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Original Research Article

Clinical evaluation of EqualsTwo® under eye gel in the management of periorbital issues in pregnant and lactating women: an open-label study

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ABSTRACT

Background: Periorbital hyperpigmentation, puffiness, and fine lines are common dermatological concerns adversely impacting quality of life. Conventional therapies, including hydroquinone and retinoids have safety limitations in pregnant and lactating women, necessitating exploration of botanical alternatives. This study evaluated the safety and efficacy of a natural-origin EqualsTwo® under eye gel in improving periorbital concerns within this sensitive population.

Methods: In this prospective, open-label, single-arm exploratory study, 72 women (12 pregnant, 60 lactating; aged 22-40 years) were enrolled; 65 completed the trial. Participants applied approximately 0.2 gm of the investigational product twice daily for 42 days. Dermatological assessments were performed using a 6-point grading scale for dark circles, Investigator's Global Assessment Scale for puffiness, and Allergan fine lines scale. Melanin concentration and fine-line metrics (count, length, width, depth) were assessed using the Antera 3D system, supported by subject-reported outcomes. Safety was monitored throughout.

Results: By day 42, 55.38% of participants achieved grade 0 for both dark circles and puffiness, while 66.15% demonstrated minimal fine lines. Instrumental assessments revealed a 10.47% reduction in melanin concentration ($p<0.0001$), 32.36% decrease in fine-line count ($p<0.0001$), 86.22% reduction in line depth ($p<0.0001$), and 69.98% decrease in line width ($p<0.0001$). All participants reported visible improvements in hydration, softness, and firmness. 100% participants expressed satisfaction, and no adverse events were recorded.

Conclusions: The investigation product demonstrated improvements across all periorbital parameters with no treatment related adverse events, supporting botanical formulations as effective alternatives in pregnant and lactating women.

Keywords: Fine lines, Lactation, Natural formulation, Periorbital hyperpigmentation, Pregnancy, Puffiness, Under-eye gel

INTRODUCTION

Under eye issues like the periorbital aesthetic concerns are common presentations, accounting for a significant proportion of patients seen in dermatology clinics.[1] An Indian study reported a prevalence of 30.76% and found the condition most common in women aged 16-25 years.[2] A later review summarised that 30% of Indian patients with periorbital hyperpigmentation were female (86.5 %) and that 53% had a family history.[3]

Concerns such as dark circles, under eye puffiness and fine lines are observed commonly in population. Dark circles, scientifically termed as periorbital hyperpigmentation, refer to the darkening of the skin beneath the eye area.[4] Many patients consider dark circles as an aesthetic stigma. Puffy eyes, also known as periorbital edema, evident when the skin surrounding the eyes becomes swollen or inflamed, resulting in a visibly swollen or "puffy" appearance.[5] While generally benign, these can significantly affect quality of life by lowering self-esteem and contributing to emotional distress.[6] In more severe cases, puffiness can cause discomfort and may even interfere with vision.[7]

Dark circles are multifactorial and may result from constitutional pigmentation, thin and translucent eyelid skin with vascular prominence, shadowing due to skin laxity, dermal melanocytosis, post-inflammatory hyperpigmentation, and pigmentary demarcation lines.[2] They are further influenced by environmental and lifestyle factors such as ultraviolet exposure, atopy, inadequate sleep, stress, alcohol intake, and smoking.[2] In the same way in Indian cohort, 71% reported stress and fatigue were prominent exacerbating factors.[6] The prevalence of periorbital hyperpigmentation during pregnancy ranges from 50-90% across different populations, with higher incidence observed in women with darker skin types and genetic predisposition.[8] Pregnancy and lactation represent periods of profound physiological change that significantly impact skin homeostasis. Hormonal fluctuations, particularly elevated levels of estrogen, progesterone, and melanocyte-stimulating hormone (MSH), trigger increased melanogenesis and can exacerbate existing pigmentary disorders or induce new ones.[9]

