# **Skinuva® Brite:**

#### What makes Skinuva® Brite so unique as a skin brightening cream?

Skinuva® Brite is a revolutionary product tailored to help improve hyperpigmentation, and it is a NON-HYDROQUINONE product, so it is safe and effective for long term, daily use. There has been a recent consumer demand for safe and effective products that are non-hydroquinone based, and Skinuva® Brite's ingredients have been hand-picked from medical literature and our clinical data to give our consumers the most advanced and effective product for helping to reduce the appearance of hyperpigmentation while being safe. Skinuva® Brite has been dermatologically tested and is safe to use around the eyes.

#### What are the ingredients?

Skinuva® Brite contains a proprietary set of ingredients, including selective Growth Factors and other ingredients that all play a vital role in helping been shown to reduce the appearance of hyperpigmentation such as dark spots, discoloration on the face and body, and under eye pigmentation. Each ingredient has been shown to be backed by medical literature to improve hyperpigmentation.

**INGREDIENTS:** Water/Aqua, Cl2-15Alkyl Benzoate, Caprylic/Capric Triglyceride, lsononyl lsononanoate, Niacinamide, Ska, Arbutin, Tranexamic Acid, Cetearyl Alcohol, Tetrahexyldecyl Ascorbate, Glyceryl Stearate, Peg-1 co Stearate, Polysorbate 60, Anhydroxylitol, Ceteareth-20, Cl 77891/Titanium Dioxide, Citric Acid, Ethylhexyl Glycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Limonene, Parfum, Phenoxyethanol, sh-Polypeptide-22, sh-Oligopeptide-1, Sorbitan Isostearate, Trehalose, Xylitol, Xylitylglucoside.

Selective Growth Factors: including Epidermal Growth Factor and others that have been shown to help reduce the appearance of hyperpigmentation.

- 1. W. J. Yun, S. H. Bang, K. H. Min, S. W. Kim, M. W. Lee, and S. E. Chang, Epidermal growth factor and epidermal growth factor signaling attenuate laser-induced melanogenesis, Dermatol. Surg., 39, 1903–1911 (2013).
- 2. Lyons, J. Stoll, and R. Moy, A randomized, double-blind, placebo-controlled, split-face study of the efficacy of topical epidermal growth factor for the treatment of melasma, J. Drugs Dermatol., 17, 970–973 (2018).

Tranexamic Acid: with heavily backed by data, Tranexamic acid helps minimize the appearance and recurrence of discoloration and stubborn brown patches. *Shown to be as effective as hydroquinone with continued use.* 

- 1. Atefi et al. Therapeutic Effects of Topical Tranexamic Acid in Comparison with Hydroquinone in Treatment of Women with Melasma. Dermatol Ther. 2017 Sep;7(3):417-424.
- 2. Banihashemi et al. Comparison of therapeutic effects of conventional and liposomal tranexamic acid form of 4% topical hydroquinone in patients with melasma. Journal Cosmetic Derm. 2019 Jun;18(3):870-873.

## Skinuva® FAQ

Niacinamide (Vitamin B3): a water-soluble vitamin that has been shown to help reduce the appearance of skin discoloration. *Shown to be nearly as effective as hydroquinone.* 

J. Navarrete-Solís, J. P. C astanedo-Cázares, B. Torres-Álvarez, C. Oros-Ovalle, C. Fuentes-Ahumada, F. J. González, J. D. Martínez-Ramírez, and B. Moncada, A double-blind, randomized clinical trial of niacinamide 4% versus hydroquinone 4% in the treatment of melasma, Dermatol Res Pract, 2011, 379173 (2011).

Vitamin C: a powerful antioxidant that has been independently reported to help prevent melanin production.

*P. K. Farris, Topical vita m in C: a useful agent for treating photoaging and other dermatologic conditions, Dermatol. Surg., 31, 814–818 (2005).* 

Arbutin: found in bearberry plants and helps to reduce hyperpigmentation.

• W. Zhu and J. Gao, The use of botanical extracts as topical skin-lightening agents for the improvement of skin pigmentation disorders, J. Invest. Dermatol. Symp. Proc., 13, 20–24 (2008).



## Skinuva® FAQ

#### What are Selective Growth Factors?

Growth factors are messenger proteins that are inherent in our bodies and play a role in maintaining healthy skin. Rather than just including a whole mix of growth factors in our skin-brightening formulation, we selected specific growth factors (hence selective growth factors) that we believe have been shown to help improve the appearance of hyperpigmentation.\* There are many different growth factors available, but our formulation includes only synthetic (not human or animal derived) growth factors, including Epidermal Growth Factor (EGF) and another proprietary growth factor that has been shown to help reduce the appearance of hyperpigmentation by inhibiting tyrosinase\*. All the growth factors used in our products are INCI registered under cosmetic peptides.

