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*Research Article*

# Efficacy and Tolerability of an Advance Face Night Cream in Reducing Facial Pigmentation and Wrinkles in Women

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**Abstract**

Background: The efficacy and tolerance of an Advance Face Night Cream in reducing facial pigmentation and wrinkles in women was evaluated.

Methods: This was a monocentric, single-group, comparative, open-label study involving healthy adult women with mild to-moderate wrinkles and at least one pigmented spot on the face. The Advance Face Night Cream was to be applied every night before bedtime along with sunscreen lotion (with sun protection factor [SPF] 50) during the day. Evaluations included clinical examination and grading of wrinkles in the crow's feet area, nasolabial region, forehead and under the eyes. Skin lightening and skin hydration effects along with subjective efficacy were also evaluated.

Results: Thirty-three women completed the study (mean age: 44.03±5.41 years). A significant decrease in the mean score of wrinkles in the crow's feet area (7.5%; p=0.004) and on the forehead and under-eye region (12.5%; p=0.001) was noted at 45 days. The 3-dimensional imaging revealed a significant decrease in the mean overall size of wrinkles after 21 and 45 days (10.0% and 9.0%; p=0.002 and p=0.003, respectively) and the mean width of wrinkles (3.5% and 4.4%; p=0.007 and p=0.001, respectively). Comparable benefits in skin radiance, color and hydration were noted at both 21 and 45 days. Other benefits included improved skin moisture, reduced visible pigmentation and wrinkles and improved overall skin appearance.

Conclusion: The topical application of Advance Face Night Cream and the appropriate usage of sunscreen lotion with SPF 50 led to a significant reduction in fine lines and the overall size and width of facial wrinkles in 3 and 6 weeks. The cream could significantly hydrate the skin, brighten the skin tone and lighten the skin color of the pigmented area in 3 weeks. No adverse events were reported by any participant during the study.

**Keywords:** Adult; Female; Forehead; Sunscreening Agents; Skin Pigmentation; Imaging, Three-Dimensional; Sun Protection Factor

## Introduction

Skin aging is a highly controlled natural process that women are particularly concerned about [1]. Dry skin, wrinkles, uneven pigmentation and sagging are all signs of aging skin [1,2]. The skin aging process is regulated by both intrinsic and extrinsic factors [2,3]. The decline in estrogen levels that occurs with age is a major intrinsic factor for skin aging in women, accelerating the appearance of skin changes, such as fine wrinkles, dryness and wasting [2]. Prolonged exposure of the skin to extrinsic factors, such as harmful Ultraviolet Radiation (UVR), has been shown to speed up the aging process, resulting in premature skin aging and aging-associated pigmentation [2].

UVR induces Deoxyribonucleic Acid (DNA) damage and the generation of Reactive Oxygen Species (ROS) and free radicals, which interact with or trigger various signaling pathways, leading to collagen degradation, cessation of new collagen synthesis and oxidation of lipids and proteins, thereby resulting in aging skin [4]. As a protective mechanism, in response to UVR exposure,

melanocytes increase melanin production in the skin [5]. Chronic sun exposure, on the contrary, causes hyperactivity of melanocytes and increases melanin production in the skin. This causes uneven pigmentation and makes the skin appear older [2]. Furthermore, prolonged exposure to Ultraviolet (UV) rays promotes melanocyte senescence, which leads to an accumulation of senescent melanocytes in the human skin, contributing to the aging process [5].

Several formulations for treating pigmentation and skin aging are currently available in the market. However, some of the ingredients found in skin lightening and antiaging creams, such as mercury, steroids, azelaic acid and others, have been linked to adverse side effects [6]. Given the safety concerns surrounding the usage of such products, there is a need for alternative, safe and efficacious creams for reducing pigmentation and wrinkles.

The advance night cream is a cosmetic product that contains glycerin; shea butter; tocopherol; a combination of water, glycerin, phenoxyethanol and *Rumex occidentalis* extract; and a combination of glycerin, water and *Terminalia ferdinandiana* fruit extract as active ingredients. The study primarily evaluated the efficacy of an Advance Face Night Cream in reducing facial pigmentation and wrinkles in women. The secondary objective was to evaluate the in-use tolerance of the night cream.