Management traditionally combines lifestyle modification with topical and procedural therapies. Vascular dark circles are treated with agents like vitamin C and phytonadione (vitamin K_1) or tretinoin, whereas pigmented types are addressed with tyrosinase inhibitors such as hydroquinone or arbutin.[2] However, hydroquinone is systemically absorbed at 35-45% and its use is restricted or banned in several countries because of risks including exogenous ochronosis.[10-12] Tretinoin and other retinoids promote collagen synthesis but are associated with teratogenicity; guidelines advise avoiding topical retinoids during pregnancy.[11] These safety concerns are particularly relevant for pregnant and lactating women, who have limited acceptable treatment options.[11] Procedural options such as chemical peels, fillers, and lasers may improve under eye appearance but are costly, require expertise, and may cause post-inflammatory hyperpigmentation, particularly in darker skin types.[2]

Growing concerns about the safety of conventional depigmenting agents have spurred interest in botanical and natural ingredients like aloesin, licorice, arbutin, niacinamide, and mulberry for safe treatment of hyperpigmentation. A systematic review reveals these ingredients help reduce pigmentation, puffiness, and fine lines while being well tolerated and acts as safe alternatives.[13] Aloe vera hydrates and calms skin, Paeonia flower extract blocks melanin production, and *Albizia julibrissin* bark extract targets glycation-linked fatigue and swelling.[14,15] Additionally, humectants like glycerin and sodium hyaluronate improve skin hydration and barrier function, which is particularly beneficial in the delicate under eye area.[15]

In response to this shift, the natural-origin EqualsTwo® under eye gel (investigation product) was developed. The formulation combines *Cucumis sativus* (cucumber) fruit extract, *Albizia julibrissin* bark extract with darutoside, *Aloe barbadensis* leaf extract, sodium hyaluronate, *Citrus paradisi* (grapefruit) fruit extract, *Paeonia albiflora* flower extract, *Cocos nucifera* fruit juice and *Echinacea angustifolia* meristem cell culture in a hydrating base. We hypothesised that twice-daily application for 42 days would safely reduce dark circles, puffiness and fine lines.

The trial evaluated the safety and efficacy of investigation product in lactating women and in healthy pregnant women during the first and second trimester; populations where traditional depigmenting agents are discouraged due to potential systemic absorption and teratogenicity; thus, addressing an important evidence gap in periocular dermatology.

METHODS

Study design and setting

This was a prospective, open-label, single-arm interventional study for a duration of 42 days conducted by Cliantha Research Limited, Ahmedabad from August 2022 to February 2023.

Participants

Women aged 22-40 years were screened for eligibility at the study site. Eligible participants were either lactating women who had delivered within the previous 42 weeks or primigravida pregnant women in the first or second trimester, with pregnancy confirmed by a qualified gynecologist. All participants were required to present with grade 2 or grade 3 under-eye dark circles and puffiness at baseline, as assessed using a six-point clinical grading scale.

Participants were excluded if they had any active dermatological conditions such as psoriasis, eczema, erythema, oedema, scars or wounds in the treatment area, clinically significant vascular conditions such as the presence of varicose veins or phlebitis or had received prior cellulite treatment within last 30 days prior to enrolment. Additional exclusion criteria included any surgical procedures within the preceding three months,

and participation in another clinical study within 90 days prior to screening.

A total of 72 women were enrolled (12 pregnant and 60 lactating women), of which 65 completed the study and were included in the analysis. 7 participants were lost to follow-up.

Intervention

Participants were instructed to apply approximately 0.2 gm of the investigation product to the undereye contour twice daily (morning and evening) for a total treatment duration of 42 consecutive days. Compliance was assessed at follow-up visits through participant self-report and product usage review.

Study objective

The primary objective of the study was to evaluate the efficacy and safety of the investigation product in improving under eye dark circles, puffiness, and fine lines in lactating and pregnant women. Efficacy assessments included both clinical grading scales and objective instrumental analyses.

Outcome measured

Primary outcomes

The primary clinical outcomes included dermatologist-graded assessments of under-eye dark circles, under eye puffiness, and under eye fine lines. Dark circles were assessed using a six-point grading scale (0 = none, dark circle not noticeable; 1 = very mild, faint purple color visible on the front and underneath the eyes that darkens when the skin is gently stretched; 2 = mild, purple shadow clearly visible without stretching, with or without slight pigmentation; 3 = moderate, deep purple shadows and/or moderate pigmentation partially observed; 4 = severe, overall uniform dark pigmentation observed above and below the eyes; 5 = very severe, uniform and very dark pigmentation observed both above and below the eyes).[16] Under eye puffiness was graded using the investigator's global assessment (0 = none; 1 = very mild; 2 = mild; 3 = moderate; 4 = severe; 5 = very severe).[17] While under eye fine lines were assessed using the Allergan fine lines scale (0 = none, no fine lines; 1 = minimal, 1-2 superficial lines; 2 = moderate, 3–5 superficial lines; 3 = severe, >5 superficial lines without cross-hatching; 4 = diffuse, diffuse superficial lines with cross-hatching).[18] Decrease in these grades indicates a reduction in the appearance of under-eye dark circles, under-eye puffiness, and under-eye fine lines.

