CLINICAL MONOGRAPH · DERMATOLOGY

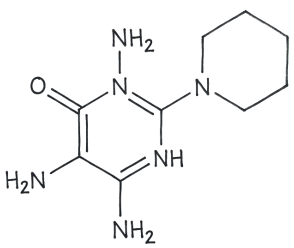
Topical Minoxidil

Hair-growth topical, often compounded with finasteride or other agents

Minoxidil is a medicine first developed in the 1970s to lower very high blood pressure. Patients on the oral tablet (Loniten) consistently grew unexpected hair, which led to the topical product Rogaine for pattern hair loss, first approved by the FDA in 1988 and later sold over the counter at 2% and 5% strengths.

Topical minoxidil is the most studied medical treatment for male and female pattern hair loss [olsen2002_5vs2]. In the last decade, dermatologists began using very low doses of the oral tablet (typically 0.25 to 5 mg per day, much lower than the 10 to 40 mg blood-pressure doses) as an off-label hair-loss treatment. This 'low-dose oral minoxidil' (LDOM) is now well-studied, and safety reviews in over a thousand patients have shown that side effects at these low doses are usually mild (extra body hair, mild fluid retention, lightheadedness) rather than the heart problems seen at higher antihypertensive doses [vanogalvan2021_safety; randolph2021_review].

Because Rogaine only comes in 2% and 5% topical strengths and Loniten only comes in 2.5 mg and 10 mg oral tablets, RonanRx compounds minoxidil under 503A when the prescriber needs something the manufactured products do not offer: low oral doses for hair-loss patients, oral suspensions for children, alcohol-free topicals for sensitive scalp, higher topical strengths, or topical combinations with finasteride and tretinoin.



EVIDENCE POSTURE FDA APPROVED WELL STUDIED REVIEWED **2026-05-11**

State-licensed 503A	Pharmacist reviewed	Doctor led	Cold-chain ready	Patient choice preserved

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FOR CLINICIANS

Minoxidil is a piperidinopyrimidine prodrug activated by scalp sulfotransferases to minoxidil sulfate, an ATP-sensitive potassium-channel opener that prolongs anagen and shortens telogen in the hair cycle [buhl1990_sulfate, messenger2004_mechanism, buhl1993_potassium] [randolph2021_review]. The oral parent compound (Loniten 2.5 and 10 mg) is FDA-approved for severe hypertension refractory to other therapy at 10, 40 mg/day, with a Boxed Warning for pericardial effusion and reflex tachycardia. The topical 2% and 5% solutions and the 5% foam (Rogaine) are FDA-approved/OTC for androgenetic alopecia (AGA) in men, with the 2% solution and 5% foam approved for AGA in women [devillez1994_women; blume_peytavi_2011_foam_solution; vexiau2002_cyproterone].

Topical efficacy in AGA is supported by pivotal randomized trials in men [olsen2002_5vs2, olsen2007_foam] and women, with a class-typical 5% superiority over 2% on target-area hair count and patient/investigator global assessment, and once-daily foam non-inferior to twice-daily solution [randolph2021_review]. The international S3 (EADV) evidence-based guideline [kanti2018_s3_guideline] recommends topical minoxidil 5% (men) and 2% twice daily or 5% once daily (women) as first-line medical therapy.

Low-dose oral minoxidil (LDOM, 0.25, 5 mg/day) is an off-label but well-studied therapy for AGA, female pattern hair loss, and chronic telogen effluvium [randolph2021_review] [lucky2004_female]. Evidence includes the Sinclair 2018 pilot combination with spironolactone [sinclair2018_pilot]; the Beach 2018 case series [beach2018_oral]; the Panchaprateep 2020 open-label single-arm trial of 5 mg/day in men with AGA [panchaprateep2020_men_5mg]; the Vañó-Galván 2021 multicenter safety analysis of 1404 patients on LDOM [vanogalvan2021_safety]; the Ramos/Nascimento 2022 randomized trial of 0.25 mg vs 1 mg in women [ramos2022_ldom_rct]; an LDOM cardiac/arrhythmia safety series in 264 patients with cardiovascular comorbidity [ramos2024_cardiac_safety]; and the 2025 international modified Delphi consensus statement on LDOM initiation [delphi2025_ldom]. Adverse events at LDOM doses are dominated by mild hypertrichosis, occasional pedal edema, lightheadedness, and rare pericardial events [vanogalvan2021_safety, trueb2022_complication, eventos_ldom_2025_jcm].

Compounded 503A roles are: (1) oral preparations at 0.25, 5 mg per dose unit, which cannot be reproduced by splitting Loniten 2.5 or 10 mg tablets without excessive dose variability; (2) oral suspensions for pediatric hair-loss indications; (3) higher-strength topical preparations (e.g., 7, 15%) for non-responders to 5%; (4) topical combination preparations adding finasteride, tretinoin, azelaic acid, or biotin to leverage independent mechanisms [kanti2018_s3_guideline, randolph_landscape_2025, oral_minoxidil_2026_review]; and (5) alcohol- or propylene-glycol-free vehicles for patients with vehicle-driven irritant contact dermatitis to commercial Rogaine [randolph2021_review].

Why Personalized Topical Minoxidil

Minoxidil's FDA-approved doses were calibrated for two very different jobs: 2.5 to 10 mg oral tablets for severe refractory hypertension, and 2% or 5% topical solution and foam for androgenetic alopecia. Neither was sized for what dermatology actually prescribes today. Low-dose oral minoxidil for hair loss sits at 0.625 to 2.5 mg, well below the smallest commercial tablet, and the right starting dose depends on baseline blood pressure, sex, body weight, whether the patient gets ankle swelling or facial hypertrichosis, and what other antihypertensives or 5-alpha-reductase inhibitors they are already on. Topical response depends on scalp sulfotransferase activity, vehicle tolerance, and whether propylene glycol triggers irritant dermatitis. None of that is in a 5% bottle.

Compounding closes that gap. A prescriber who knows the chart can order 0.625, 1.25, or 2.5 mg oral capsules to titrate LDOM precisely, pediatric oral suspensions for hypertension dosing by weight, topical strengths above 5% for non-responders, propylene-glycol-free or alcohol-free vehicles for sensitive scalps, and combination topicals with finasteride, tretinoin, or azelaic acid that match the clinician's regimen instead of forcing three separate bottles. The molecule is the same one the FDA reviewed in Rogaine and Loniten. The strength, the route, and the vehicle are built for the individual patient.

This is the older arrangement pharmacy ran on before mass manufacturing arrived: a prescriber wrote for one named patient, and a pharmacist prepared it. Modern state inspection, USP standards, and pharmacist accountability keep that arrangement honest.

Quick Facts About Topical Minoxidil

Category: Potassium-channel-opening vasodilator with hair-growth effect after sulfotransferase activation to minoxidil sulfate

Active ingredient: Minoxidil (2,4-diamino-6-piperidinopyrimidine-3-oxide); a prodrug activated in scalp by sulfotransferase to minoxidil sulfate

FDA-approved branded forms: Rogaine (topical 2% solution; 5% solution and 5% foam, switched to OTC monograph status) and Loniten (oral tablets 2.5 mg and 10 mg for severe hypertension refractory to other therapy)

Routes: Topical (solution, foam, compounded combinations); oral (tablet, compounded suspension or low-strength capsule)

Evidence posture: Topical 2% and 5% formulations have multiple FDA-pivotal randomized trials in androgenetic alopecia in men and women. Oral minoxidil 10, 40 mg/day is FDA-approved for severe hypertension. Low-dose oral minoxidil (LDOM) at 0.25, 5 mg/day for hair loss is off-label but well-studied: prospective cohorts, randomized trials, and a 1404-patient safety series support broad use.

FDA-approval status: Topical Rogaine 2% and 5% are FDA-approved/OTC for androgenetic alopecia. Oral minoxidil (Loniten) is FDA-approved as a Rx for severe hypertension. Low-dose oral minoxidil for hair loss and compounded combination preparations are not FDA-approved indications.

Compounded under: 503A, patient-specific prescription only. Typical 503A roles: low-dose oral minoxidil (0.25, 5 mg) for hair loss outside the manufactured 2.5/10 mg strengths; topical combinations (minoxidil + finasteride + tretinoin ± biotin or azelaic acid); higher-strength topical preparations above 5%; and oral suspensions for pediatric dosing

Important compounding caution: Oral minoxidil retains the Loniten Boxed Warning at hypertensive doses for fluid retention and pericardial effusion. Reported cardiac and edema events at low-dose oral hair-loss doses (0.25, 5 mg/day) are uncommon but not zero; cardiac and volume-status review is part of the prescribing workup.

SPECIALS: PATIENT-SPECIFIC PRESCRIPTION ONLY

Topical Minoxidil described in this monograph is a 503A compounded preparation. Every dose is made on a prescription, for a named patient, by a licensed pharmacist. It is not a stocked, mass-manufactured product.

- **Made to order, not off a shelf.** No batch sits in a warehouse waiting for buyers. Your prescription triggers the prep.
- **Named-patient label.** The bottle carries one patient's name. The batch records carry one prescription.
- **Dose, strength, and route chosen for the patient.** A prescriber decides what gets compounded, not a manufacturer who set the strength for a trial population.
- **Licensed pharmacist on the hook.** A real person, with a license that can be pulled, signs off on every prep. State inspectors check the facility.
- **Compounded drugs are not FDA-approved.** They should not be evaluated using branded-drug trial data alone. Availability varies by state and prescribed medication.