## Material and Methods

### *Study Design and Duration*

This was a monocentric, single-group, comparative, open-label study where the values of measured variables on follow-up visits were compared with baseline values. This study was carried out for 45 days.

### *Study Population*

#### *Inclusion Criteria*

The study included healthy female volunteers aged 18-55 years with mild-to-moderate wrinkles and at least one pigmented spot on the face. Only those participants who were willing to avoid unusual sun exposure as far as possible for the entire study duration and agreed not to use any other similar products during the entire study were included in the study.

#### *Exclusion Criteria*

The following female participants were excluded from the study: those who were pregnant (confirmed by urine pregnancy test) or lactating; undergoing therapy for any other dermatological conditions/disorders that may interfere with the study outcomes (e.g., psoriasis, eczema, dermatitis, or severe sun damage); hypersensitive to any of the components of the test product; receiving UV therapy; any hard damage to the skin (e.g., excessive sunburn or suntan); under systemic medical treatment (presently or in the past 30 days), which may interfere with the performance of the study treatment; using skin-whitening medications in the 2 months before the trial period; and under exclusion period or participating in any other clinical trial/s within 1 month before screening.

### *Study Plan*

The overall study plan is described in Table 1. Safety and efficacy measurements and the time points at which they were carried out have been mentioned in the plan.

| | **Visit 1 (day 0) (baseline)** | **Visit 2 (day 21) (follow-up visit 1)** | **Visit 3 (day 45) (follow-up visit 2)** |
|---|---|---|---|
| Explanation of the study and procedures | X | | |
| Collecting and documenting informed consent | X | | |
| Inclusion/exclusion criteria | X | | |
| Demographic information | X | | |
| Medical history/prior treatments | X | | |
| Clinical grading | X | X | X |
| Photographs | X | X | X |

| | | | |
|---|---|---|---|
| 3D imaging | X | X | X |
| Spectrophotometer readings | X | X | X |
| Skin hydration readings | X | X | X |
| Clinical evaluation for in-use tolerance | | X | X |
| Self-assessment for tolerance | | X | X |
| Self-assessment for efficacy | | X | X |
| Test product dispensation | X | | |
| Test product retrieval | | | X |
| Concomitant treatment recording | X | X | X |
| Adverse events | X | X | X |
| Final report | | | X |

**Table 1:** Study process.

*Test Product and Its Application*

The test product Biluma Advance Face Night Cream (Batch No: HBM-0319/04) was provided by the sponsor. The key ingredients of the test product and their properties have been enumerated in Table 2. The participants were instructed to gently rub a thin layer of the Advance Face Night Cream (about 1 g) over the face and neck and around the eyes, every night before bedtime. The face had to be washed and towel dried before every application. The participants were also instructed to apply 3 mL of sunscreen lotion of Sun Protection Factor (SPF) 50 grade (Batch No: JNW0021) over the face and neck areas twice daily.

| Sl. No. | INCI Name | Ingredient | Function |
|---|---|---|---|
| 1 | EDTA | EDTA disodium | Chelating agent |
| 2 | Aqua | DM water | Solvent |
| 3 | Glycerin | Glycerin IP | Humectant |
| 4 | Acrylamide/sodium acrylate copolymer | Lecigel™ (functional) | Active agent |
| 5 | Lecithin | | Active agent |
| 6 | Glyceryl stearate citrate | Heliofeel™ (functional) | Active agent |
| | Polyglyceryl-3 stearate | | Active agent |
| | Hydrogenated lecithin | | Active agent |
| | Tocopherol | | Active agent |
| 7 | *Prunus amygdalus dulcis* (almond) oil | Almond oil | Emollient |
| 8 | Cetearyl alcohol | Cetostearyl alcohol | Emulsifying agent |
| 9 | *Butyrospermum parkii* butter (Shea) | Lipex® shea | Moisturizing and softening agent |
| 10 | *Macadamia ternifolia* seed oil | SCB macadamia oil | Moisturizing and softening agent |
| 11 | Glycerin | Superox-C™ AF | Active |
| | Water | | |
| | *Terminalia ferdinandiana* fruit extract | | |
| 12 | Water | Tyrostat-09™ | Skin-lightening agent |
| | Glycerin | | |
| | *Rumex occidentalis* extract | | |
| | Phenoxyethanol | | |
| DM: Demineralization; EDTA: Ethylenediaminetetraacetic acid; INCI: International Nomenclature of Cosmetic Ingredients; IP: Indian Pharmacopoeia. SCB: Southern Cross Botanicals | | | |