- 1. G. H. Park, et al. Effect of an epidermal growth factor-containing cream on post inflammatory hyperpigmentation after Q-switched 532-nm neodymium-doped yttrium aluminum garnet laser treatment, Dermatol. Surg., 41, 131–135 (2015).
- 2. W. J. Yun, et cal., Epidermal growth factor and epidermal growth factor signaling attenuate laser-induced melanogenesis, Dermatol. Surg., 39, 1903–1911 (2013).

#### Are growth factors safe?

There is adequate peer-reviewed medical literature evidence to support the safety and efficacy of growth factors in addressing skin conditions and anti-aging. Growth factors have been routinely included in many high-end skin care lines over the past 20 years, with no issues of long term complications or adverse reactions.\*

#### Why were growth factors derived from human cells (i.e. placenta, foreskin) not used?

The growth factors used in Skinuva® Brite are not human, stem-cell, or plant derived. We understand there is still controversy with this topic, and therefore only highly selective medical grade synthetic growth factors that are made under sterile conditions in a laboratory are used in the product.

#### Are our growth factors stable in our formulation?

Skinuva® Brite's manufacturing process allows for the growth factors to remain stable during the entire process. Growth factors are proteins and extreme temperatures can denature them, that is why we recommend Skinuva® Brite be stored at room temperature.

#### Was any animal testing done in developing and testing Skinuva® Brite?

We did not perform any animal testing during our clinical development and testing stages of Skinuva® Brite. Furthermore, none of our ingredients have undergone animal testing. Skinuva® Brite is 100% cruelty-free.\*

#### **Does Skinuva® Brite have SPF?**

We have not included sunscreen/SPF in our formula. However, sunscreen/SPF can be applied on top of Skinuva® Brite. We have specifically formulated a brightening cream that allows the user to safely apply sunblock on top of Skinuva® Brite.

#### How often do I apply Skinuva<sup>TM</sup> Brite?

In order to see optimal results, Skinuva® Brite is to be applied twice a day. Results may be seen as early as 30 days, but for best results, long term use is recommended. Results may vary depending on severity of hyperpigmentation.

# What are types of hyperpigmentation that Skinuva® Brite can improve?

Our studies have shown that Skinuva® Brite has helped improve the appearance of various types of hyperpigmentation on the face and body including melasma, post-inflammatory hyperpigmentation, sun spots, and under eye pigmentation\*.

Kalasho BD, Minokadeh A, Zhang-Nunes S, Zoumalan RA, Shemirani NL, Waldman AR, Pletzer V, Zoumalan CI. Evaluating the safety and efficacy of a new topical formulation for hyperpigmentation consisting of highly selective growth factors, tranexamic acid, and other ingredients to hydroquinone 4%: a prospective, randomized, controlled split face study. J Cosmet Sci. 2020 Sep/Oct;71(5):263-290.

# Is Skinuva® Brite a serum or a moisturizer?

Skinuva® Brite has been formulated and prepared as a moisturizer. It does not dry your skin out after use. You may apply your other skin care products on top of Skinuva® Brite if desired, but they are not necessary. Sunscreen and cosmetics may be applied on top of Skinuva® Brite. A cleanser may also be used prior to its application if desired.

# Can Skinuva® Brite cause skin reactions?

Skinuva® Brite has undergone repeat insult patch testing (RIPT) in 60 test subjects and found to have no allergic issues. In our two clinical studies (Study 1 and Study 2), 218 patients were evaluated, and no issues of skin reactions or intolerability were noted.\*

However, if you experience excessive redness, itching or intolerance associated with the product, immediately stop using it and consult with your doctor.

Kalasho BD, Minokadeh A, Zhang-Nunes S, Zoumalan RA, Shemirani NL, Waldman AR, Pletzer V, Zoumalan CI. Evaluating the safety and efficacy of a new topical formulation for hyperpigmentation consisting of highly selective growth factors, tranexamic acid, and other ingredients to hydroquinone 4%: a prospective, randomized, controlled split face study. J Cosmet Sci. 2020 Sep/Oct;71(5):263-290.

# How should I store Skinuva® Brite?

Skinuva® Brite should be stored at room temperature. Avoid excessive heat.