How This Differs from a Research-Use-Only Website

A research-use-only website ships a vial from a warehouse. There is no prescription, no pharmacist, no facility inspection, and no way to recall the product if something is wrong with it. If the vial is mislabeled, contaminated, or under-potent, there is nobody whose license is at stake.

A 503A compounding pharmacy is the other thing. The doctor writes the prescription. A licensed pharmacist, whose name is on the label, prepares the medicine in a facility the state inspects. If something goes wrong, there is a person and a license on the hook, and a documented chain of custody on every lot. That accountability is what makes it safe.

What is Topical Minoxidil?

Minoxidil is 2,4-diamino-6-piperidinopyrimidine-3-oxide, a piperidinopyrimidine derivative first synthesized at the Upjohn Company in the 1960s and developed as an oral antihypertensive. It is a prodrug: the parent compound is essentially inactive at the molecular target, and clinical effect depends on sulfotransferase-mediated conversion to minoxidil sulfate in tissue. The skin (specifically the outer root sheath of hair follicles) and the kidney are the principal sites of sulfation [buhl1990_sulfate, messenger2004_mechanism].

The FDA-approved manufactured forms are: (1) Loniten oral tablets, 2.5 mg and 10 mg, for severe hypertension refractory to maximum doses of a diuretic plus two other antihypertensives, with usual hypertensive dosing of 10, 40 mg/day in single or divided doses; and (2) Rogaine topical preparations, 2% solution, 5% solution, and 5% foam, for hereditary hair loss. Rogaine 2% solution was first approved in 1988 (Rx, men), reformulated for women, and transitioned to OTC status under the topical minoxidil OTC monograph; the 5% solution and 5% foam followed [olsen2002_5vs2, olsen2007_foam, randolph2021_review].

Minoxidil for hair loss is also dispensed in pharmacist-prepared dosage forms not available as manufactured products. The two clinically important compounded categories are low-dose oral preparations (typical doses 0.25, 0.5, 1, 1.25, 2.5, or 5 mg, compounded as capsules or oral solutions) for the LDOM hair-loss indication, and topical combination preparations that pair minoxidil with finasteride and/or tretinoin on a single vehicle to leverage non-overlapping mechanisms in AGA [kanti2018_s3_guideline, randolph_landscape_2025].

How Topical Minoxidil Works

Minoxidil's antihypertensive action is direct arteriolar vasodilation through opening of ATP-sensitive potassium (K-ATP) channels in vascular smooth muscle, producing reflex sympathetic activation, fluid retention, and the cardiac-side-effect profile that drives the Loniten Boxed Warning. Hair growth was originally observed as a class-typical hypertrichosis side effect in oral antihypertensive use and was repurposed to topical therapy at concentrations that produce negligible systemic exposure [randolph2021_review, oral_minoxidil_2026_review] [messenger2004_mechanism].

The hair-growth mechanism depends on conversion of minoxidil to minoxidil sulfate by follicular sulfotransferases (principally SULT1A1). Minoxidil sulfate acts as a K-ATP channel opener on the hair follicle's dermal papilla and outer root sheath, prolonging the anagen (growth) phase, shortening telogen, increasing follicle size, and producing the characteristic 2- to 8-week early shed (telogen synchronization) that precedes regrowth [buhl1990_sulfate; buhl1993_potassium; headington1993_telogen].

Variability in scalp sulfotransferase activity explains a portion of clinical non-response to topical minoxidil and motivates compounded oral or combination preparations in patients who fail topical 5% monotherapy [randolph_landscape_2025, kanti2018_s3_guideline].

Biological Role of Topical Minoxidil

Minoxidil is a synthetic drug, not an endogenous compound; it has no native biological role. Its hair-growth effect is mediated through scalp sulfotransferase activation to minoxidil sulfate and downstream K-ATP channel opening in the dermal papilla and outer root sheath of hair follicles [buhl1990_sulfate, buhl1993_potassium, messenger2004_mechanism].

The hair cycle on which minoxidil acts comprises three phases: anagen (active growth, normally 2, 6 years on the scalp), catagen (regression, ~2 weeks), and telogen (resting, ~2, 3 months before shedding). In androgenetic alopecia, androgen-driven miniaturization shortens anagen and prolongs telogen, producing progressively finer, shorter hairs. Minoxidil reverses this pattern by prolonging anagen and shortening telogen [headington1993_telogen, messenger2004_mechanism]. The transient 'minoxidil shed' observed 2, 8 weeks after initiation reflects synchronous exit of telogen hairs as resting follicles enter a new anagen phase.

Detailed Mechanism of Topical Minoxidil

Minoxidil itself is a weak K-ATP channel agonist. Activation requires N-O sulfation to minoxidil sulfate, catalyzed by phenol sulfotransferases including SULT1A1. The sulfated metabolite hyperpolarizes the cell membrane by opening Kir6.x/SUR-family channels, with downstream effects on cyclic nucleotide signaling, vascular endothelial growth factor (VEGF) expression in the dermal papilla, prostaglandin E2 synthesis, and Wnt/β-catenin pathway activity that have been described in cultured hair follicles and dermal papilla cells [buhl1990_sulfate, buhl1993_potassium, messenger2004_mechanism].

At the hair-cycle level, minoxidil shortens the duration of telogen, induces premature entry of telogen follicles into anagen (causing the well-known early shed seen 2, 8 weeks after initiation or dose escalation, sometimes called 'minoxidil shed'), prolongs anagen, and increases the diameter of miniaturized hairs in androgenetic alopecia [headington1993_telogen, messenger2004_mechanism] [olsen2002_5vs2]. The pivotal AGA trials document this effect on target-area hair count and on hair diameter over 16, 48 weeks.

Systemic minoxidil at antihypertensive doses (10, 40 mg/day) produces direct arteriolar vasodilation, reflex tachycardia, salt-and-water retention, and (in some patients) pericardial effusion. Low-dose oral minoxidil at hair-loss doses (0.25, 5 mg/day) produces measurable but typically modest reductions in blood pressure and uncommon clinically significant fluid retention; the cardiovascular safety profile at LDOM doses is dominated by mild orthostatic symptoms, occasional lower-limb edema, and hypertrichosis [vanogalvan2021_safety, ramos2024_cardiac_safety, oral_minoxidil_2026_review].

Topical bioavailability is low (approximately 1.4% systemic absorption of an applied dose under normal scalp conditions per pharmacokinetic reviews) and clinical effect on blood pressure with labeled topical use is negligible in adults without underlying cardiovascular disease [randolph2021_review, randolph_landscape_2025]. Pediatric exposure to topical minoxidil, particularly accidental ingestion of the topical solution, can produce systemic hypotension and tachycardia; this drives the OTC labeling restriction in children under 18 [olsen2007_foam; lucky2004_female; devillez1994_women].

Topical Minoxidil Research History

Minoxidil was developed at the Upjohn Company in the late 1960s as an oral antihypertensive. The Loniten tablet was approved by the FDA in 1979 for severe hypertension refractory to other therapy. Within months of marketing, dermatologists and cardiologists reported hypertrichosis as a class-typical adverse effect, with most patients on chronic Loniten developing increased facial, limb, and trunk hair within 3, 6 weeks. This observation led Upjohn to develop a topical formulation for pattern hair loss.

Topical 2% minoxidil solution (Rogaine) was approved by the FDA in 1988 for androgenetic alopecia in men. The Savin 1987 multicenter trial [savin1987_topical] established efficacy of topical minoxidil on target-area hair count and patient-assessed hair regrowth in male pattern baldness. The DeVillez 1994 trial [devillez1994_women] extended approval to women on 2% solution. The Olsen 2002 pivotal 5% vs 2% trial in men [olsen2002_5vs2] established the dose-response curve and supported approval of 5% solution. The Lucky 2004 pivotal trial in women [lucky2004_female] tested 5% and 2% solutions against placebo in female pattern hair loss. Olsen 2007 reported the multicenter randomized 5% foam trial in men [olsen2007_foam], leading to approval of the foam vehicle (less scalp irritation, no overnight wash). The Blume-Peytavi 2011 trial [blume_peytavi_2011_foam_solution] established once-daily 5% foam non-inferiority to twice-daily 2% solution in women. The Vexiau 2002 trial [vexiau2002_cyproterone] compared topical minoxidil 2% to cyproterone acetate in women with female AGA.

Mechanism research established sulfation as the activation step [buhl1990_sulfate] and K-ATP channel opening as the molecular action on hair follicles [buhl1993_potassium]; Messenger and Rundegren consolidated the mechanism in a widely cited review [messenger2004_mechanism]. Headington's 1993 review of telogen effluvium [headington1993_telogen] framed the early shed phenomenon that became central to patient counseling.