**Table 2:** Composition of the test product Advance Face Night Cream.

**Data Collection**

In this study, the skin antiaging effect of the product was evaluated by the study investigator based on the clinical examination and grading of wrinkles in the crow's feet area (Jin Ho Chung scale),[7] wrinkles in the nasolabial region and wrinkles and fine lines on the forehead and under the eyes. Additionally, wrinkle measurements were recorded using three-dimensional (3D) imaging with Antera 3D® (Miravex Limited, Dublin, Ireland). The skin-lightening effect of the product on luminescence (L) and pigmentation was evaluated spectrophotometrically using L and Individual Typology Angle (ITA) values [8,9]. Skin hydration was measured using the MoistureMeter Stratum Corneum (MMSC) readings with MMSC Compact (Delfin Technologies, Kuopio, Finland). Efficacy was also evaluated subjectively using a self assessment questionnaire. A pretested structured questionnaire was administered to participants to understand their perception of the effects of the product.

*Statistical Analysis*

The collected data were subjected to descriptive and analytical analysis. Student's t-test and Wilcoxon signed-rank test were applied to evaluate the significance, if any and interpreted at a 5% level of significance. The Statistical Package for the Social Sciences (SPSS) version 10.0 software was used for statistical analysis.

*Subject Information and Consent*

The participants were informed (orally and in writing) about all the details related to the study objectives and procedures along with the potential risks and benefits. All participant queries were responded to by the principal investigator/coinvestigator and all participants signed the informed consent form.

*Ethical Statement and Ethical Conduct*

The study documents were reviewed and the trial was approved by the Institutional Ethics Committee for cosmetic trials. The study followed the principle of the Declaration of Helsinki and its amendments in confirmation with the Good Clinical Practices principles and Schedule Y.

**Results**

*Demographic Data*

A total of 33 participants completed the study and the mean age (± standard deviation) of the participants was 44.03±5.41 years (range: 34-54 years).

*Efficacy*

*Clinical Assessment of Wrinkles and Fine Lines*

No significant changes were noted in the mean score of wrinkles in the crow's feet area from baseline after 21 days of the night cream application. However, a significant decrease in this score from baseline (7.5%; p=0.004) was seen after 45 days of application (Table 3). No significant change was noted in the mean score (length) of wrinkles in the nasolabial area from baseline after 21 and 45 days of night cream application (Table 3). Topical application of the night cream for 21 days revealed no significant change in the mean score of wrinkles and fine lines on the forehead and under-eye region. However, after 45 days of application, a significant decrease was noted in the mean score of wrinkles and fine lines on the forehead and under-eye region from baseline (12.5%; p=0.001) (Table 3).