Secondary outcomes

Secondary outcomes included instrumental evaluation of melanin concentration and fine line metrics (count, length, width, and depth) using a three-dimensional skin analysis system (Antera). Image processing and quantitation were performed using Image Pro software along with the Antera system's analysis modules to obtain objective metrics. Participant-reported outcomes were collected via a structured subject satisfaction questionnaire addressing perceived reduction in dark circles, puffiness, and fine lines along with improvement in moisturization, softness, smoothness, suppleness, nourishment and skin tightness. A product response index evaluating ease of use, spreadability, absorption, fragrance, greasiness, and overall liking was also filled by the participant.

Safety outcomes

Safety was evaluated by monitoring adverse events, with particular attention to hypersensitivity or local irritation throughout the study period.

Study procedures and visits

Following written informed consent and screening, eligible participants were enrolled and assessed at baseline (day 1). Subsequent follow-up visits were conducted at day 14±2 days, day 28±2 days, and day 42±2 days. At each visit, dermatological assessments, instrumental evaluations, standardized imaging, and patient-reported outcomes were collected. Adverse events were monitored throughout the treatment period.

Statistical analysis

Statistical analysis was performed using SPSS version 25. Continuous variables were expressed as mean±standard deviation or median, where applicable. Changes were calculated from baseline and at each visit (day 14, day 28, and day 42). Non-parametric Wilcoxon Signed-Rank tests were applied to assess changes in instrumental parameters, with a two-sided significance level of 0.05. Descriptive statistics were used for summarizing clinical grading scales and patient-reported outcomes.

Ethical considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. This clinical study was registered at CTRI (Clinical Trial Registry of India) under the trial registration number CTRI/2022/08/044565.

RESULTS

Baseline demographic characteristics

The mean age was 29.2±3.75 years for 72 participants who were enrolled in the study. The baseline demographic characteristics of participants are reported in Table 1.

Table 1: Baseline demographic characteristics of study participants (n=72).

Variables	Mean±SD
Age (years)	29.2±3.75
Height (cm)	158.2±7.34
Weight (kg)	61.3±9.46
BMI (kg/m^2)	24.3±3.18

Primary outcomes

Reduction in under eye dark circles

At baseline, 52.31% participants were graded as 2 (mild) while 47.69% were assigned grade 3 (moderate). Improvement was observed across visits, and by day 42, 55.38% of participants were graded as 0 (no dark circles), while the remaining were in grade 1 (very mild). The proportion of grades of dark circles across the different follow up visits is represented in Figure 1.

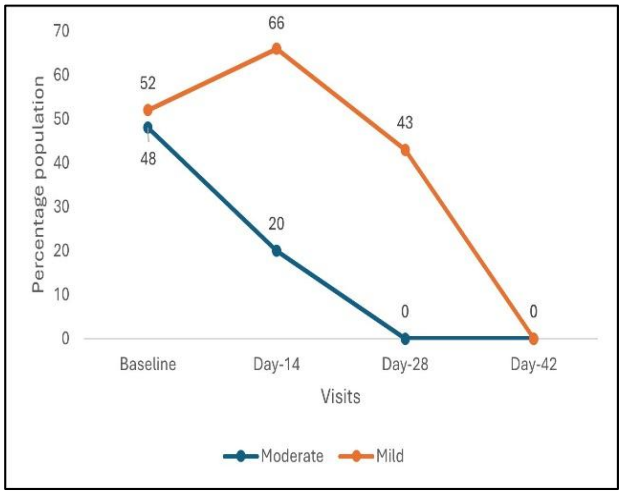

Figure 1: Proportion of under eye dark circles grades across the different follow-up visit (baseline, day 14, day 28, and day 42).