Low-dose oral minoxidil for hair loss emerged in the 2010s. The first systematic descriptions are the Beach 2018 case series [beach2018_oral] and the Sinclair 2018 pilot study combining LDOM with spironolactone in female pattern hair loss [sinclair2018_pilot]. The Panchaprateep 2020 single-arm open-label trial [panchaprateep2020_men_5mg] showed efficacy of oral minoxidil 5 mg/day in men with AGA. The Vañó-Galván 2021 multicenter safety analysis in 1404 patients [vanogalvan2021_safety] established the modern LDOM tolerability profile and remains the largest published safety experience. The Ramos/Nascimento 2022 randomized trial [ramos2022_ldom_rct] compared 0.25 mg vs 1 mg oral minoxidil in women with

female pattern hair loss. The 2024 cardiac-safety analysis of LDOM in 264 patients with hypertension and arrhythmia [ramos2024_cardiac_safety] addressed the most common cardiology concern about the off-label dose range. The 2025 international modified Delphi consensus statement [delphi2025_ldom] provided structured initiation, monitoring, and contraindication guidance. Trüeb 2022 [trueb2022_complication] reported a serious LDOM adverse event, anchoring the safety counseling.

Contemporary reviews [randolph2021_review, oral_minoxidil_2026_review, randolph_landscape_2025] consolidate topical, oral, and emerging sublingual formulations; the international S3 (EADV) guideline [kanti2018_s3_guideline] formalizes treatment algorithms. The Nestor 2021 review [nestor2021_aga_review] places minoxidil in the broader treatment landscape including finasteride, dutasteride, low-level laser therapy, and platelet-rich plasma. Cicatricial-alopecia retrospective evidence supports compounded topical combinations (tacrolimus + clobetasol + minoxidil) in a specific dermatologic niche [cicatricial_combo_2025].

Topical Minoxidil Timeline

- **1979** • FDA approves Loniten (oral minoxidil tablets 2.5 mg and 10 mg) for severe hypertension refractory to maximum doses of a diuretic plus two other antihypertensives; Boxed Warning for pericardial effusion and reflex tachycardia
- **1987** • Savin reports multicenter trial of topical minoxidil in male pattern baldness, efficacy on target-area hair count and global assessment [savin1987_topical]
- **1988** • FDA approves topical 2% minoxidil solution (Rogaine) for androgenetic alopecia in men
- **1990** • Buhl et al [buhl1990_sulfate]. establish minoxidil sulfate as the active metabolite that stimulates hair follicles (Journal of Investigative Dermatology)
- **1993** • Buhl et al [buhl1993_potassium; headington1993_telogen]. characterize potassium channel conductance as a control mechanism in hair follicles; Headington publishes telogen effluvium framework explaining the 'minoxidil shed'
- **1994** • DeVillez trial extends topical 2% minoxidil to female androgenetic alopecia (Archives of Dermatology) [devillez1994_women]
- **1996, 1997** • Topical 2% minoxidil transitions to OTC under the FDA topical minoxidil OTC monograph
- **1999** • Roberts et al [roberts1999_finasteride]. publish clinical dose-ranging studies with finasteride in men with male pattern hair loss, the principal partner agent for combination compounded therapy

2002 • Olsen et al. publish randomized trial of 5% vs 2% topical minoxidil and placebo in men with androgenetic alopecia (JAAD), supports approval of 5% solution; Vexiau et al [olsen2002_5vs2; vexiau2002_cyproterone]. compare topical minoxidil 2% to cyproterone acetate in women with female AGA (BJD)

2004 • Lucky et al [lucky2004_female; messenger2004_mechanism]. publish pivotal randomized placebo-controlled trial of 5% and 2% topical minoxidil solutions in female pattern hair loss (JAAD); Messenger and Rundegren publish the canonical mechanism review (BJD)

2007 • Olsen et al [olsen2007_foam]. publish multicenter randomized placebo-controlled trial of 5% topical minoxidil foam in men with androgenetic alopecia (JAAD), supports approval of foam vehicle

2011 • Blume-Peytavi et al [blume_peytavi_2011_foam_solution]. publish randomized trial of 5% minoxidil foam once daily vs 2% solution twice daily in women with androgenetic alopecia (JAAD)

2018 • Beach publishes early case series of oral minoxidil for androgenetic and traction alopecia; Sinclair et al [beach2018_oral; sinclair2018_pilot; kanti2018_s3_guideline]. publish pilot of low-dose oral minoxidil + spironolactone in female pattern hair loss; the EADV S3 guideline for androgenetic alopecia is published

2020 • Panchaprateep and Lueangarun publish open-label single-arm trial of oral minoxidil 5 mg once daily in men with androgenetic alopecia [panchaprateep2020_men_5mg]

2021 • Vañó-Galván et al. publish the 1404-patient multicenter LDOM safety study (JAAD), the modern reference for adverse-event prevalence at hair-loss doses; Randolph and Tosti publish JAAD review of oral minoxidil efficacy and safety; Nestor et al [vanogalvan2021_safety; randolph2021_review; nestor2021_aga_review]. publish broad androgenetic alopecia treatment review

2022 • Nascimento e Silva / Ramos et al. publish randomized trial of 0.25 mg vs 1 mg LDOM in women with female pattern hair loss (JAAD); Trüeb et al [ramos2022_ldom_rct; trueb2022_complication]. report a serious LDOM complication (JAAD Case Reports)

2024 • Multicenter LDOM cardiac-safety analysis in 264 patients with hypertension and arrhythmia (Actas Dermo-Sifiliográficas) [ramos2024_cardiac_safety]

2025 • International modified Delphi consensus statement on LDOM initiation published in JAMA Dermatology; J Clin Med review of LDOM adverse events; Frontiers in Pharmacology review of topical, oral, and sublingual minoxidil formulations [delphi2025_ldom; eventos_ldom_2025_jcm; randolph_landscape_2025]

2025 • Hypertrichosis characterization study of 24-week 5 mg/day LDOM in men with male pattern hair loss (Int J Trichology); retrospective analysis of compounded topical tacrolimus + clobetasol + minoxidil for primary cicatricial alopecias [ldom_5mg_hypertrichosis_2025; cicatricial_combo_2025]

2026 • Comprehensive review of oral minoxidil for alopecia treatment, risks, benefits, and recommendations (Am J Clin Dermatol) [oral_minoxidil_2026_review]

Clinical Contexts for Topical Minoxidil

Androgenetic alopecia in men FDA APPROVED

FDA-approved indication for topical Rogaine 2% and 5% solution and 5% foam.

Topical minoxidil 5% (solution or foam) is FDA-approved/OTC for male androgenetic alopecia and is recommended as first-line topical therapy by the EADV S3 guideline [kanti2018_s3_guideline]. The Olsen 2002 pivotal trial [olsen2002_5vs2] (N=393, 48 weeks) demonstrated superiority of 5% solution over both 2% solution and placebo on target-area hair count and patient/investigator global assessment, with the 5% group showing ~45% greater hair-count change than the 2% group. The Olsen 2007 5% foam trial [olsen2007_foam] and the Savin 1987 multicenter trial [savin1987_topical] support efficacy across vehicles. Compounded use is reserved for patients with vehicle-driven irritant dermatitis on commercial Rogaine, non-responders to 5% who are candidates for higher-strength topical or combination therapy with topical finasteride or tretinoin [randolph_landscape_2025], or those for whom oral therapy is indicated.

Branded product: Rogaine 5% (solution and foam, OTC)

Androgenetic alopecia / female pattern hair loss in women FDA APPROVED

FDA-approved indication for topical Rogaine 2% solution and 5% foam.

Topical minoxidil 2% solution and 5% foam are FDA-approved/OTC for female androgenetic alopecia. The DeVillez 1994 trial [devillez1994_women] established 2% solution efficacy in women. The Lucky 2004 pivotal trial [lucky2004_female] randomized 381 women with female pattern hair loss to 5% solution, 2% solution, or vehicle for 48 weeks; both active treatments demonstrated significant hair-count and global-assessment improvements vs vehicle, with a non-significant trend favoring 5%. The Blume-Peytavi 2011 trial [blume_peytavi_2011_foam_solution] established once-daily 5% foam non-inferiority to twice-daily 2% solution in women, supporting the OTC 5% foam approval for women [kanti2018_s3_guideline]. The Vexiau 2002 trial [vexiau2002_cyproterone] compared topical minoxidil 2% to oral cyproterone acetate in women with female AGA, both effective; minoxidil favored in non-hyperandrogenic patients.

Branded product: Rogaine 2% solution and 5% foam (OTC)

Severe refractory hypertension in adults FDA APPROVED

FDA-approved indication for oral Loniten tablets.

Oral minoxidil (Loniten) is FDA-approved for severe hypertension that is not manageable with maximum doses of a diuretic plus two other antihypertensives [randolph2021_review; oral_minoxidil_2026_review]. Usual dose is 10, 40 mg/day in single or divided doses (initial 5 mg/day; maximum 100 mg/day). The Loniten label carries a Boxed Warning for pericardial effusion (occasionally progressing to tamponade), reflex tachycardia and angina, and salt and water retention requiring concomitant diuretic. Use in modern practice is uncommon as second- or third-line alternatives have expanded.

Branded product: Loniten (oral minoxidil tablets 2.5 mg and 10 mg)

Female pattern hair loss / chronic telogen effluvium with low-dose oral minoxidil WELL STUDIED

Off-label, well-studied use of LDOM at 0.25, 5 mg/day in women.