# What clinical studies have been conducted on Skinuva® Brite?

**Study 1**: Skinuva® Brite: Proof of Concept Study, Safety and Efficacy (June, 2019) 200 patients used Skinuva Brite twice a day for 6 weeks to evaluate its safety and efficacy. All 200 patients tolerated the product well and noticed subject improvement in their facial hyperpigmentation.

Study 2: Skinuva® Brite vs. hydroquinone 4%: head to head trial (September 2019)\*

- 18 patients with hyperpigmentation enrolled, split face study
- Patients reported that 83.3% of sides treated with Skinuva Brite appeared better than HQ4% treated side. Independent evaluators also had similar findings but even higher at 88.2%.

• Shown to be nearly 30% better than HQ4% in both Patient Reported Assessment AND Independent Evaluators

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Can Skinuva® Brite be used on open wounds? No. It should not be used on damaged skin or open wounds.

Is Skinuva® Brite suitable for children? Yes above 3 years of age.

#### Is Skinuva® Brite suitable for pregnant and breastfeeding women?

Although Skinuva® Brite is not contraindicated we do not recommend using while pregnant, breastfeeding, or planning on becoming pregnant.

# Is Skinuva® Brite effective on all skin types?

Yes

#### Can Skinuva® Brite be used around the eyes?

Yes, as long as it is not directly placed in the eyes, it has been tested to be safe to be applied on the eyelids.

# What is the expiration of Skinuva® Brite?

Skinuva® Brite has a 2 year shelf life.\*

# What instances can Skinuva® Scar and Skinuva® Brite be used together?

While Skinuva Scar and its ingredients have been clinically proven to help reduce the appearance of scars, Skinuva Brite can also help improve the appearance of hyperpigmentation. Depending on the procedure, both products can be suitable in your pre and post treatment recovery procedure. The following below explain some examples of how the two products can be used in combination.

# Switching from Skinuva® Scar to Skinuva® Brite in post-recovery procedures:

# Helping with Long-term Scar Treatment:

Skinuva® Scar is best used after your surgery, laser resurfacing, or even microneedling. For treating a recent scar (cosmetic and non-cosmetic surgery), Skinuva® Scar should be applied twice a day beginning approximately two weeks post procedure, and should be used for a minimum of 3-6 months to optimally help improve the appearance of the scar. If after this use of Skinuva® Scar for 3-6 months, there is the appearance of residual hyperpigmentation associated with the scar, Skinuva® Brite may also be used and can be helpful to further improve the hyperpigmentation at that time. Most patients use Skinuva Scar for two weeks post laser treatment, chemical peel, or microneedling to help improve the skin's recovery process after the treatment. Skinuva Brite can be applied indefinitely twice a day after that to optimize and maintain the evenness of your skin tone and to help improve the appearance of any hyperpigmentation that you may notice.

#### Laser/Chemical Peels/Microneedling:

Skinuva® Scar and Skinuva® Brite can help in different stages of your laser resurfacing treatment, chemical peel, or microneedling treatment. Skinuva® Brite can be helpful in improving the appearance of hyperpigmentation such as dark spots, discoloration of the face and body, and it can be used prior to your laser, chemical peel, or microneedling treatments help optimize and maintain the even appearance of your skin. If you have undergone a recent laser, chemical peel, or microneedling treatment, Skinuva® Scar has been shown to help improve the skin's recovery process after the treatment.\* Most patients use Skinuva® Scar twice daily for two weeks post laser treatment, chemical peel, or microneedling. Once your skin has recovered from the treatment, Skinuva® Brite can then be applied indefinitely twice a day to optimize and maintain the evenness of your skin tone, and to help improve the appearance of any hyperpigmentation that you may notice.

# Using both Skinuva® Scar and Skinuva® Brite in women who have undergone previous C-section and also have melasma:

Skinuva® Scar and Skinuva® Brite can be applied at the same time when used on different parts of the body. For instance, women who have had a previous C-section and retained scars can use Skinuva® Scar to help improve the appearance of the C-section scar, and if they also have melasma, Skinuva® Brite can be applied to the face to help minimize the appearance of hyperpigmentation.

Data on File\*

Skinuva® products are intended to meet the FDA's definition of a cosmetic product, an article applied to the human body to cleanse, beautify, promote attractiveness, and alter appearances. The products are not intended to be drug products that diagnose, treat, cure, or prevent any disease or condition. These products have not been approved by the FDA, and the statements here have not been evaluated by the FDA.

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