescribed with expert care by our hair loss specialist so that we can support you to be the you you want to be. We understand that hair loss is a complex and often distressing journey. Our mission is to provide clinically-backed, high-strength solutions that meet the rigorous

safety standards of the General Pharmaceutical Council (GPhC) and the Medicines and Healthcare products Regulatory Agency (MHRA).

## **What is Dutasteride 0.02% / Azelaic Acid 5% Topical Spray?**

PharmaBee offers a specialized, high-strength topical spray containing Dutasteride 0.02% and Azelaic Acid 5% for the treatment of male pattern hair loss (androgenetic alopecia) in adult men. This formulation is a prescription-only compounded medication, specifically designed for those who require a potent alternative to standard over-the-counter treatments.

**Important Regulatory Information:** This product is an unlicensed "special" medicine. While the individual active ingredients—Dutasteride and Azelaic Acid—are licensed in the UK for other medical conditions (such as prostate enlargement or skin inflammation), this specific combined spray formulation for hair loss does not hold a UK marketing authorisation. It is prescribed "off-label" by our UK-registered hair loss specialists when they deem it clinically appropriate for your specific needs after a thorough review of your consultation.

## **How does Dutasteride 0.02% / Azelaic Acid 5% Topical Spray work?**

This topical formulation targets the biological root causes of hair thinning by combining two active ingredients that work synergistically:

**Dutasteride 0.02%:** This is a powerful inhibitor of both Type I and Type II 5-alpha reductase enzymes. These enzymes are responsible for converting testosterone into Dihydrotestosterone (DHT), the primary hormone that causes hair follicles to miniaturise, weaken, and eventually stop producing hair. By blocking these enzymes directly at the scalp, Dutasteride achieves significantly higher DHT suppression than other treatments, helping to reverse follicle shrinkage.

**Azelaic Acid 5%:** This ingredient provides a dual benefit. It acts as a local inhibitor of the 5-alpha reductase enzyme, further reducing DHT activity at the scalp level.

Additionally, it supports overall scalp health and may reduce local inflammation, creating an optimal environment for hair regrowth.

Together, these ingredients work to widen blood vessels (acting as a vasodilator), improving the flow of oxygen and nutrients to the hair follicles. This prolongs the anagen (growth) phase and reduces the telogen (resting) phase of the hair cycle, leading to increased hair density and thickness.

## **How should I use Dutasteride 0.02% / Azelaic Acid 5% Topical Spray?**

To ensure safety and efficacy, this spray must be used exactly as advised by our specialist and the directions in the Patient Information Leaflet.

**Frequency:** Apply 1ml once daily at the same time each day.

### **Application Steps:**

- Ensure your hair and scalp are clean and dry.
- Part your hair to expose the thinning areas of the scalp.
- Spray the solution directly onto the skin of the scalp.
- Gently spread the liquid with your fingertips if necessary to ensure even coverage.
- Wash your hands thoroughly with soap and water immediately after application to avoid accidental absorption or transfer.
- Drying and Washing: Allow the solution to dry fully before styling your hair or going to bed. Do not wash your hair or get the scalp wet for at least 4 hours after application to ensure full absorption.

## **Scalp Health and Lifestyle: Maximising Your Results**

While our high-strength spray provides the clinical foundation for regrowth, supporting your treatment with healthy lifestyle choices and proper scalp care can enhance your results.

### **1. Scalp Hygiene and Environment**

A healthy scalp is the environment in which your hair grows. Using a gentle, pH-balanced shampoo helps remove sebum (oil) buildup and environmental pollutants that can clog follicles. Avoid excessively hot water when washing, as this can strip the scalp of natural oils and cause irritation, which may be exacerbated by the active ingredients in the spray.

## 2. Nutritional Support

Hair follicles are among the most metabolically active tissues in the body.

Ensure your diet is rich in:

**Protein:** Hair is primarily made of keratin; adequate protein intake is essential for hair structure.

**Iron and Zinc:** These minerals play a crucial role in hair cell growth and repair.

**Biotin and B-Vitamins:** These support the production of keratin and overall hair health.

## 3. Stress Management

High levels of chronic stress can push hair follicles into the resting phase prematurely (telogen effluvium). While androgenetic alopecia is hormonal, managing stress through exercise, sleep, and mindfulness can prevent additional stress-related thinning.

## 4. Gentle Handling

Avoid tight hairstyles that put physical tension on the hair (traction alopecia). When the hair is wet, it is at its most fragile; use a wide-tooth comb and avoid vigorous towel-drying.