LDOM in women is supported by the Sinclair 2018 pilot combining 0.25 mg oral minoxidil with spironolactone 25 mg [sinclair2018_pilot]; the Vañó-Galván 2021 multicenter safety experience in 1404 patients (median dose 1 mg/day in women) [vanogalvan2021_safety]; the Ramos/Nascimento 2022 randomized trial of 0.25 mg vs 1 mg in women with female pattern hair loss [ramos2022_ldom_rct]; the 2025 international modified Delphi consensus statement [delphi2025_ldom]; and contemporary reviews [randolph2021_review, oral_minoxidil_2026_review, randolph_landscape_2025]. Mild hypertrichosis (especially facial) is the most common adverse event; pedal edema and orthostatic symptoms occur in a minority; serious cardiac events are uncommon at these doses [vanogalvan2021_safety, ramos2024_cardiac_safety, eventos_ldom_2025_jcm].

Male androgenetic alopecia with low-dose oral minoxidil WELL STUDIED

Off-label, well-studied use of LDOM at 1.25, 5 mg/day in men.

LDOM in men is supported by the Beach 2018 case series [beach2018_oral]; the Panchaprateep 2020 open-label single-arm trial of 5 mg once daily in men with AGA (N=30, 24 weeks, demonstrated increased hair count and patient global assessment vs baseline) [panchaprateep2020_men_5mg]; the Vañó-Galván 2021 1404-patient safety series (median 5 mg/day in men) [vanogalvan2021_safety]; the 2025 hypertrichosis characterization study at 5 mg/day [ldom_5mg_hypertrichosis_2025]; and the international Delphi consensus [delphi2025_ldom]. Typical regimens in men are 1.25, 5 mg/day, often combined with topical minoxidil 5% or oral finasteride 1 mg/day for additive efficacy [oral_minoxidil_2026_review, randolph_landscape_2025].

Off-Label Uses of Topical Minoxidil

Alopecia areata (adjunctive) EMERGING

Off-label; topical and low-dose oral minoxidil used as adjuncts to immunomodulators in patchy and patterned alopecia areata.

Topical minoxidil 5% has been used adjunctively in alopecia areata for decades without high-quality randomized controlled evidence as monotherapy. Recent systematic reviews and case series describe combined LDOM and immunomodulator regimens with promising response in patchy and patterned alopecia areata, though randomized comparative data are limited [oral_minoxidil_2026_review].

Traction alopecia and chronic telogen effluvium EMERGING

Off-label; supported by case series and open-label experience.

Beach 2018 included oral minoxidil use in traction alopecia [beach2018_oral]; the Vañó-Galván 2021 safety series included patients with chronic telogen effluvium and lichen planopilaris [vanogalvan2021_safety]; the Randolph 2021 review summarizes the broader off-label use pattern [randolph2021_review].

Primary cicatricial alopecias (combined topical with tacrolimus + clobetasol) EMERGING

Off-label; retrospective evidence supports compounded topical combinations.

A 2025 retrospective analysis of compounded topical tacrolimus + clobetasol + minoxidil for primary cicatricial alopecias reported clinical stabilization in a meaningful subset; this is an example of the compounded combination use case in dermatology [cicatricial_combo_2025].

FDA-Approved Uses of Topical Minoxidil

Brand	Indication	Year	Route
Loniten	Severe hypertension associated with target organ damage and not manageable with maximum therapeutic doses of a diuretic plus two other antihypertensive drugs	1979	Oral tablet (2.5 mg, 10 mg)
Rogaine (topical 2% solution)	Androgenetic alopecia in men and women (FDA-approved 1988 Rx for men; later for women; subsequently transitioned to OTC under the topical minoxidil OTC monograph)	1988	Topical solution
	Androgenetic alopecia, 5% solution OTC for men, 5% foam OTC for men and women		

Brand	Indication	Year	Route
Rogaine (topical 5% solution and 5% foam)		1997 (5% solution); 2006 (5% foam)	Topical solution or foam

Oral minoxidil (Loniten) is FDA-approved for severe hypertension refractory to a diuretic plus two other antihypertensive drugs at usual doses of 10, 40 mg/day in single or divided doses (maximum 100 mg/day) [delphi2025_ldom]. The Loniten label [fda_label_loniten] carries a Boxed Warning for pericardial effusion (occasionally progressing to tamponade), reflex tachycardia and angina, and severe salt and water retention requiring concomitant diuretic therapy. Hypertrichosis is a labeled adverse effect that prompted the development of topical minoxidil for hair loss [lucky2004_female; olsen2007_foam; devillez1994_women].

Topical minoxidil (Rogaine and its generics) is FDA-approved/OTC for androgenetic alopecia [fda_label_rogaine, fda_otc_topical_minoxidil] [olsen2002_5vs2]. The 2% solution is approved for men and women, the 5% solution is approved for men, and the 5% foam is approved for both men and women [blume_peytavi_2011_foam_solution]. Approval is based on randomized trials demonstrating increased target-area hair count and patient and investigator global assessment vs placebo over 16, 48 weeks. Use beyond 12 months is generally required to maintain effect; discontinuation results in return to the pre-treatment hair-loss trajectory within 3, 6 months.

Low-dose oral minoxidil (LDOM) for hair loss is not an FDA-approved indication [vanogalvan2021_safety; ramos2022_ldom_rct; randolph2021_review]. It is supported by a well-developed off-label literature base and is widely prescribed by dermatologists and primary care clinicians in the United States and internationally.

Compounded Topical Minoxidil (503A)

Compounded minoxidil is dispensed under 503A on patient-specific prescriptions when the manufactured Rogaine and Loniten products cannot meet a documented clinical need. The clinically common 503A scenarios for minoxidil are: (1) low-dose oral preparations at 0.25, 0.5, 1, 1.25, 2.5, or 5 mg per dose unit, which are not commercially available, Loniten is supplied only as 2.5 mg and 10 mg tablets, and clinical guidance recommends starting LDOM at 0.25, 1 mg/day in women and 1.25, 2.5 mg/day in men [delphi2025_ldom, vanogalvan2021_safety, ramos2022_ldom_rct]; (2) oral suspensions for pediatric hair-loss indications where swallowing tablets is impractical; (3) higher-strength topical preparations (typically 7, 15%) for documented non-responders to 5%, supported by mechanism (sulfotransferase capacity variability) and small comparative series, though randomized data are limited [randolph_landscape_2025]; (4) topical combination preparations that pair minoxidil with finasteride and/or tretinoin and/or azelaic acid on a single vehicle, leveraging non-overlapping mechanisms (sulfotransferase-activated K-ATP opening, 5α-reductase inhibition, follicular keratinization)

[kanti2018_s3_guideline, randolph_landscape_2025]; and (5) alcohol-free or propylene-glycol-free vehicles for patients with vehicle-driven irritant or allergic contact dermatitis on commercial 2% or 5% Rogaine.

Compounded preparations are not bioequivalent to Rogaine or Loniten. For topical preparations, clinical effect depends on both drug concentration and vehicle properties (propylene-glycol content, alcohol content, foam vs solution rheology); for oral preparations, dose individualization at sub-tablet strengths cannot be reliably accomplished by tablet splitting of Loniten because the 2.5 mg scored tablet does not split reliably to 0.25 or 1 mg. Compounded preparations therefore extend the labeled minoxidil therapy into dose and vehicle ranges not commercially available, on a per-patient documented basis.

Use of compounded minoxidil at any oral dose requires the same cardiovascular and volume-status review as the manufactured Loniten tablet, scaled to the dose. LDOM trials and safety series at 0.25, 5 mg/day report adverse events dominated by hypertrichosis and mild edema; serious cardiac events (pericardial effusion, tamponade, severe tachycardia) are uncommon but documented [trueb2022_complication, vanogalvan2021_safety, ramos2024_cardiac_safety]. The 2025 modified Delphi consensus statement [delphi2025_ldom] frames initiation, baseline workup, dose titration, and red-flag monitoring for LDOM.

Topical Minoxidil Formulations and Routes

Form	Concentration	Description
Compounded oral capsule (low-dose)	0.25, 0.5, 1, 1.25, 2.5, or 5 mg per capsule	Patient-specific capsules of low-dose oral minoxidil compounded under USP <795> for hair-loss indications. Fills a dose gap between the manufactured 2.5 mg and 10 mg Loniten strengths that cannot be reliably reproduced by tablet splitting.
Compounded oral suspension	Custom, typically 0.1, 1 mg/mL aqueous suspension	Patient-specific oral suspension for pediatric hair-loss indications or for adults unable to swallow capsules. Beyond-use date and storage per USP <795>.
Compounded topical solution or foam (high strength)	Custom, typically 6, 15% minoxidil	Higher-strength topical preparation for documented non-responders to commercial 5% Rogaine. Vehicle can be propylene-glycol-free or alcohol-free for vehicle-sensitive patients.
Compounded topical combination	Typical: minoxidil 5, 7% + finasteride 0.1, 0.25% ± tretinoin 0.025% ± azelaic acid	Single-vehicle topical preparation pairing minoxidil with finasteride (5α-reductase inhibition), tretinoin (follicular keratinization), and/or azelaic acid for additive AGA mechanisms.
	2% solution, 5% solution, 5% foam	

Form	Concentration	Description
Manufactured topical Rogaine (reference product)		FDA-approved OTC topical minoxidil for androgenetic alopecia. 2% solution for men and women; 5% solution for men; 5% foam for men and women.
Manufactured Loniten oral tablet (reference product)	2.5 mg and 10 mg	FDA-approved Rx oral minoxidil for severe refractory hypertension; the only manufactured oral minoxidil strengths and the source of off-label LDOM repurposing for hair loss.