| Parameter | Score (mean ± SD) Day 0 | Day 21 | Day 45 | Mean difference (day 0 to day 21) | Mean difference (day 0 to day 45) | P1 | P2 |
|---|---|---|---|---|---|---|---|
| **Clinical assessment** | | | | | | | |
| Wrinkles in the crow's feet area[a] | 3.58±0.56 | 3.52±0.51 | 3.30±0.73 | −0.06±0.24 | −0.27±0.52 (−7.5%)* | 0.160 | 0.004¶ |
| Nasolabial wrinkle | 5.64±0.93 | | 5.64±0.93 | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | 5.64±0.93 | | 0.00±0.00 | 0.00±0.00 | 1.000 | 1.000 |
| Wrinkles/fine lines on the forehead and under-eye region[b] | 2.64±0.49 | 2.55±0.51 | 2.30±0.47 | −0.09±0.29 | −0.33±0.48 (−12.5%)* | 0.084 | 0.001# |
| **3D imaging** | | | | | | | |
| Overall wrinkle size (mm) | 16.21±4.24 | 14.58±3.69 | 14.75±3.91 | −1.62±2.85 (−10.0%)* | −1.46±2.63 (−9.0%)* | 0.002¶ | 0.003# |
| Depth of wrinkle (mm) | 0.06±0.02 | 0.06±0.01 | 0.06±0.01 | 0.00±0.01 | 0.00±0.01 | 1.000 | 1.000 |
| Width of wrinkle (mm) | 1.13±0.10 | 1.09±0.11 | 1.08±0.12 | −0.04±0.08 (−3.5%)* | −0.05±0.08 (−4.4%)* | 0.007# | 0.001# |
| Max. depth of wrinkle (mm) | 0.11±0.03 | 0.11±0.03 | 0.11±0.03 | 0.00±0.02 | 0.00±0.02 | 1.000 | 1.000 |
| **Spectrophotometric assessment** | | | | | | | |
| Skin radiance /luminescence (L) | 48.39±3.56 | 49.16±3.37 | 49.70±3.50 | 0.78±1.34 (+1.6%)* | 1.32±1.69 (+2.7%)* | 0.001# | 0.001# |
| Skin lightening/ color (ITA) | −05.80±12.32 | −02.95±11.13 | −01.33±11.45 | 2.85±5.14 (+49.1%)* | 4.47±6.09 (+77.1%)* | 0.002# | 0.001# |
| **Skin hydration assessment** | | | | | | | |
| MoistureMeter stratum corneum readings | 23.43±11.36 | 31.16±13.85 | 35.62±16.24 | 7.72±9.85 (+32.9%)* | 12.19±12.45 (+52.0%)* | 0.001# | 0.001# |

3D: Three-dimensional; ITA: Individual typology angle; L: Luminescence; SD: Standard Deviation
aJin Ho Chung scale: Grading scale: 0-7; 0= no wrinkles, 7= severe wrinkles
bGrading scale: 0-4; 0= no wrinkles, 4= severe wrinkles
*Mean % change from baseline where "+" indicates an increase and "−" indicates a decrease
P1: p-value for the mean difference at day 21 from day 0; P2: p-value for the mean difference at day 45 from day 0
¶Significant as $p<0.05$ (Wilcoxon signed-rank test)
#Significant as $p<0.05$ (Student's t-test)

**Table 3:** Changes in the mean score of skin parameters in study participants (N=33).

*3D Imaging-Assisted Assessment of Wrinkles*

A significant decrease in the mean overall size of wrinkles was noted after 21 and 45 days of night cream application (10.0% and 9.0%; p=0.002 and p=0.003, respectively) (Table 3). However, no change was noted in the mean depth and mean maximum depth of wrinkles after 21 and 45 days of night cream application (Table 3). A significant decrease was noted in the mean width of wrinkles after 21 and 45 days of application (3.5% and 4.4%; p=0.007 and p=0.001, respectively) (Table 3).

*Spectrophotometer Assessment of Skin Radiance and Skin Color*

A significant increase was noted in the mean L value after 21 and 45 days of night cream application (1.6% and 2.7%; p=0.001 for both days, respectively) (Table 3). After 21 and 45 days of cream application, a significant increase was noted in the mean ITA values (49.1% and 77.1%; p=0.002 and p=0.001, respectively) (Table 3).

*Measurement of Skin Hydration*

There was a significant increase in the mean MMSC readings from baseline after 21 and 45 days of cream application (32.9% and 52.0%; p=0.001 for both days, respectively) (Table 3; Fig. 1).

