PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: GHK-Cu/Niacinamide
Form: Topical Cream

Drug Class:

- GHK-Cu: Peptide complex (endogenous tripeptide); Copper-binding growth factor analog
- Niacinamide: Vitamin B3 derivative

Mechanism of Action[1,2,3]: When compounded together, GHK-Cu/Niacinamide can deliver anti-aging and soothing effects simultaneously to support firmer, smoother, brighter, and more refreshed-looking skin while addressing several visible signs associated with aging and environmental stress. It is intended to:

- Encourage the skin's natural production and remodeling of collagen and elastin, proteins that help maintain firmness and elasticity. These supportive effects may help soften the appearance of fine lines and improve overall skin texture over time.
- Support fibroblasts and keratinocytes, important cells involved in maintaining and renewing the skin. By supporting these natural repair processes, it may help improve the appearance and quality of aging or environmentally stressed skin.
- Support the skin's natural barrier and help it retain moisture more effectively. A healthier barrier can leave skin feeling smoother, more hydrated, and less susceptible to dryness and irritation.
- Reduce the transfer of pigment into surface skin cells, which may gradually improve the appearance of dark spots and uneven tone

Indications Commonly Prescribed For:

- Fine lines and early visible signs of aging
- Loss of firmness or elasticity
- Uneven or rough skin texture
- Dull or tired-looking skin
- Uneven skin tone
- Dark spots and visible discoloration
- Red or blotchy-looking skin
- Dryness and weakened skin-barrier function
- Visible effects of sun and environmental exposure
- Supporting smoother, healthier-looking skin
- Overall improvement in skin quality and appearance

Before Use: Let your healthcare provider know if you

- Have any medication allergies before you take this compounded preparation.
- Have any liver or kidney problems.
- Are taking any supplements of medications
- Are using any other topical treatments

Compounded medications are not FDA-approved and may differ in risks, benefits, and side effects from FDA-approved products. These statements have not been evaluated by the FDA and are not intended to diagnose, treat or cure any disease or condition and do not indicate any claims of safety or efficacy. Individual results may vary.

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Contraindications:

- Known hypersensitivity to GHK-Cu, niacinamide, copper-containing ingredients, or formulation components
- Copper metabolism disorders (e.g., Wilson's disease hemochromatosis)
- Application to actively infected or severely damaged skin without clinical evaluation
- Use immediately following aggressive dermatologic procedures unless directed by the treating clinician

Cautions: Let your Healthcare provider know if you experience any adverse side effects. Apply sunscreen daily during the duration of treatment. Do not apply directly to eyes and mucous membranes.

Warnings and Precautions:

- Monitor for signs of copper overload with prolonged systemic use.
- Copper peptides can oxidize in low-pH formulas; avoid mixing with strong acids or pure vitamin C serums.
- Use daily broad-spectrum sunscreen due to increases in UV sensitivity to prevent photoaging, discoloration, or additional visible skin damage.
- Compromised skin may absorb topical ingredients differently and may be more prone to irritation. Timing after lasers, chemical peels, microneedling, or other procedures should be determined by the treating clinician.

Adverse Reactions: If you experience any side effects or adverse reactions, including those not listed, please contact your healthcare provider. Seek emergency care if symptoms are severe.

Common:

- Mild skin irritation
- Mild redness
- UV sensitivity
- Temporary burning or stinging
- Itching
- Dryness
- Mild irritation
- Application-site sensitivity

Serious, but Rare:

- Contact dermatitis
- Copper toxicity
- Allergic Reactions (hives, swelling)
- Persistent inflammatory reactions

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Interactions:

- Retinoids: Tretinoin, retinol, and related products may increase dryness or irritation when introduced simultaneously. Stagger use.
- AHAs/BHAs: Glycolic, lactic, salicylic, and other exfoliating acids may increase sensitivity and barrier irritation. Stagger use.
- Chemical peels or resurfacing treatments: Recently treated skin may be more reactive, so application timing should be individualized.
- Other copper-containing products: Additional exposure may be unnecessary and could complicate assessment of irritation or treatment response.

Use in Specific Populations:

- Pregnancy: Lack of safety data
- Geriatrics: Frequently used for anti-aging benefit
- Pediatrics: Avoid use
- Post-procedure: Excellent for healing and redness reduction

Storage:

- Store in original container at room temperature (up to 30°C or 86°F)
- Store in a cool dry place away from heat, sunlight, and moisture

How to Use: This compounded preparation is in the form of a topical cream. The cream is a special container that will administer 0.6ml dose. Clean desired area prior to use. To administer remove the protective covering on the top of the dispenser. Place the jar on a flat surface. Using clean, dry hands, gently press down on the top of the pump. This will dispense a measured amount of cream through the center opening. Confirm the cream has exited the holes at the top of the dispenser. Apply the cream onto the desired area. Continue to rub the area until the cream is evenly dispersed over the desired area. Replace the protective cover and store the device until next dose. If you miss a dose apply as soon as you remember, but not at the time for the next dose. The desired results may take up to several weeks.

Monitoring Parameters:

- Skin response over 8–12 weeks
- Copper and ceruloplasmin levels in extended systemic protocols

Citations:

1. Maquart FX, Pickart L, Laurent M, Gillery P, Monboisse JC, Borel JP. Stimulation of collagen synthesis in fibroblast cultures by the tripeptide-copper complex glycyl-L-histidyl-L-lysine-Cu2+. FEBS Lett. 1988;238(2):343-346. doi:10.1016/0014-5793(88)80509-x
2. Bissett DL, Miyamoto K, Sun P, Li J, Berge CA. Topical niacinamide reduces yellowing, wrinkling, red blotchiness, and hyperpigmented spots in aging facial skin. *Int J Cosmet Sci*. 2004;26(5):231-238. doi:10.1111/j.1467-2494.2004.00228.x

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