# CUSTOM TOPICAL HAIR LOSS THERAPY

*Finasteride · Minoxidil · Caffeine · Ketoconazole*

*Prescriber Reference Guide · The Medicine Shoppe, York PA*

**Multi-Ingredient · Topical Delivery · DHT Blockade · Physician-Supervised · Rx Required**

## Program Overview

Male pattern hair loss (androgenetic alopecia) is driven primarily by dihydrotestosterone (DHT), which progressively miniaturizes susceptible hair follicles. This compounded topical formula delivers up to four active agents directly to the scalp, targeting DHT synthesis, follicular blood flow, cellular metabolism, and scalp inflammation simultaneously and at the site of action. Topical delivery substantially reduces systemic hormonal exposure compared to oral therapy -- directly addressing the most common barrier to finasteride prescribing.

### Key Clinical Advantages

- Multi-mechanism approach -- DHT inhibition, vasodilation, follicle stimulation, and anti-inflammatory activity in a single daily application
- Topical finasteride delivers meaningful follicular DHT blockade with substantially lower serum DHT suppression than oral finasteride -- reducing the risk of systemic sexual side effects
- Customizable formulation -- prescriber selects the combination and concentrations appropriate to the patient's pattern, severity, and tolerability
- Non-controlled -- no DEA scheduling, no prescribing restrictions, no prior authorization required
- Compounded to specification -- the four-ingredient combination is not commercially available; compounding enables precise dosing of each component
- Cash pay, straightforward pricing -- no insurance authorization burden

## Pathophysiology of Androgenetic Alopecia

Androgenetic alopecia results from a genetically determined sensitivity of hair follicles to DHT, produced locally from testosterone via 5-alpha reductase (5-AR) enzymes. DHT binds androgen receptors in the dermal papilla, shortening the anagen (growth) phase and progressively miniaturizing the follicle across successive cycles. The result is conversion of terminal hairs to fine vellus hairs, initially at the crown and hairline in male pattern loss.

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| **5-Alpha Reductase** | Converts testosterone to DHT locally in the follicle. Type II predominates in scalp follicles and is the primary target of finasteride. |
| **DHT & Androgen Receptors** | DHT binds androgen receptors in dermal papilla cells with ~5x greater affinity than testosterone, triggering follicular miniaturization and premature catagen entry. |
| **Follicular Miniaturization** | Progressive shortening of anagen phase across cycles reduces hair diameter and pigmentation. Advanced miniaturization leads to terminal follicle loss. |
| **Scalp Inflammation** | Perifollicular micro-inflammation is increasingly recognized as a contributor to follicle miniaturization and fibrosis in androgenetic alopecia. |
| **Anagen:Telogen Ratio** | Healthy scalp: ~90% anagen. AGA-affected scalp: anagen phase shortens, telogen proportion rises, resulting in visible thinning despite active follicles. |

# Active Ingredients -- Mechanisms of Action

## 1. Finasteride (Topical)

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| **Mechanism** | Inhibits type II 5-alpha reductase, blocking conversion of testosterone to DHT in the scalp follicle. Reduces intra-follicular DHT levels with substantially less systemic DHT suppression than oral finasteride. |
| **Evidence** | Multiple RCTs demonstrate efficacy of topical finasteride in AGA. Studies show comparable local DHT suppression to oral finasteride with significantly lower serum DHT reduction (~50% less systemic suppression in some studies), supporting a reduced systemic side effect profile. |
| **Topical vs. Oral** | Oral finasteride (1 mg/day) reduces serum DHT by ~65-70%. Topical formulations achieve meaningful scalp DHT reduction with serum suppression in the 10-30% range depending on concentration and vehicle -- substantially reducing systemic hormonal exposure. |
| **Typical Concentration** | 0.1-0.25% in solution or gel base; individualized per prescriber preference and patient response |