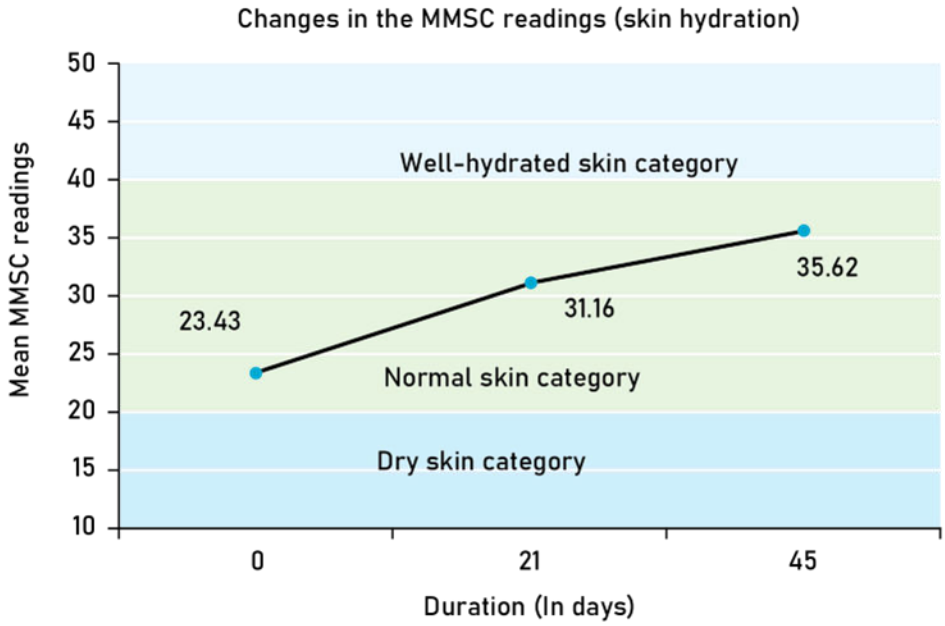


**Figure 1:** Changes in the mean MMSC readings (skin hydration). MMSC: MoistureMeter stratum corneum.

*Questionnaire-Based Efficacy Evaluation*

Fig. 2 shows the proportion of participants with top 2 scores (agree and strongly agree) for various parameters evaluated in the questionnaire. It was revealed that after 21 and 45 days of the test product application, 100.0% of participants agreed that their facial skin felt moisturized; 93.9% and 97.0% of participants, respectively, agreed that the product reduced visible pigmentation on their face; 57.6% and 97.0% of participants, respectively, agreed that the product reduced wrinkles in the crow's feet area; 60.6% and 97.0% of participants, respectively, agreed that the product reduced facial wrinkles and fine lines; and 100.0% and 97.0% of participants, respectively, agreed that the product improved the overall appearance of their skin (Fig. 2).

