REVIAN RED Light Therapy Safe and Effective for Hair Growth

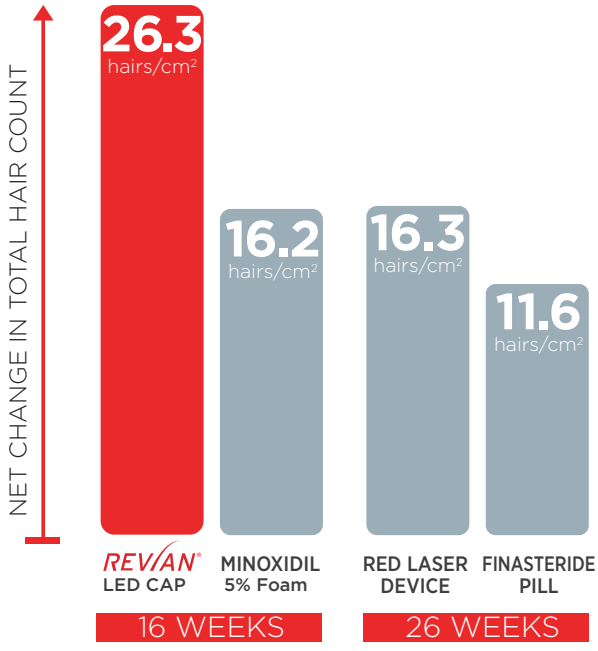
REVIAN RED's Modulated Light Therapy (MLT) introduces a new class of treatment for androgenetic alopecia.

Androgenetic alopecia is a common form of hair loss that affects an estimated 50 million men and 30 million women in the United States. Male pattern hair loss is typically characterized by a receding hairline or balding of the crown, while female pattern hair loss appears as overall thinning or widening of the midline.

Given the prevalence of hair loss in society today, health care providers (HCP) frequently encounter patients seeking medical advice regarding hair growth interventions. Current FDA regulated treatment options include topical minoxidil, oral finasteride for men, low-level laser light therapy (LLLT), and *REVIAN* RED Modulated Light Therapy. *REVIAN* RED utilizes dual activating wavelengths of precise LED light as a new class of modulated light therapy (MLT) that unlocks the body's ability to stimulate hair growth.

When patients present seeking medical advice regarding hair growth solutions, they generally express interest in something that is minimally invasive and that can be efficiently self-administered at home. They want exceptional, measurable results that exceed alternative options, and they want to be able to attain results while multi-tasking—whether that's watching the game or shopping online—without worrisome risks or cumbersome side effects.

Figure 1: *REVIAN* RED Grows More Hair in Less Time



**No head-to-head trials were conducted. Percentages are derived from cross study comparisons to published results for net change in hair counts vs. placebo/control arm.*

REVIAN RED Clinical Results

The FDA-cleared *REVIAN* RED system (#K173729) has clinically demonstrated the ability to stop hair loss, and subsequently promote hair growth. Results from a pivotal clinical trial provide evidence that subjects, on average, may experience a greater net increase in total hair counts than those published for alternative chemical-based topicals, prescription drugs, and laser devices, based on cross-study comparisons. **(Figure 1)**

The *REVIAN* RED clinical trial was specifically designed with the rigor of a pharmaceutical trial.

— Dr. Rodney Sinclair, Principal Investigator, Dermatologist and Professor of Medicine at Melbourne University

The randomized, double-blind, placebo-controlled trial, enrolled adult males and females, 18 to 65 years of age with diagnosis of androgenetic alopecia. Participants agreed to refrain from using all other hair growth products or treatments (oral or topical medication, including over the counter herbal medications) during the study. Study subjects were randomly provided either an activated red-light-based hair growth treatment cap or a placebo cap with no light therapy. They were treated 10 minutes per day for up to 26 weeks. The primary endpoint for this clinical trial was the mean change in target area hair count between active and sham treated subjects at week 16. Total hair counts were obtained from computer assisted scans of digital photographs taken of a defined target area (1 cm^2) centered around a tattoo located in the anterior mid area of the scalp. The efficacy evaluable population was defined as participants who completed at least 16 weeks of treatment, had no major protocol violations, and who were at least 80% compliant with the 10 minutes per day treatment regimen for the duration of the trial.

After 16 weeks, trial participants who were treated with the red light therapy and were at least 80% compliant (n=18) had an average of 26.3 more hairs per cm^2 compared to where they started than those participants who wore a placebo cap but received no light therapy (n=18). Subjects treated with the placebo cap continued to lose hair over the duration of the study.