Reduction in under eye puffiness

Reduction in puffiness was noted across all visits. At baseline, 40% participants had moderate eye puffiness (grade 3), and the remaining 60% participants had mild eye puffiness (grade 2). By Day 42, 55.38 % of participants showed no eye puffiness (grade 0), while 43.08% had very mild eye puffiness (grade 1). Only 1.54% participants were at grade 2 at the end of the study. The proportion of grades of under eye puffiness across the different follow up visits is represented in Figure 2.

Reduction in under eye fine lines

At the start of the study, 40% participants had severe fine lines (grade 3) and the remaining 60% had moderate fine lines (grade 2). By day 42, 66.15% participants had shifted to minimal fine lines (grade 1), with 1.54% participants showing no fine lines (grade 0). 32.31% participants were in grade 2 at the end of the study. The proportion of grades of under eye fine lines across the different follow-up visits was as represented in Figure 3.

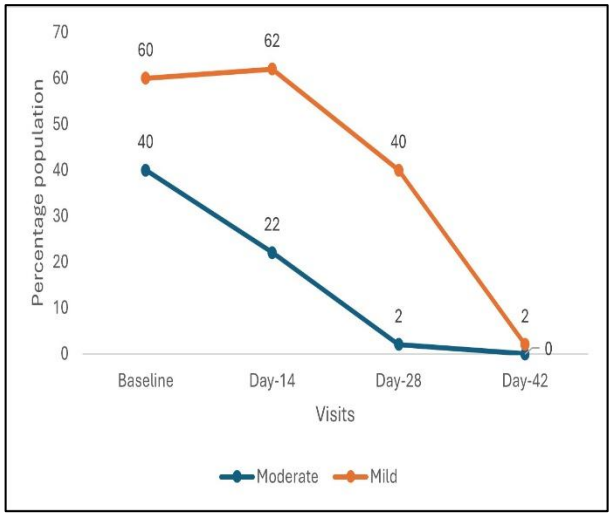

Figure 2: Proportion of under eye puffiness grades across the different follow-up visit (baseline, day 14, day 28, and day 42).

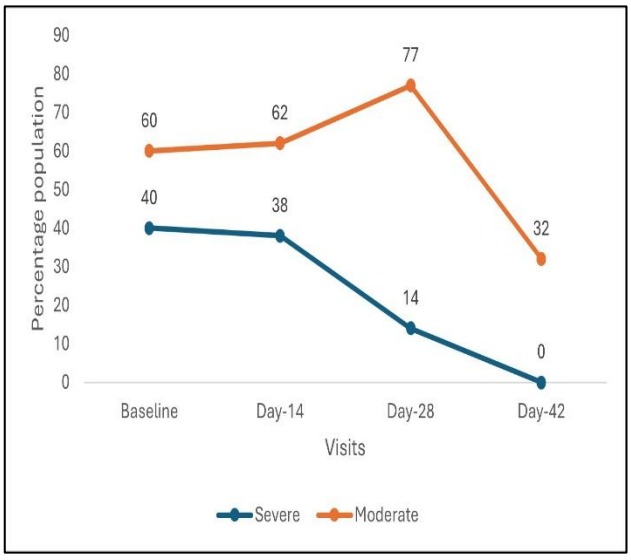

Figure 3: Proportion of grades of under eye fine lines across different severity grades across the different follow-up visit (baseline, day 14, day 28, and day 42).

Secondary outcomes

Objective 3D assessments demonstrated consistent improvements across fine-line parameters and melanin concentration. Fine-line parameters demonstrated 32.36% reduction in count, 37.10% in length, 69.98% in average width, and 86.22% in average depth. The percentage

reduction of fine-line parameters compared to baseline was as represented in Figure 4.

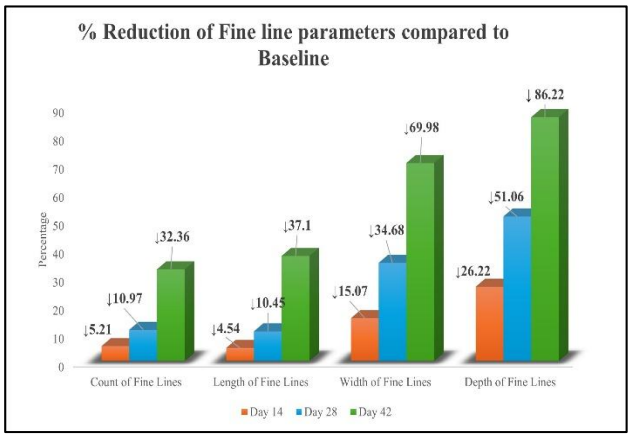

Figure 4: Percentage reduction of fine lines parameters compared to baseline.