## 2. Minoxidil

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| **Mechanism** | Potassium channel opener -- widens arterioles supplying the follicle, increasing dermal papilla blood flow and oxygen delivery. Also directly stimulates follicle cell proliferation, increases follicle size, and prolongs the anagen phase. |
| **Evidence** | FDA-approved for AGA (topical). Decades of RCT and real-world evidence support hair regrowth and stabilization in both male and female pattern loss. Most effective in combination with DHT-blocking agents. |
| **Synergy with Finasteride** | Minoxidil and finasteride address AGA via orthogonal mechanisms -- vascular/growth stimulation vs. DHT blockade. Multiple studies confirm superior outcomes with combination vs. monotherapy. |
| **Typical Concentration** | 2-5% in solution base; higher concentrations available per prescriber specification |

## 3. Caffeine

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| **Mechanism** | Phosphodiesterase inhibitor -- elevates cyclic AMP (cAMP) in follicle cells, stimulating cell proliferation and metabolism. Counteracts DHT-induced suppression of hair matrix keratinocyte growth and extends anagen phase in vitro. |
| **Evidence** | In vitro studies demonstrate caffeine penetrates the follicle and directly counteracts DHT-induced growth suppression at the cellular level. Clinical data (Fischer et al.) support caffeine-containing topicals in AGA as part of a multi-ingredient approach. |

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| **Additive Value** | Complements finasteride (DHT blockade) and minoxidil (vasodilation) with a third distinct mechanism -- direct follicle cell stimulation independent of androgen pathways. |
| **Typical Concentration** | 0.2-1% in solution base |

### 4. Ketoconazole

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| **Mechanism** | Antifungal with anti-androgenic properties -- inhibits androgen synthesis and binds androgen receptors, reducing scalp DHT activity through a pathway distinct from 5-AR inhibition. Also reduces perifollicular inflammation, which contributes to follicle miniaturization in AGA. |
| **Evidence** | RCT data (Pierard-Franchimont et al.) demonstrate ketoconazole increases hair density and shaft diameter in AGA patients, with effect size comparable to 2% minoxidil in some studies. Additive benefit when combined with finasteride and minoxidil. |
| **Anti-Inflammatory Role** | Addresses the inflammatory component of AGA not targeted by DHT blockade or vasodilatory mechanisms alone -- completing the multi-pathway approach. |
| **Typical Concentration** | 0.5-2% in solution base |

## Topical Delivery -- The Side Effect Advantage

The primary reason many patients and prescribers hesitate with finasteride is the well-documented minority risk of sexual side effects (libido changes, erectile dysfunction, ejaculatory dysfunction) associated with sustained systemic DHT suppression. Topical delivery significantly mitigates this risk by concentrating the drug at the scalp while limiting systemic absorption.

| | Oral Finasteride 1 mg | Topical Finasteride |
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| **Serum DHT Suppression** | ~65-70% | ~10-30% (dose-dependent) |
| **Scalp DHT Reduction** | Effective | Effective |
| **Systemic Hormonal Exposure** | High | Substantially lower |
| **Sexual Side Effect Risk** | ~2-5% in trials; persistent effects reported in a subset | Reduced -- consistent with lower systemic exposure |
| **Hair Regrowth Efficacy** | Well-established (FDA-approved) | Comparable scalp DHT suppression in studies |

## Patient Selection

**Ideal Candidates**

- Male pattern hair loss (Norwood-Hamilton scale) -- crown thinning, hairline recession, or diffuse vertex loss
- Patients interested in finasteride but concerned about systemic side effects of oral therapy

- Patients who have tried OTC minoxidil alone with suboptimal results and want a more comprehensive approach
- Early-stage AGA -- intervention is most effective before significant follicle loss has occurred
- Patients who prefer a single daily topical application over an oral medication regimen
- Patients with concomitant scalp inflammation or seborrheic dermatitis who may benefit from ketoconazole

### Contraindications & Cautions

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| **Women / Pregnancy** | Finasteride is absolutely contraindicated in pregnancy (teratogenic -- Category X). Women should not handle crushed or broken finasteride preparations. Female AGA formulations without finasteride available on request. |
| **Liver Disease** | Finasteride and ketoconazole are both hepatically metabolized; use with caution in significant hepatic impairment. |
| **CYP3A4 Interactions** | Ketoconazole is a potent CYP3A4 inhibitor. At topical concentrations systemic absorption is low, but caution is warranted with narrow therapeutic index CYP3A4 substrates (e.g., certain statins, immunosuppressants, antiarrhythmics). |
| **Scalp Skin Disruption** | Avoid application to broken, abraded, or inflamed skin -- increases systemic absorption unpredictably. |