The safety of *REVIAN* RED was carefully monitored and recorded. There were no treatment discontinuations due to an adverse event and there were no device related serious

adverse events reported in the trial for any of the treatment arms. In the safety population (Intent-to-Treat), there was also a trend toward more hair growth for *REVIAN* RED than placebo.

REVIAN RED Checks All the Boxes

The *REVIAN* RED system comprises a wireless, wearable cap that is controlled by a mobile phone' app. The rechargeable battery-operated cap functions to provide a hair loss treatment using precisely selected, dual wavelengths of LED light (620 and 660 nm) which provide broader scalp coverage and better skin penetration than red lasers used in low level laser therapy (LLLT). The *REVIAN* RED system essentially unlocks the body's own ability to stimulate hair growth through the stimulation of Nitric Oxide which has numerous benefits for scalp health. Nitric Oxide targets all four pathogenic factors known to be associated with hair loss; **(Figure 2)** inhibiting androgen synthesis and the activity of 5a-reductase to halt production of dihydrotestosterone (DHT), enhancing natural growth factors and reducing inflammatory signaling cascades, and increasing blood flow to the hair follicle through its Nobel Prize winning functionality as a vasodilator. With increased blood flow supplying more nutrients to the hair follicles, the system not only generates new hair, it further strengthens it to prevent future hair loss.

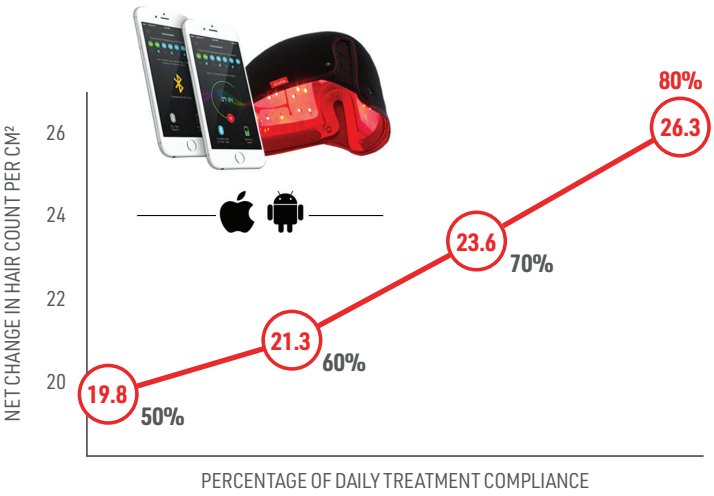
Figure 2: Nitric Oxide targets all four pathogenic factors known to be associated with hair loss.

	Follicular Transplant	Minoxidil	Low-Level Light Therapy (LLLT)	Finasteride	Nitric Oxide
Androgen reduction	✗	✗	✗	✓	✓
5a-reductase inhibitor	✗	✗	✗	✓	✓
Anti-inflammatory	✗	✗	✓	✗	✓
Vasodilation	✗	✓	✓	✗	✓

Compliance is Key

For any hair growth regimen to work, compliance is crucial, and this is another area where *REVIAN* RED excels. The integrated smart phone App provides a user-friendly way to plan treatment sessions. It also tracks daily progress and provides a direct link to *REVIAN* RED's client service team. The App's ability to support adherence to the regimen is among *REVIAN* RED's main differentiators. In fact, participants in the randomized placebo-controlled clinical trial who were at least 80% adherent to the protocol grew more hair on average than the broad study population. **(Figure 3)**

Figure 3: Increased daily use of *REVIAN* RED equals more daily hair growth.



We are so confident that compliance is key to seeing great results, we offer our customers a 100% money-back guarantee. When using the mobile App, if a user completes 8 out of every 10 once-daily treatments and doesn't see the growth they expect after 6 months, send the unit back and *REVIAN* will provide a full refund.

In Conclusion

The *REVIAN* RED System's superior efficacy, convenience, and safety in comparison to other available hair growth interventions is clear. *REVIAN* RED has minimal side effects, no contraindications, and its chemical-free system allows patients to safely and effectively 'layer' or simultaneously use other hair growth therapies, such as Platelet Rich Plasma (PRP), hair transplant, topical solutions, and/or nutritional supplements.

Indications for Use:

The *REVIAN* RED System is indicated to treat androgenetic alopecia and to promote hair growth in males who have Norwood-Hamilton classifications of IIa–V patterns of hair loss and to treat androgenetic alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I–IV.

Data on file. ClinicalTrials.gov Identifier: NCT04019795.

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