Routes used in published literature: topical, oral.

Topical Minoxidil Dosing

Route	Population	Range	Duration	Study type
Topical	Men with androgenetic alopecia (Rogaine 5% labeled regimen)	5% solution: 1 mL applied to dry scalp twice daily; or 5% foam: half a capful (~1 g) applied to dry scalp twice daily	Continuous; effect plateaus around 12 months; discontinuation reverses gains within 3, 6 months	FDA-approved OTC labeled regimen
Topical	Women with androgenetic alopecia (Rogaine 2% solution or 5% foam labeled regimen)	2% solution: 1 mL twice daily; or 5% foam: half a capful (~1 g) once daily	Continuous; effect plateaus around 12 months; discontinuation reverses gains within 3, 6 months	FDA-approved OTC labeled regimen
Oral	Adults with severe refractory hypertension (Loniten labeled regimen)	Initial 5 mg/day; usual maintenance 10, 40 mg/day in single or divided doses; maximum 100 mg/day. Co-administer with a diuretic and a beta-blocker per Boxed Warning	Indefinite while clinically indicated	FDA-approved labeled regimen
Oral	Women with female pattern hair loss (LDOM, off-label, compounded)	0.25 mg once daily titrated to 1 mg once daily; some patients	Indefinite while clinically beneficial; effect reverses on discontinuation	Randomized trial (Ramos/Nascimento 2022); multicenter safety cohort (Vañó-Galván 2021); pilot trial (Sinclair 2018);

Route	Population	Range	Duration	Study type
		maintained on 2.5 mg/day		international Delphi consensus (2025)
Oral	Men with androgenetic alopecia (LDOM, off-label, compounded)	1.25 mg once daily titrated to 5 mg once daily; typical maintenance 2.5, 5 mg/day	Indefinite while clinically beneficial; effect reverses on discontinuation	Open-label single-arm trial (Panchaprateep 2020); case series (Beach 2018); multicenter safety cohort (Vañó-Galván 2021); international Delphi consensus (2025)

Doctor-prescribed and titrated. For topical minoxidil, dosing follows the OTC label and is unaffected by body weight or organ function in adults [vanogalvan2021_safety]. For LDOM, dosing is generally initiated at 0.25, 1 mg/day in women and 1.25, 2.5 mg/day in men, titrated at 4- to 8-week intervals based on tolerability (hypertrichosis, lightheadedness, edema) and response. The Delphi consensus statement [delphi2025_ldom] formalizes baseline cardiovascular review, dose initiation, and follow-up cadence. Maximum LDOM doses in the published series range up to 5 mg/day, with higher doses moving toward the antihypertensive range and the Loniten Boxed Warning profile.

Combined oral therapy with finasteride 1 mg/day (men) or spironolactone 25, 100 mg/day (women) is commonly layered in dermatology practice on the basis of additive mechanisms; the Sinclair 2018 pilot study [sinclair2018_pilot] formally tested the LDOM + spironolactone combination. Combined topical and oral minoxidil therapy is supported by case series but has not been formally tested in a randomized trial; the international S3 guideline [kanti2018_s3_guideline] frames combination strategy [vanogalvan2021_safety].

Topical Minoxidil Safety

Topical minoxidil safety is dominated by local effects. Scalp pruritus, erythema, dryness, and irritant contact dermatitis occur in approximately 5, 15% of users, attributable in many cases to propylene glycol or alcohol in the vehicle rather than to minoxidil itself, the 5% foam formulation reduces this incidence relative to the 5% solution [25]. The early-treatment shed (synchronous telogen exit 2, 8 weeks after initiation) is a pharmacodynamic effect, not a safety event, but is the principal reason for early discontinuation; pre-treatment counseling reduces dropout [21]. Hypertrichosis at sites adjacent to the application area (forehead, sideburns, cheeks in women) is dose- and vehicle-dependent and improves with reduced application volume.

Systemic absorption from topical minoxidil at labeled doses is approximately 1.4% of the applied dose, producing negligible cardiovascular effects in adults without underlying disease [21]. Accidental ingestion or

excessive application can produce systemic hypotension and tachycardia, particularly in children; topical labels restrict use to adults [22].

Oral minoxidil at antihypertensive doses (10, 40 mg/day) carries the Loniten Boxed Warning for pericardial effusion (occasionally progressing to tamponade), reflex tachycardia and angina, and severe salt-and-water retention requiring concomitant diuretic. At low-dose oral hair-loss doses (0.25, 5 mg/day), the safety profile is substantially milder [21]. The Vañó-Galván 2021 multicenter analysis of 1404 LDOM patients [17] reported hypertrichosis (15.1% of patients), lightheadedness (1.7%), fluid retention (1.3%), tachycardia (0.9%), headache (0.4%), periorbital edema (0.3%), and insomnia (0.2%); treatment was discontinued in 1.7% of patients for adverse events. The 264-patient cardiac-safety analysis in patients with hypertension and arrhythmia [20] reported no excess of significant cardiac events at LDOM doses. The 2025 J Clin Med review [25] catalogs the adverse-event spectrum and management. Serious adverse events (pericardial effusion, tamponade) have been reported and are the subject of the Trüeb 2022 case report [19]; cardiology consultation is reasonable before initiating LDOM in patients with pre-existing cardiac disease or arrhythmia.

Hypersensitivity to minoxidil or to vehicle components is uncommon but documented [21]. Patients with documented allergic contact dermatitis on commercial Rogaine should be patch-tested to differentiate minoxidil-specific from vehicle-specific (propylene glycol, alcohol) reactions; vehicle-substituted compounded preparations frequently resolve the reaction.

Contraindications

Topical minoxidil is contraindicated in patients with known hypersensitivity to minoxidil or to vehicle components, and in patients with scalp conditions that disrupt the skin barrier (active dermatitis, recent scalp surgery, sunburn, abrasions) where systemic absorption may be elevated. Topical OTC labeling restricts use to adults ≥18 years; pediatric topical use is off-label and requires prescriber judgment.

Oral minoxidil (Loniten labeled regimen and LDOM) is contraindicated in pheochromocytoma (catecholamine-mediated paradoxical effects) and in known hypersensitivity to minoxidil. Relative contraindications for LDOM include pre-existing significant pericardial disease, congestive heart failure not controlled on a diuretic, hemodynamically significant aortic stenosis, recent myocardial infarction, and active arrhythmia not under cardiology management [212017]. Cardiology consultation is reasonable in patients with these conditions before initiating LDOM.

Pregnancy and lactation: see Special Populations.

Drug interactions

Topical minoxidil at labeled doses has no clinically significant systemic drug-drug interactions. Concomitant use of topical tretinoin or topical corticosteroids may increase systemic absorption of minoxidil by altering scalp barrier function; this is the mechanistic rationale for some compounded

combination topical preparations but is also a counseling point for patients using other topicals on the scalp.

Oral minoxidil at hypertensive doses requires co-administration of a diuretic to prevent salt-and-water retention and typically a beta-blocker or other sympatholytic to attenuate reflex tachycardia, per the Loniten labeling. Concomitant guanethidine can produce profound orthostatic hypotension and is contraindicated. At LDOM doses, the most clinically common interaction is additive hypotension or fluid retention with other antihypertensives, NSAIDs (sodium retention), or systemic corticosteroids [21][22]. Prescribers initiating LDOM should review the full medication list and adjust antihypertensive regimens accordingly.

Adverse events

Topical minoxidil: scalp pruritus and irritation (5, 15%), dryness, irritant or allergic contact dermatitis (often vehicle-mediated), hypertrichosis at application-adjacent sites (forehead, cheeks, particularly in women using 5% solution), and an early synchronous telogen shed 2, 8 weeks after initiation that resolves with continued use [24] [12]. Serious systemic adverse events from labeled topical use are rare in adults without underlying cardiovascular disease.

Oral minoxidil at antihypertensive doses: pericardial effusion (3% across early reports, sometimes progressing to tamponade), reflex tachycardia, angina exacerbation, severe salt-and-water retention with peripheral edema and weight gain, hypertrichosis (essentially universal at chronic dosing), and rare ECG changes, the basis for the Loniten Boxed Warning [24].

Low-dose oral minoxidil at hair-loss doses (0.25, 5 mg/day): the Vañó-Galván 2021 series in 1404 patients [17] reported hypertrichosis (15.1%), lightheadedness (1.7%), fluid retention (1.3%), tachycardia (0.9%), headache (0.4%), periorbital edema (0.3%), and insomnia (0.2%); 1.7% discontinued for adverse events [24]. The Ramos 2022 randomized trial of 0.25 vs 1 mg in women [18] reported facial hypertrichosis as the dominant tolerability issue with a dose-response relationship favoring the 0.25 mg dose for tolerability [53]. The 264-patient cardiac safety study [20] in patients with hypertension and arrhythmia did not detect an excess of significant cardiac adverse events. The 2025 J Clin Med review [25] characterizes the LDOM adverse-event spectrum and management. The Trüeb 2022 case report [19] documents a serious LDOM adverse event and is the reference for serious-event counseling.