By day 42, melanin concentration decreased by about 10.47% ($p<0.0001$). The reduction in average concentration of melanin was as represented in Figure 5.

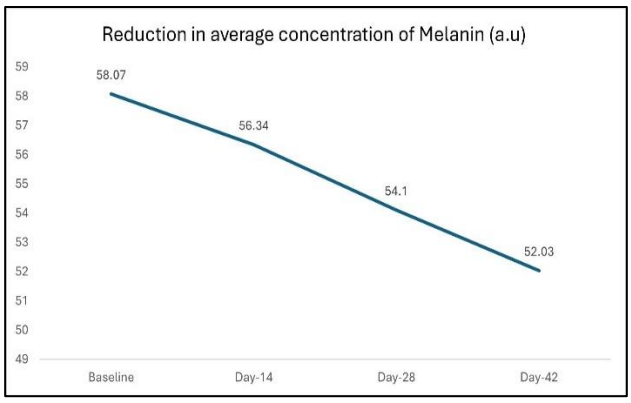

Figure 5: Reduction in average concentration of melanin compared to baseline as per 3D analysis system.

*a.u: arbitrary units.

Subject satisfaction

Participant-reported outcomes demonstrated positive perceptions of the investigation product. All participants reported a perceived reduction in the appearance of under-eye dark circles, puffiness, and fine lines, accompanied by improvements in periorbital skin moisturization, tightness, softness, smoothness, suppleness, and nourishment.

All participants reported agreed or strongly agreed that the gel was easy to apply, spread well, absorbed quickly, had a pleasant fragrance, and was non-greasy. Overall, high proportions of participants (>98%) indicated satisfaction with the product and expressed a positive preference for its use.

Safety outcomes

No treatment-related adverse events were reported during the study period. No cases of hypersensitivity, erythema, oedema, or ocular irritation (burning rash, dryness) were observed following product use throughout the entire study duration.

DISCUSSION

The present open-label, single-arm study evaluated a natural under-eye gel in 72 women and demonstrated improvements across clinical and instrumental parameters in under-eye dark circles, puffiness and fine lines by day 42, with high participant satisfaction and no reported adverse events. This trial is notable for enrolling postpartum and pregnant women; a population in whom treatment options are limited due to safety concerns.[10] The condition carries psychosocial burden which is highlighted in Sheth et al article who notes that dark circles significantly affect quality of life and are often the first facial feature people notice.[6] The periocular area has thin skin and a rich vasculature, making it susceptible to pigmentary and structural changes.[4] Addressing these multifactorial mechanisms requires interventions that are both efficacious and well tolerated. Our results suggest that a multifaceted, natural-ingredient under eye gel can meet these requirements therefore have important implications for women during pregnancy and lactation, for whom safe and effective treatments are scarce.[11]

More than half of participants had complete resolution of dark circles and puffiness, and two-thirds had only minimal fine lines at the end of study. These improvements align with results of Nobile et al where a topical gel applied twice daily for 28 days significantly decreased under-eye bags and dark-circle colour while increasing skin moisturisation and elasticity; although the study emphasised that longer follow-up might be necessary for maximal wrinkle reduction.[19] Similarly, a clinical trial using *Salix alba* bark extract cream (2%) over eight weeks found enhanced vascular integrity and hyaluronic-acid synthesis, resulting in reduced dark-circle pigmentation and improved skin elasticity.[20] Therefore, periorbital hyperpigmentation and edema may lead to reduced outcome by interventions targeted on melanin synthesis, vascular congestion, and dermal matrix integrity. Similarly, Zargaran et al demonstrated that 20% *Artemisia absinthium* extract significantly decreased periocular melanin and erythema when compared to a placebo.[21] Overall, these findings support that botanical formulations can reduce periorbital hyperpigmentation and swelling. Our results extend this evidence to a sensitive population (pregnant and lactating women) by demonstrating improvements without any safety signals. Conventional treatments such as hydroquinone, arbutin, retinoids and vitamin C reduce melanogenesis by inhibiting tyrosinase and promoting collagen synthesis.[2] Our natural-origin EqualsTwo® under eye gel likely achieved similar benefits without these risks. The

dermatologist-assessed reductions could be explained by synergistic effects of botanical ingredients with antioxidant and anti-inflammatory properties; in particular, *Aloe barbadensis* contains aloesin, a known tyrosinase inhibitor that reduces UV-induced pigmentation, and Paeonia extracts possess monoterpene glycosides with potent antioxidant and antityrosinase activity.[22,23]