## Dosing & Administration

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| **Frequency** | Once daily application to affected scalp areas |
| **Application** | Apply 1-2 mL to dry scalp using dropper or pump; part hair to expose scalp; apply directly and spread with fingertips. Wash hands after application. |
| **Timing** | Evening application preferred -- allows absorption during rest; reduces transfer risk vs. morning use |
| **Drying Time** | Allow 3-5 minutes to dry before styling or lying down. Solution base absorbs quickly with minimal residue. |
| **Early Shedding** | Shedding in the first 4-8 weeks is common and indicates follicular cycling -- not treatment failure. Counsel patients proactively to prevent unnecessary discontinuation. |
| **Assessment Timeline** | Stabilization of loss: 3-4 months. Visible new growth and increased density: typically 6 months. Formal assessment with standardized photographs recommended at 6-12 months. |
| **Duration** | AGA therapy is long-term maintenance. Discontinuation typically results in resumption of hair loss within 6-12 months. Ongoing use is required to sustain benefit. |

## Monitoring & Follow-Up

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| **Baseline** | Document hair loss pattern with standardized photographs (consistent lighting and positioning); medication reconciliation for CYP3A4-sensitive drugs; confirm no pregnancy risk |
| **4-8 Weeks** | Address early shedding concerns proactively; assess scalp tolerability (irritation, erythema, contact dermatitis) |
| **3-4 Months** | Assess for stabilization of active loss; evaluate tolerability; adjust concentrations if needed |
| **6-12 Months** | Formal photographic comparison; assess for new growth and increased density; determine whether to continue, adjust, or escalate |
| **Ongoing** | Annual review; reassess formulation and drug interactions with any new prescriptions; monitor for any systemic finasteride effects (sexual function) |
| **Scalp Irritation** | Mild irritation may occur early -- often related to vehicle. Reduce frequency or switch to gentler base if persistent. Discontinue if contact dermatitis develops. |

## Formulation & Dispensing

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| **Dosage Form** | Topical solution in alcohol/propylene glycol base (standard) or alternative vehicle per prescriber preference -- compounded at The Medicine Shoppe |
| **Ingredients** | Finasteride, minoxidil, caffeine, and ketoconazole -- any combination or all four; concentrations specified by prescriber |
| **Available Variations** | Two-ingredient (e.g., finasteride + minoxidil), three-ingredient, or full four-ingredient formula. Female-appropriate versions (minoxidil + caffeine + ketoconazole, without finasteride) available. |
| **Custom Concentrations** | All concentrations customizable per prescriber specification |
| **Quantity** | 30-day supply standard; 60- or 90-day available on request |
| **Pricing** | Cash pay -- contact pharmacy for current pricing by formula |
| **BUD / Storage** | Per USP compounding standards; store at room temperature away from light; labeled on each preparation |

# Ordering & Contact Information

All preparations require a valid prescription specifying the desired ingredients and concentrations. Patients fill directly at our pharmacy. No prior authorization required.

## How to Order

- By phone -- call (717) 846-0500; ask for the compounding pharmacist; have patient name, DOB, desired ingredients, concentrations, and quantity ready
- By fax -- send prescription to (717) 845-8767; specify each ingredient and concentration; indicate any vehicle preference
- E-prescribe -- select 'Compound' as medication type; list each ingredient with strength in the Sig/Comments field (e.g., 'Finasteride 0.1% / Minoxidil 5% / Caffeine 0.5% / Ketoconazole 1% topical solution')

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| **The Medicine Shoppe**<br>1698 S Queen St · York, PA 17403 | Phone: (717) 846-0500<br>Fax: (717) 845-8767 |

*For educational purposes only -- not medical advice. Prescription required. Individual results may vary.*