Monitoring Topical Minoxidil Therapy

Topical minoxidil: baseline assessment of scalp condition, patient counseling on the early telogen shed (2, 8 weeks after initiation), and education that effect plateaus at 12 months and reverses on discontinuation. No laboratory monitoring is required for labeled topical use.

Low-dose oral minoxidil: baseline blood pressure, heart rate, weight, screening for pre-existing cardiovascular disease (history of pericardial disease, congestive heart failure, ischemic heart disease,

arrhythmia, aortic stenosis), and review of concomitant antihypertensives. Patients with established cardiac disease or arrhythmia should be reviewed by cardiology before initiation [delphi2025_ldom, ramos2024_cardiac_safety]. On therapy, follow-up at 4, 8 weeks to assess heart rate, blood pressure, weight, lower-limb edema, hypertrichosis, and treatment response; subsequent follow-up every 3, 6 months. Patients should be educated to report new dyspnea, chest pain, palpitations, peripheral edema, or rapid weight gain [trueb2022_complication, vanogalvan2021_safety].

Topical Minoxidil in Special Populations

Topical Minoxidil Evidence Quality

Evidence supporting topical minoxidil for androgenetic alopecia is strong and longitudinal [devillez1994_women; blume_peytavi_2011_foam_solution; vexiau2002_cyproterone]. Pivotal randomized trials in men [savin1987_topical, olsen2002_5vs2, olsen2007_foam] and women support the 2%, 5%, and 5% foam approvals. The EADV S3 evidence-based guideline [kanti2018_s3_guideline] recommends topical minoxidil 5% as first-line topical therapy for both sexes [lucky2004_female]. Contemporary reviews [randolph2021_review, nestor2021_aga_review, randolph_landscape_2025] integrate topical, oral, and emerging delivery modalities.

Evidence supporting low-dose oral minoxidil for hair loss has matured from case series [beach2018_oral] through pilot trials [sinclair2018_pilot] to randomized trials (Ramos/Nascimento 2022, 0.25 vs 1 mg in women [ramos2022_ldom_rct]; Panchaprateep 2020 open-label 5 mg in men [panchaprateep2020_men_5mg]), large multicenter safety cohorts (Vañó-Galván 2021, N=1404 [vanogalvan2021_safety]; 264-patient cardiac safety analysis [ramos2024_cardiac_safety]), and an international modified Delphi consensus statement on initiation [delphi2025_ldom]. The 2025 J Clin Med adverse-event review [eventos_ldom_2025_jcm], the 2025 hypertrichosis characterization study [ldom_5mg_hypertrichosis_2025], and the 2026 Am J Clin Dermatol review [oral_minoxidil_2026_review] consolidate the contemporary LDOM literature. This evidence base supports the 'well-studied' tier for LDOM despite the off-label regulatory status.

Evidence specifically supporting compounded combination topicals (minoxidil + finasteride ± tretinoin ± azelaic acid) and higher-strength compounded topicals is more limited, small comparative series and mechanism-based extrapolation from the topical minoxidil and oral finasteride pivotal trials [roberts1999_finasteride, kanti2018_s3_guideline, randolph_landscape_2025]. Compounded combination therapy is generally well-tolerated and is supported by class-of-evidence reasoning rather than dedicated pivotal trials; this aligns with the 'well-studied' tier for the compounded use case.

Major Topical Minoxidil Clinical Studies

Study	Design	Participants	Duration	Finding
Olsen et al. (2002, JAAD), 5% vs 2% topical minoxidil in men with AGA	Randomized, double-blind, placebo-controlled trial of 5% solution vs 2% solution vs placebo in men with androgenetic alopecia	393	48 weeks	5% solution superior to 2% solution and to placebo on target-area hair count and patient/investigator global assessment; 5% group showed ~45% greater hair-count change than 2% group [olsen2002_5vs2]. Supported FDA approval of 5% strength.
Olsen et al. (2007, JAAD), 5% minoxidil foam in men with AGA	Multicenter, randomized, double-blind, placebo-controlled trial of 5% topical minoxidil foam in men with androgenetic alopecia	—	16 weeks	5% foam significantly increased target-area hair count and patient-rated hair growth vs vehicle, with reduced scalp irritation relative to historical solution data, supported approval of the foam vehicle [olsen2007_foam].
Lucky et al. (2004, JAAD), 5% and 2% topical minoxidil in women with FPHL	Randomized, placebo-controlled trial of 5% and 2% topical minoxidil solutions vs vehicle in women with female pattern hair loss	381	48 weeks	Both 5% and 2% solutions produced significant hair-count and global-assessment improvements vs vehicle; non-significant trend favoring 5% [lucky2004_female]. Supported FDA approval for women.
DeVillez et al. (1994, Arch Dermatol), 2% minoxidil in female AGA	Randomized, double-blind, placebo-controlled trial of 2% topical minoxidil solution in women with androgenetic alopecia	—	32 weeks	2% solution produced significantly greater hair regrowth than placebo; supported FDA approval of the 2% strength for women [devillez1994_women].
Blume-Peytavi et al. (2011, JAAD),	Randomized, single-blind trial of	—	24 weeks	5% foam once daily non-inferior to 2% solution twice daily on target-area hair

Study	Design	Participants	Duration	Finding
5% foam once daily vs 2% solution twice daily in women	5% minoxidil foam once daily vs 2% minoxidil solution twice daily in women with androgenetic alopecia			count, with reduced application-site irritation, supported OTC approval of 5% foam for women [blume_peytavi_2011_foam_solution].
Vexiau et al. (2002, BJD), minoxidil 2% vs cyproterone acetate in female AGA	Controlled 12-month randomized trial of topical minoxidil 2% vs oral cyproterone acetate in women with female androgenetic alopecia	—	12 months	Both treatments produced significant hair growth; minoxidil favored in non-hyperandrogenic patients, cyproterone in hyperandrogenic patients [vexiau2002_cyproterone].
Savin (1987, JAAD), topical minoxidil in male pattern baldness	Multicenter trial of topical minoxidil in male pattern baldness	—	—	Established efficacy of topical minoxidil on target-area hair count and patient-assessed hair regrowth; foundational evidence for the 1988 FDA approval [savin1987_topical].
Buhl et al. (1990, J Invest Dermatol), minoxidil sulfate is the active metabolite	Mechanistic study comparing minoxidil and minoxidil sulfate effects on hair follicles	—	—	Minoxidil sulfate, the sulfotransferase product, is the active metabolite that stimulates hair follicles; minoxidil itself is essentially inactive at the target [buhl1990_sulfate].
Buhl et al. (1993, J Invest Dermatol), Potassium channel conductance as a control mechanism in hair follicles	In vitro mechanistic study of K-ATP channel activity in hair follicles	—	—	K-ATP channel opening by minoxidil sulfate hyperpolarizes hair follicle cells and prolongs anagen, molecular basis for the hair-growth effect [buhl1993_potassium].
Messenger and Rundegren (2004, BJD),	Canonical mechanism review integrating	—	—	Sulfotransferase activation to minoxidil sulfate followed by K-ATP channel opening on dermal papilla and outer root

Study	Design	Participants	Duration	Finding
Minoxidil: mechanisms of action on hair growth	sulfotransferase, K-ATP, and hair-cycle data			sheath underlies the prolongation of anagen and shortening of telogen [messenger2004_mechanism].
Headington (1993, Arch Dermatol), Telogen effluvium: new concepts and review	Conceptual review of hair-cycle perturbation and telogen effluvium	—	—	Framed the synchronous telogen exit ('shed') seen with minoxidil initiation and dose changes, the basis for current patient counseling on the 2- to 8-week early shed [headington1993_telogen].
Beach (2018, Dermatol Ther), Oral minoxidil for androgenetic and traction alopecia	Case series of oral minoxidil for androgenetic and traction alopecia, focused on tolerability and the 'five C's' of oral therapy	—	—	Demonstrated feasibility of low-dose oral minoxidil for hair loss with manageable tolerability, one of the foundational LDOM publications [beach2018_oral].
Sinclair (2018, Int J Dermatol), LDOM + spironolactone in FPHL	Pilot study of low-dose oral minoxidil (0.25 mg) + spironolactone (25 mg) once daily in women with female pattern hair loss	—	—	Combination therapy produced meaningful hair regrowth with tolerable adverse-event profile, first systematic LDOM combination report in women [sinclair2018_pilot].
Panchaprateep and Lueangarun (2020, Dermatol Ther), Oral minoxidil 5 mg in men with AGA	Open-label, single-arm trial of oral minoxidil 5 mg once daily in men with androgenetic alopecia, with global photographic assessment	—	24 weeks	Significant increases in target-area hair count and patient and investigator global assessment; tolerability acceptable with hypertrichosis as the principal adverse effect [panchaprateep2020_men_5mg].
Vañó-Galván et al. (2021, JAAD), Safety of LDOM in 1404 patients	Multicenter retrospective safety analysis of low-	1404	—	Hypertrichosis 15.1%, lightheadedness 1.7%, fluid retention 1.3%, tachycardia 0.9%; treatment discontinued in 1.7% for adverse events. The reference safety