Instrumental analyses corroborated the clinical findings and indicated that the investigation product's natural ingredients may act via complementary mechanisms. Objective measurements showed decreased melanin concentration and substantial reductions in fine-line count, length, width and depth. These outcomes are consistent with a recent study of a multi-action serum, which achieved a 47.9% reduction in periorbital hyperpigmentation after six weeks of twice-daily use without adverse effects.[24] These data corroborate the dermatologist-graded improvements and mirror findings in other studies. In controlled trials, it has been demonstrated that natural depigmenting agents like arbutin, niacinamide, and liquorice extracts significantly lower melasma scores.[22] *Paeonia lactiflora* flower extracts exhibit strong free-radical scavenging and tyrosinase inhibition, which may account for reduced melanin and fine-line parameters.[23] Our formulation also includes *Albizia julibrissin* bark extract with darutoside, which in combination has been patented for reducing under-eye puffiness and improving upper-eyelid sagging (via glycogenase inhibition and dermal microvascular support), although peer-reviewed evidence is limited. *Cucumis sativus* (cucumber) fruit extract has soothing, hydrating and anti-inflammatory effects and has been traditionally used to relieve periorbital edema; combined with *Citrus paradisi* (grapefruit) extract, rich in vitamin C, the formulation may support collagen synthesis and brighten pigmentation. Coconut water (*Cocos nucifera* juice) provides electrolytes and minor amino acids that improve skin moisturization, while Echinacea angustifolia meristem cell culture extract exhibits wound-healing and antioxidant properties in vitro. These ingredients synergistically through multiple pathways inhibiting tyrosinase and melanogenesis, scavenging reactive oxygen species, strengthening capillary walls, and providing deep hydration, led to reduced melanin deposition, vascular congestion and fine-line formation.

This study shows that investigation product can safely and effectively minimise puffiness and periorbital hyperpigmentation in a population where invasive procedures and accepted depigmenting agents are frequently inadvisable. These findings may have real-world implications, as many individuals seek non-pharmacologic solutions for dark circles due to cultural preferences and safety concerns.[10] This also come as a solution for many women seeking gentle yet efficacious solutions during pregnancy and lactation when safety considerations limit therapeutic options. To validate these results, exploring subgroup responses, and understanding the molecular mechanisms by which botanical constituents work, controlled trials involving larger, diversified populations with more prolonged periods are necessary. Despite these drawbacks, our research suggests that a comprehensive, safe, yet effective method of combining extracts from *Cucumis sativus*, *Albizia julibrissin*, *Aloe barbadensis*, sodium hyaluronate, *Paeonia lactiflora*, *Citrus paradisi*, *Cocos nucifera*, and *Echinacea angustifolia* extracts may result in significant enhancements in periorbital appearance. Results confirm the safety of twice-daily application of the product over 42 days. Investigation product is safe to use for pregnant and lactating female population.

Therefore, the investigation product is a potential new alternative for pregnant and lactating women as well as for individuals seeking gentle yet effective treatments to manage periorbital hyperpigmentation and associated signs of fatigue.

Nevertheless, several limitations should be acknowledged. The single-arm, non-randomised design precludes direct comparison with placebo or other treatments, and the short follow-up may underestimate long-term efficacy. Baseline characteristics of completers versus non-completers were not reported, potentially introducing attrition bias.

CONCLUSION

EqualsTwo® under eye gel effectively reduced periorbital hyperpigmentation, puffiness, and fine lines while being well tolerated in pregnant and lactating women. The formulation's botanical ingredients provided visible aesthetic improvements without any adverse effects, addressing a key therapeutic gap for this sensitive population. These findings support its potential as a safe, gentle, and effective alternative to conventional under-eye treatments that carry safety concerns in pregnancy and lactation.

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