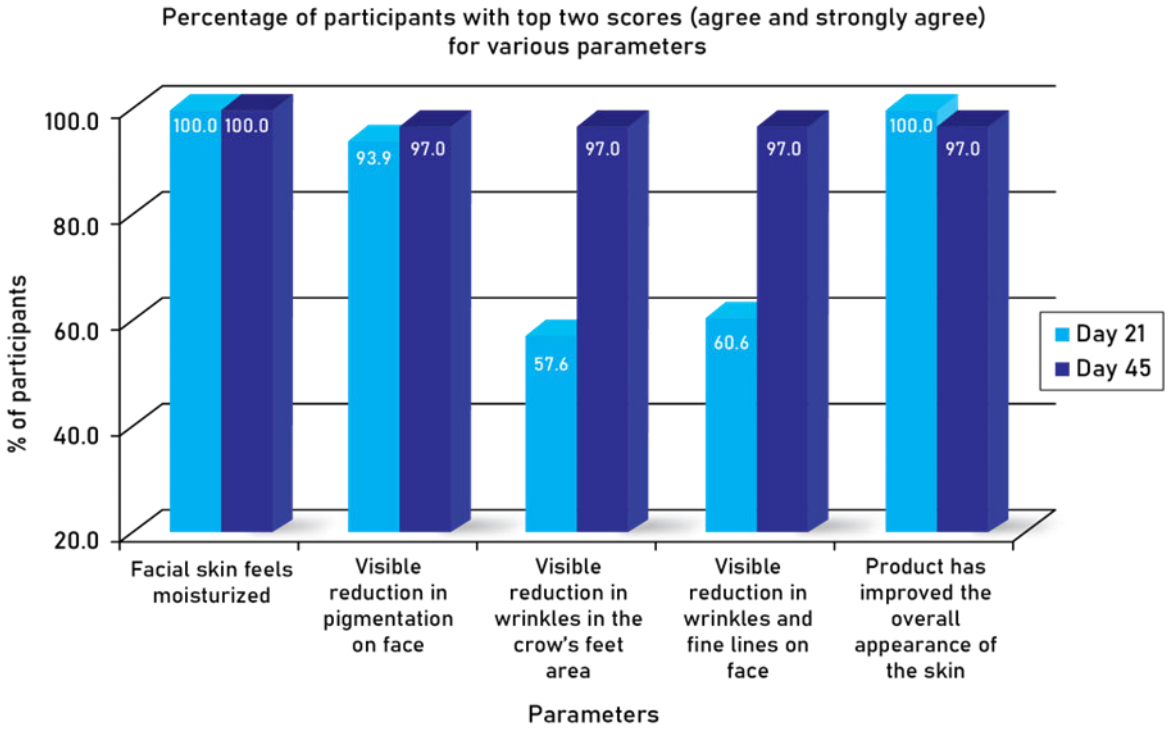


**Figure 2:** Proportion of participants with top two scores (agree and strongly agree) for various parameters.

*Safety and In-Use Tolerance Evaluation*

The results revealed that none of the participants experienced any skin intolerances, such as pricking, tingling, itching, redness, or burning during the study. No adverse events were reported by any participant during the study.

**Discussion**

The findings of this 6-week, single-arm, open-label study suggest that the Advance Face Night Cream in association with the sunscreen lotion with SPF 50 is effective and tolerable for the management of facial pigmentation and wrinkles among women aged between 35 and 55 years of age. Moreover, regular use of this cream at nighttime produced a substantial increase in skin hydration on days 21 and 45 from baseline (+32.9% and +52.0%).

The benefits noted with the usage of the Advance Face Night Cream can be attributed to the active ingredients of the cream. Tocopherol has been found to control the damage induced by the action of UVR-mediated free radicals and ROS on the skin [4,10]. Owing to its antioxidant properties, tocopherol is one of the constituents of over-the-counter topical creams to treat hyperpigmentation, guard against UVR and alleviate aging damage [11]. A combination of water, glycerin, phenoxyethanol and *Rumex occidentalis* extract is known to lower melanin production by inhibiting the tyrosinase enzyme. A combination of glycerin, water and *Terminalia ferdinandiana* fruit extract is an active ingredient extracted from *T. ferdinandiana* (Kakadu plum). It scavenges free radicals and boosts collagen and hyaluronic acid synthesis. Being rich in vitamin C and polyphenols, it is known to lower the appearance of signs of aging, such as wrinkles and fine lines, promote skin brightness and radiance and improve the smoothness of the skin tone [12]. Vitamin C exhibits antioxidant, photoprotective, antiaging and skin-lightening properties [13]. Vitamin C is reported to work synergistically with vitamin E in protecting against free radical-induced damage to the skin [13].

The initial signs of skin aging among women are reportedly noted during the age of 30 years as estrogen levels start declining. As age progresses, the skin tends to become dry and thin. Notably, wrinkles begin to appear around the eyes and along the frown lines on the forehead. A general loss in the skin tone and unevenness in the skin color also become evident as age progresses [14]. Such changes in the skin owing to intrinsic or extrinsic factors are of significant concern for women. Nonpharmacologic therapies that are available over the counter are often useful in addressing these concerns [15].