Study	Design	Participants	Duration	Finding
	dose oral minoxidil for hair loss			series for modern LDOM practice [vanogalvan2021_safety].
Nascimento e Silva / Ramos et al. (2022, JAAD), Randomized trial of 0.25 mg vs 1 mg LDOM in women	Randomized clinical trial of low-dose oral minoxidil 0.25 mg vs 1 mg daily for female pattern hair loss	—	24 weeks	Both doses improved hair density; 1 mg produced greater hair count change but with higher rates of facial hypertrichosis [ramos2022_ldom_rct]. Established the dose-response and tolerability trade-off for women's LDOM.
Trüeb et al. (2022, JAAD Case Reports), Serious complication of LDOM	Case report of a serious low-dose oral minoxidil complication	—	—	Documented a serious LDOM adverse event; the reference case for counseling and for cardiology workup before initiation [trueb2022_complication].
Cardiac safety of LDOM (2024, Actas Dermo-Sifiliográficas), 264 patients with hypertension and arrhythmia	Multicenter study of low-dose oral minoxidil safety in patients with hypertension and arrhythmia	264	—	No excess of significant cardiac adverse events at LDOM doses in patients with pre-existing cardiovascular comorbidity; supports use in cardiology co-management [ramos2024_cardiac_safety].
International modified Delphi consensus (2025, JAMA Dermatology), LDOM initiation	International modified Delphi consensus statement on low-dose oral minoxidil initiation for patients with hair loss	—	—	Provided structured initiation, dose titration, baseline cardiovascular workup, and red-flag monitoring guidance for LDOM in clinical practice [delphi2025_ldom].
Randolph and Tosti (2021, JAAD), Oral minoxidil for hair loss: efficacy and safety review	Narrative review of oral minoxidil for hair loss	—	—	Consolidated efficacy and safety evidence across LDOM publications through 2021; established the framing used by subsequent reviews and the Delphi consensus [randolph2021_review].

Study	Design	Participants	Duration	Finding
Roberts et al. (1999, JAAD), Finasteride dose-ranging in men with MPHL	Clinical dose-ranging studies with finasteride, a type 2 5α-reductase inhibitor, in men with male pattern hair loss	—	—	Established the 1 mg/day finasteride dose for male androgenetic alopecia, the principal partner agent in compounded combination topicals and in oral combination therapy with LDOM [roberts1999_finasteride].
Kanti et al. (2018, JEADV), EADV S3 guideline for AGA	Evidence-based S3 guideline for the treatment of androgenetic alopecia in women and men	—	—	Topical minoxidil 5% recommended as first-line topical therapy for both sexes; combination strategies framed for use after monotherapy plateau [kanti2018_s3_guideline].
24-week 5 mg LDOM hypertrichosis characterization (2025, Int J Trichology)	Prospective characterization of hypertrichosis induced by 24 weeks of 5 mg/day oral minoxidil in men with male pattern hair loss	—	—	Hypertrichosis prevalence, distribution, and management in men on 5 mg/day LDOM; the dominant tolerability issue at this dose [ldom_5mg_hypertrichosis_2025].
LDOM adverse events review (2025, J Clin Med)	Narrative review of adverse events of low-dose oral minoxidil treatment for alopecia	—	—	Catalogs the LDOM adverse-event spectrum (hypertrichosis, edema, lightheadedness, cardiac) and management; companion to the Delphi initiation consensus [eventos_ldom_2025_jcm].
Oral Minoxidil for Alopecia Treatment (2026, Am J Clin Dermatol)	Comprehensive review of oral minoxidil for alopecia treatment, risks, benefits, and recommendations	—	—	Most recent integrative review of LDOM for AGA, female pattern hair loss, telogen effluvium, alopecia areata, and traction alopecia, with practical prescribing guidance [oral_minoxidil_2026_review].

Topical Minoxidil Pharmacokinetics & Pharmacodynamics

Pharmacokinetics

Oral minoxidil is rapidly and almost completely absorbed (≥90% bioavailability), with time to maximum concentration of approximately 1 hour [oral_minoxidil_2026_review]. The terminal half-life is approximately 4 hours, but hemodynamic effect persists 24, 72 hours due to the long duration of the K-ATP-channel-opening effect. Metabolism is principally hepatic via glucuronidation (minoxidil glucuronide is the major metabolite) and sulfation to minoxidil sulfate (the active metabolite). Renal excretion accounts for approximately 12% of an oral dose as parent compound; the remainder is excreted as glucuronide and other metabolites.

Topical minoxidil bioavailability is approximately 1.4% of the applied dose under normal scalp conditions, producing negligible systemic exposure in adults without underlying disease [randolph2021_review] [oral_minoxidil_2026_review]. Vehicle composition (propylene glycol, ethanol, water ratios; foam vs solution) and scalp barrier integrity modulate absorption; abraded or inflamed scalp can substantially increase systemic exposure. The sulfotransferase activation step occurs principally in the outer root sheath at the site of application, which is why topical exposure with low systemic absorption nonetheless produces a robust local pharmacodynamic effect.

Low-dose oral minoxidil (0.25, 5 mg/day) produces small but measurable reductions in blood pressure and modest reflex tachycardia in some patients [oral_minoxidil_2026_review]. The pharmacokinetics of oral LDOM are linear scaling of the Loniten profile to the lower dose. The compounded oral preparation should be designed for dose accuracy at sub-tablet strengths because the Loniten 2.5 mg scored tablet cannot reliably split to 0.25 mg or 1 mg.

Pharmacodynamics

Pharmacodynamic effects in hair follicles include prolonged anagen, shortened telogen, increased follicle diameter, increased hair count, and (transiently) a synchronous telogen shed 2, 8 weeks after initiation. Cardiovascular pharmacodynamic effects of oral minoxidil are direct arteriolar vasodilation, reflex tachycardia, and salt-and-water retention, the basis for the Loniten Boxed Warning and for LDOM monitoring [messenger2004_mechanism].

Target-area hair count, patient and investigator global assessment, and trichoscopy-based hair density measurements are the principal clinical pharmacodynamic endpoints in AGA trials [olsen2002_5vs2, lucky2004_female, ramos2022_ldom_rct] [messenger2004_mechanism]. Effect onset is gradual (visible improvement typically at 12, 16 weeks); plateau is at 9, 12 months; discontinuation reverses gains within 3, 6 months.

Comparing Topical Minoxidil Formulations

Manufactured topical products are Rogaine and generics at 2% solution (men and women), 5% solution (men), and 5% foam (men and women). Foam vehicle reduces scalp irritation relative to solution at the same concentration and allows once-daily dosing in women per Blume-Peytavi 2011 [blume_peytavi_2011_foam_solution]. Vehicle differences (propylene glycol content, alcohol content) are the principal driver of vehicle-mediated dermatitis; compounded preparations can be propylene-glycol-free or alcohol-free for vehicle-sensitive patients.

Manufactured oral product is Loniten at 2.5 mg and 10 mg tablet strengths. Compounded oral preparations at 0.25, 0.5, 1, 1.25, and 5 mg per capsule (or as oral suspensions) extend dosing into the LDOM range that Loniten cannot reliably accommodate by tablet splitting [delphi2025_ldom, ramos2022_ldom_rct].

Compounded combination topicals (minoxidil + finasteride ± tretinoin) pair non-overlapping mechanisms on a single vehicle; comparative trials versus monotherapy minoxidil are limited but mechanism-based extrapolation supports the combination in AGA [kanti2018_s3_guideline, randolph_landscape_2025].

Topical Minoxidil Storage and Handling

Manufactured Rogaine and Loniten are stored at room temperature (20, 25°C) in their original packaging. Topical solutions and foam are flammable due to ethanol content; store away from open flame. Compounded topical and oral preparations are stored per the pharmacy's stability data and beyond-use date assignment under USP <795> for nonsterile preparations; refrigerated storage is not required for typical formulations but may extend BUD for certain oral suspensions [usp_795].

Topical Minoxidil Compounding & Operations

503A compounding

Compounded minoxidil is prepared under 503A on patient-specific prescriptions in state-licensed compounding pharmacies. RonanRx prepares nonsterile preparations (oral capsules, oral suspensions, topical solutions, topical foams) per USP General Chapter <795>, the official compendial standard for nonsterile pharmaceutical compounding, with documented active ingredient sourcing, gravimetric verification, beyond-use date assignment, and full lot traceability [usp_795].

Each compounded batch is documented per state board of pharmacy retention rules with full traceability from API lot through dispensing. Active pharmaceutical ingredient is sourced from FDA-registered facilities with documented certificates of analysis.

Pharmacist review

Each prescription for compounded minoxidil undergoes pharmacist review prior to dispensing. The review confirms: a documented patient-specific clinical reason that manufactured Rogaine and/or Loniten cannot meet the clinical need (sub-tablet oral dose for LDOM, oral suspension for pediatric dosing, higher-strength topical, vehicle substitution for vehicle-sensitive scalp, or topical combination with finasteride/tretinoin); appropriate baseline workup for oral preparations (blood pressure, heart rate, cardiovascular history per the Delphi consensus [delphi2025_ldom]); review of concomitant medications including other antihypertensives, NSAIDs, and topical scalp medications; and a prescribed regimen consistent with the LDOM literature [vanogalvan2021_safety, ramos2022_ldom_rct].