### **Treatment Timeline: What to Expect**

Consistency is vital. Because the hair growth cycle is a slow biological process, changes take time.

- **Initial Shedding (Weeks 2–8):** You may notice a temporary increase in hair shedding. This is a positive sign that the medication is working to shift old, thin hairs out to make room for new, stronger growth.
- **Stabilisation (Months 3–6):** Most men will notice that their hair loss has stopped progressing.
- **Visible Improvement (Months 6–12):** This is when you will typically see noticeable thickening and regrowth in previously thinning areas.
- **Peak Benefit (2 Years):** Maximum results are usually achieved after 24 months of continuous use.

**Maintenance:** This is a long-term treatment. If application is stopped, DHT levels will rise, and hair loss is likely to resume within 6 to 12 months.

#### **Possible Side Effects**

Side effects are generally uncommon with topical application as there is less systemic absorption compared to oral tablets. However, as with all prescription treatments, they can occur.

#### **4. Possible Side Effects**

**Common (Local):** Mild scalp irritation, redness, dryness, or itching at the application site.

**Systemic/Hormonal:** Although rare with a 0.02% spray, some men may experience reduced libido, erectile dysfunction, decreased semen volume, or breast tenderness/swelling.

**General:** Headache, dizziness, or fatigue.

**Rare but Serious:** Chest pain, rapid heartbeat, shortness of breath, severe swelling, or persistent sexual dysfunction.

**Mental Health:** Rare reports of severe depression or suicidal thoughts have been associated with 5-alpha reductase inhibitors.

Seek urgent medical attention if you experience any serious symptoms. If you notice changes in mood or persistent sexual side effects, stop use and consult your doctor or our specialist immediately.

## FAQ

### **Q: Is it safe to use an unlicensed "special" medication?**

Yes. "Special" medications are legal, regulated, and commonly used when a patient's clinical needs cannot be met by a licensed product. Our clinicians only prescribe these formulations after a full assessment to ensure they are safe and appropriate for you.

### **Q: Can I use this spray if I am already taking oral Finasteride or Dutasteride?**

You should not combine multiple 5-alpha reductase inhibitors (like oral and topical Dutasteride) without explicit guidance from our specialist, as this can increase the risk of systemic side effects.

### **Q: Will this affect my PSA blood tests?**

Yes. Dutasteride can lower PSA (Prostate Specific Antigen) levels by about 50%. If you are having a blood test for prostate cancer screening, you must tell your doctor you are using this treatment so they can interpret the results correctly.

### **Q: What happens if a woman comes into contact with the spray?**

Women, especially those who are pregnant or planning to become pregnant, must not use or handle this product. Dutasteride can be absorbed through the skin and may cause serious birth defects in a male foetus. If accidental contact occurs, the area should be washed immediately with soap and water.

### **Q: Can I use other hair products with the spray?**

Yes, but you must allow the spray to dry completely (which takes about 30–60 minutes) before applying any styling gels, waxes, or sprays.

## Who should NOT use this medication?

Safety is our highest priority. This treatment is not suitable for everyone:

- **Women:** This medicine is strictly for men only.
- **Age:** Anyone under the age of 18.
- **Allergies:** Anyone with a known allergy to Dutasteride, Azelaic Acid, or any of the ingredients.
- **Medical Conditions:** Those with severe uncontrolled cardiovascular disease, liver impairment, or existing prostate conditions should speak to a specialist first.
- **Scalp Health:** Do not use if your scalp is infected, inflamed, or broken.

## How can I get Dutasteride 0.02% / Azelaic Acid 5% Topical Spray?

Getting started with PharmaBee is a simple, safe, and discreet process:

- **Online Consultation:** Complete our quick and confidential hair loss questionnaire.
- **Clinical Review:** Your consultation is reviewed by a UK-registered prescriber to ensure the treatment is safe for you.
- **Prescription and Dispensing:** if appropriate, a private prescription is issued and dispensed by our GPhC-registered pharmacy.
- **Discreet Delivery:** Your medication is delivered to your door in discreet packaging, often as soon as the next day.

**PharmaBee - supporting you to be the you you want to be.**

### Regulated, Safe & Trusted

**PharmaBee is a registered and regulated UK online pharmacy. All treatments are prescribed and dispensed in accordance with current clinical guidelines.**

- Registered with the General Pharmaceutical Council (GPhC).
- Certified by LegitScript for compliance and regulatory adherence.
- Report side effects via the MHRA Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