The outcomes noted in the present study suggest that the Advance Face Night Cream can be useful for women over 30 years of

age with concerns related to wrinkles. A significant reduction in the wrinkles and fine lines in the crow's feet area and on the forehead and under the eyes was noted after 45 days of using the night cream. Additionally, 3D optical imaging demonstrated a significant decrease in the overall size and average width of wrinkles in the crow's feet area following 21 and 45 days of usage. Spectrophotometric analysis indicated a significant increase in skin radiance or L and a reduction in skin pigmentation at both follow-up visits.

Skin hydration also increased significantly after 3 and 6 weeks of the cream application. This could be attributed to the presence of moisturizing agents in the cream, such as glycerin and shea butter.

Human studies show that a combination of water, glycerin, phenoxyethanol and *R. occidentalis* extract has been used to treat various types of hyperpigmentation. It helped in reducing the appearance of age spots and improving skin lightening in Asian skin after 3 weeks of usage [16]. A clinical study found that topical application of a serum containing *R. occidentalis* extract reduced age spots by 15% after 3 weeks and by 25% after 6 weeks when compared with the values at baseline [17]. A randomized trial revealed that *R. occidentalis* extract was as efficacious as the gold standard skin lightening agent Hydroquinone (HQ) in the treatment of melasma [18]. Prolonged topical use of HQ is known to cause many unwanted effects, such as ochronosis, contact dermatitis, irritative dermatitis, nail discoloration and post-inflammatory pigmentation [18,19]. Hence, *R. occidentalis* extract can be considered a safe and effective alternative to HQ for skin lightening in patients with melasma [18]. Furthermore, in a clinical study by Zasada, et al., the combination of *R. occidentalis* extract with niacin, shea butter and vitamin E in a topical cream showed a synergistic skin-lightening effect on 26 healthy women with hyperpigmentation. At 3 and 6 weeks, 88% and 96% of participants had a 13% and 20% reduction in melanin synthesis, respectively. This resulted in a considerable reduction in UV-induced pigmentation spots and redness of the skin. Significant improvements in skin hydration, flexibility and softness were also observed, leaving participants with healthier looking skin. In 92% of participants, the topical formulation was well tolerated and restored skin color alignment [20]. Compared with these results, our study showed a significant reduction in skin pigmentation as well as a significant increase in skin hydration at 3 and 6 weeks after product application.

Overall, a combination of water, glycerin, phenoxyethanol and *R. occidentalis* extract in combination with other ingredients helped reduce pigmentation without harming the skin, resulting in a lighter skin tone in the present study. Glycerin and shea butter present in the cream as moisturizing agents contributed to increased skin hydration. Tocopherol and a combination of glycerin, water, antioxidant components and *T. ferdinandiana* fruit extract, helped to minimize visible signs of aging on the face, such as facial wrinkles, fine lines and pigmentation.

The perception of the users plays an important role in the selection of cosmetic products. No adverse events were reported by any of the participants throughout the study. Skin intolerances, such as prickling, tingling, itching, redness, or burning sensations on the face, were not experienced by any of the participants during the study. The subjective evaluation revealed that all participants were satisfied with the results and believed that topical application of the cream hydrated their skin, brightened their skin tone, decreased wrinkles and fine lines and enhanced the overall appearance of their skin. Based on clinical evaluation and subjective assessment, Advance Face Night Cream used regularly along with a sunscreen lotion with SPF 50 could brighten, lighten and hydrate the skin in 3 weeks and reduce wrinkles and fine lines in 6 weeks without any harm to the skin.

## Conclusion

The present study demonstrated that the topical application of the Advance Face Night Cream along with the appropriate usage of sunscreen lotion with SPF 50 resulted in a significant reduction in fine lines and the overall size and width of facial wrinkles in 3 and 6 weeks. The cream could significantly hydrate the skin, brighten the skin tone and lighten the skin color of the pigmented area in 3 weeks. Based on clinical evaluation and subjective assessment, the cream was very well received and well tolerated by all participants.

## Conflict of Interests

The authors declare that there is no conflict of interest for this paper.

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