RonanRx does not fill prescriptions that read as routine substitution of compounded for manufactured product without documented clinical rationale, consistent with FDA guidance on compounded copies of commercially available drugs.

Quality and traceability

Active pharmaceutical ingredients are sourced from FDA-registered facilities with documented certificates of analysis. Each batch is recorded with lot numbers traceable to API source, compounding date, beyond-use date, and dispensing pharmacist of record. Finished product lot records are retained per state board of pharmacy retention requirements.

Cold chain

Compounded minoxidil is not a cold-chain product. Standard room-temperature shipping is used; refrigerated storage is generally not required for capsules, topical solutions, topical foams, or short-dating oral suspensions per the pharmacy's stability data.

Frequently Asked Questions About Topical Minoxidil

What is the difference between Rogaine, Loniten, and compounded minoxidil?

Rogaine is the topical FDA-approved/OTC product (2% solution, 5% solution, 5% foam) for androgenetic alopecia [olsen2002_5vs2]. Loniten is the oral FDA-approved Rx product (2.5 mg and 10 mg tablets) for severe refractory hypertension. Compounded minoxidil is pharmacy-prepared on a patient-specific prescription, typical 503A roles are low-dose oral preparations at 0.25, 5 mg for hair loss (filling the dose gap between the manufactured 2.5 mg and 10 mg Loniten tablets), oral suspensions for pediatric dosing, higher-strength topical preparations, vehicle-substituted topicals for sensitive scalp, and topical combinations with finasteride or tretinoin [delphi2025_ldom; vanogalvan2021_safety].

Is low-dose oral minoxidil safe at hair-loss doses?

The largest published safety series (Vañó-Galván 2021, N=1404) reported hypertrichosis in 15.1%, lightheadedness in 1.7%, fluid retention in 1.3%, and tachycardia in 0.9%, with treatment discontinuation for adverse events in 1.7% [vanogalvan2021_safety; delphi2025_ldom]. A separate 264-patient series in patients with hypertension and arrhythmia did not detect an excess of significant cardiac events at LDOM doses [ramos2024_cardiac_safety]. Serious adverse events (e.g., pericardial effusion) have been reported and remain a counseling point [trueb2022_complication]. Baseline cardiology review is appropriate in patients with pre-existing cardiovascular disease before starting LDOM.

Why is the early shed (telogen shed) part of starting minoxidil?

Minoxidil shifts resting (telogen) hair follicles into a new growth (anagen) phase [messenger2004_mechanism]. The synchronous exit of telogen hairs produces a temporary increased shedding 2, 8 weeks after starting or escalating treatment [headington1993_telogen]. This is a pharmacodynamic effect, not a safety event, and resolves with continued use. Counseling on this effect at initiation reduces early discontinuation.

Is 5% topical minoxidil more effective than 2%?

In men with androgenetic alopecia, yes, the Olsen 2002 pivotal trial demonstrated approximately 45% greater hair-count change with 5% solution than with 2% solution at 48 weeks [olsen2002_5vs2]. In women, the Lucky 2004 trial found both strengths effective with only a non-significant trend favoring 5% [lucky2004_female]. The Blume-Peytavi 2011 trial established that 5% foam once daily is non-inferior to 2% solution twice daily in women, with reduced scalp irritation [blume_peytavi_2011_foam_solution].

When is compounded minoxidil appropriate?

Compounded minoxidil is dispensed under 503A only when manufactured Rogaine or Loniten cannot meet a patient-specific clinical need. Common scenarios: low-dose oral capsules at 0.25, 5 mg for hair-loss patients (Loniten only comes in 2.5 mg and 10 mg, and tablet splitting is unreliable at these low doses); oral suspensions for pediatric dosing; higher-strength topical for documented 5% non-responders; vehicle-substituted topical (alcohol-free or propylene-glycol-free) for vehicle-mediated dermatitis on Rogaine; and topical combinations with finasteride or tretinoin [delphi2025_ldom; ramos2022_ldom_rct].

How does oral minoxidil for hair loss differ from oral minoxidil for blood pressure?

The dose. Loniten is dosed at 10, 40 mg/day for severe hypertension and carries a Boxed Warning for pericardial effusion, reflex tachycardia, and fluid retention. Low-dose oral minoxidil (LDOM) for hair loss is dosed at 0.25, 5 mg/day, a fraction of the antihypertensive dose [vanogalvan2021_safety; ramos2024_cardiac_safety; randolph2021_review]. The published LDOM safety literature shows substantially milder adverse events at these doses, dominated by hypertrichosis and mild edema rather than serious cardiac events.

Does RonanRx sell compounded minoxidil directly to patients?

No. Compounded minoxidil requires a patient-specific prescription written by a licensed clinician for an identified patient, plus pharmacist review before dispensing. RonanRx is not a direct-to-consumer storefront.

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How to Access Topical Minoxidil

Compounded Topical Minoxidil is dispensed under 503A on a patient-specific prescription. Depending on your role, the next step looks different.

FOR PRESCRIBING CLINICIANS

Offer this medication

A pharmacist will follow up within two business days. We'll cover state availability, supported formulations, and what integration looks like for your clinic.

ronanrx.com/request-partnership-call

PATIENT WITH A DOCTOR

Receive your prescription

If your doctor has prescribed Topical Minoxidil, sign up so we can prepare and ship your medication. The signup wizard collects intake and connects you to the prescribing workflow.

ronanrx.com/patients

PATIENT WITHOUT A DOCTOR

Find a partner clinic

RonanRx prescribes through partner clinics — we don't initiate prescriptions on this site. Read how the referral process works and how to find a partner clinic in your state.

ronanrx.com/find-clinic

Other compounds RonanRx makes

This monograph is one of many in the RonanRx formulary. Every compound below is prepared under 503A on a patient-specific prescription. Browse the full catalog at ronanrx.com/medications and ronanrx.com/peptides, or scan the codes at right for each index.

Medications

Peptides

MEDICATIONS (40)

Alpha-Lipoic Acid (ALA) — Antioxidant & mitochondrial
Coenzyme Q10 (CoQ10) — Antioxidant & mitochondrial
Glutathione — Antioxidant & mitochondrial
NAD+ / NMN — Antioxidant & mitochondrial
Compounded Topical Anesthetics (BLT, LET) — Dermatology
Topical Minoxidil — Dermatology
Topical Tretinoin — Dermatology
Compounded Magnesium — Energy & nutritional
Cyanocobalamin — Energy & nutritional
High-Dose Vitamin D — Energy & nutritional
Hydroxocobalamin — Energy & nutritional
Iron (Compounded) — Energy & nutritional
L-Carnitine — Energy & nutritional
Methylcobalamin (B12) — Energy & nutritional
Methylfolate — Energy & nutritional
Anastrozole — Hormone optimization
Clomiphene & Enclomiphene — Hormone optimization
DHEA — Hormone optimization
Estradiol — Hormone optimization
Estriol — Hormone optimization
Human Chorionic Gonadotropin (HCG) — Hormone optimization
Pregnenolone — Hormone optimization
Progesterone — Hormone optimization
Testosterone — Hormone optimization
Compounded Metformin — Metabolic & weight
Compounded Semaglutide — Metabolic & weight
Compounded Tirzepatide — Metabolic & weight
Lipotropic Injection (MIC, MICC) — Metabolic & weight
Low-Dose Naltrexone (LDN) — Metabolic & weight
Naltrexone-Bupropion Combination — Metabolic & weight
Topiramate — Metabolic & weight
Bremelanotide / PT-141 — Sexual health
Compounded Sildenafil — Sexual health
Compounded Tadalafil — Sexual health
Trimix Injection — Sexual health
Compounded Gabapentin — Sleep & recovery
Compounded Melatonin — Sleep & recovery
Compounded T3 (Liothyronine) — Thyroid
Compounded T3/T4 Combinations — Thyroid
Compounded T4 (Levothyroxine) — Thyroid

PEPTIDES (21)

Sermorelin — Available now

Tesamorelin — Available now

AOD-9604 — Growth-hormone axis (under FDA review)

CJC-1295 — Growth-hormone axis (under FDA review)

GHRP-2 / GHRP-6 — Growth-hormone axis (under FDA review)

Hexarelin — Growth-hormone axis (under FDA review)

Ipamorelin — Growth-hormone axis (under FDA review)

MK-677 / Ibutamoren — Growth-hormone axis (under FDA review)

5-Amino 1MQ — Metabolic & longevity (under FDA review)

Epitalon / Epithalon — Metabolic & longevity (under FDA review)

MOTS-C — Metabolic & longevity (under FDA review)

Thymosin Alpha-1 / Thymalin — Metabolic & longevity (under FDA review)

DSIP, Delta Sleep-Inducing Peptide — Neuro & cognitive (under FDA review)

Selank — Neuro & cognitive (under FDA review)

Semax — Neuro & cognitive (under FDA review)

Vasoactive Intestinal Peptide (VIP) — Neuro & cognitive (under FDA review)

BPC-157 — Tissue repair (under FDA review)

KPV — Tissue repair (under FDA review)

LL-37 — Tissue repair (under FDA review)

Pentadeca Arginate (PDA) — Tissue repair (under FDA review)

TB-500 / Thymosin Beta-4 — Tissue repair (under FDA review)