

**EFFECTIVE HAIR STRENGTHEN- glycerin solution
NUGGELA & SULE SL**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Effective Hair Strengthen topical solution

ACTIVE INGREDIENTS PURPOSE

Glycerin 4.97%..... Skin Protectant

Warnings

For external use only.

Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children.

When using this product do not get into eyes.

Children under 6 months: as a doctor.

WARNINGS

Stop use and ask a doctor if rash occurs

Children under 6 months: ask a doctor

Warnings

Keep out of reach of children

Questions or comments?

+ 305 670 0979 M-F 9:00 am to 5:00 pm

Other Information

. keep the product in a cool and dry place

Directions

- follow the directions in the leaflet for proper use
- for better results, combine this product with Nuggela & Sule Premium shampoo and Conditioner

RECOMMENDATION TO ENHANCE ITS EFFECTS

It is recommend to wash always your hair with Nuggela & Sulé Premium Shampoo to enhance the effectiveness of the treatment. It is also recommend to apply the ampoules at night to improve their effectiveness.

CAUTIONS

- Do not swallow.
- Do not inject.
- For external use only.
- Keep out of reach of children.
- Avoid direct contact with eyes, rinse with water if necessary.

NUGGELA & SULÉ HAIR PRODUCTS

- **Nuggela & Sulé Premium Shampoo**, enhanced with red onion extract, Glycoenergizer Hair and Dead Sea Salts. Strengthens the hair, delivering shine and softness to your hair.
- **Nuggela & Sulé Extreme Conditioner** facilitates combing while strengthening the hair and providing volume and an Extreme shine.
- **Nuggela & Sulé Hair Regenerator**, a cocktail of actives which benefit the capilar regeneration by strengthening and increasing the hairs density.
- **Polynesia-Keratin Premium Shampoo**, THE TOP OF THE SHAM-POOS strengthening hair from the fibre to the follicle, improving vitality from the inside out. Highly recommended for use after a Keratin treatment, Hair Botox, Hyaluronic Acid treatment, etc.
- **Nuggela & Sulé Revolution Oil**, is the first oil blend presented as a MOUSSE that moisturises, nourishes, repairs, protects, tames frizz and provides shine to the hair.
- **Keratin-Hyaluronic ampoules**, specially formulated using Keratin and Hyaluronic Acid, which repairs everyday hair damage, whilst instantly reconstructing from root to tip, sealing and hydrating hair fibre.
- **Multivitamin Energy ampoules**, a true beauty enhancer which illuminates hair from root to tip, whilst nourishing and strengthening from within.

Dermatologically tested
Daily use
For all types of hair
Made in European Union

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www.nuggelasule.com

Nuggela & Sulé is a company devoted to the care of skin and hair. It stands out in the world of cosmetics for the recovery of the most successful traditional remedies, throughout history, for the manufacture of high quality and efficient products.

The company's name takes after one of the most important islands in Polynesia, named in homage to the Maori god Nga Sulé, which means "son of heaven", staunch defender of nature and the use of its resources.

Nuggela & Sulé Effective Hair Strengthen Ampoules Pure energy for your hair

The formula used in Nuggela & Sulé Ampoules is based on the extraordinary concentration of its active ingredients. The blend of Glycoenergizer Hair and Red Onion Extract offer an additional energy boost that stimulates and strengthens the hair. This product is highly recommended for weak, thin or devitalised hair.

INDICATED FOR:

Strengthening the hair, weak or brittle hair.

- follow the directions in the leaflet for proper use
- for better results, combine this product with Nuggela & Sule Premium shampoo and Conditioner

Uses

- regenerates and stimulates the hair
- nourish the scalp and provides the needed strenght to the broken and damaged hair
- provides skin protection to the scalp

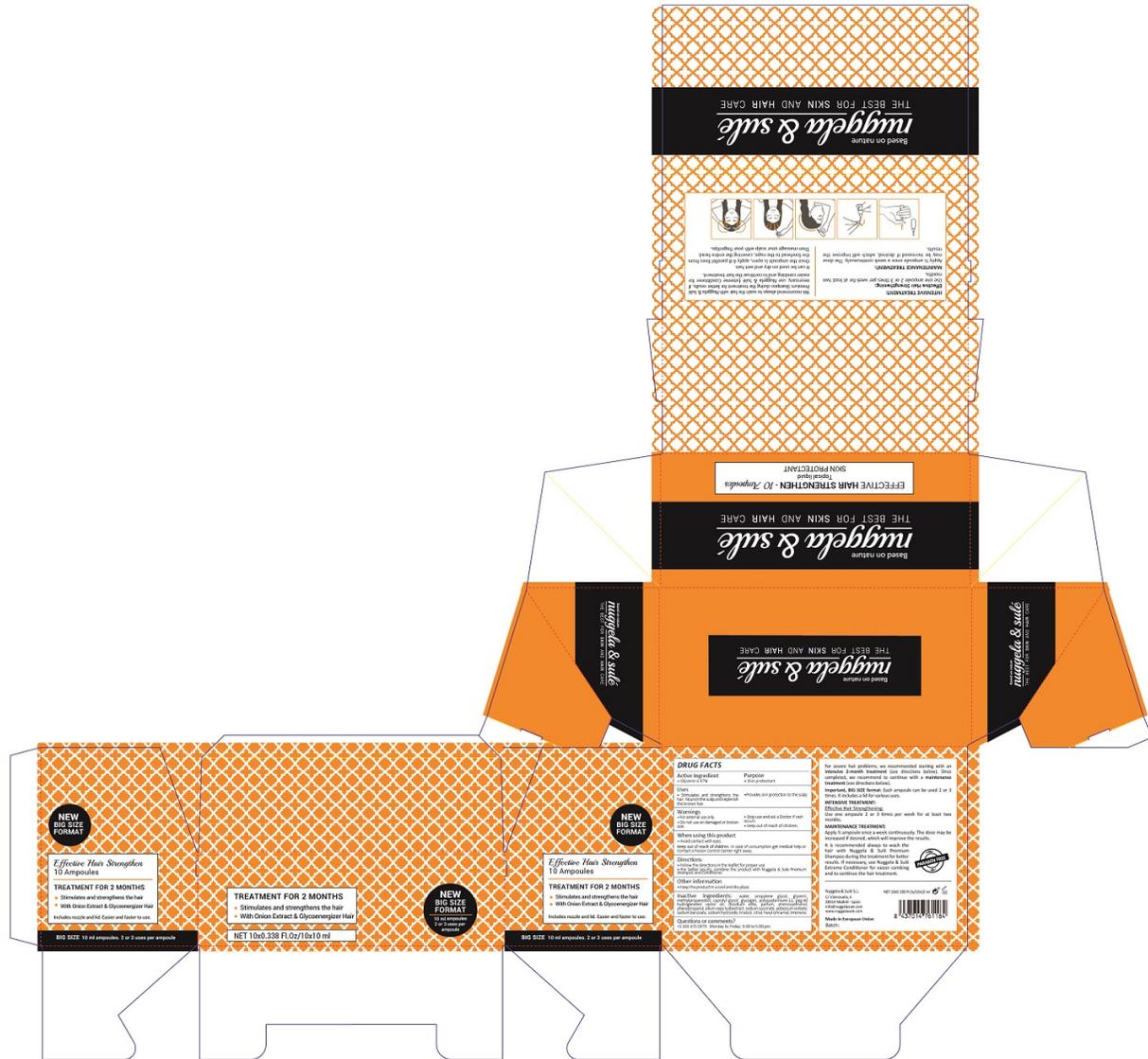
Inactive Ingredients

AQUA, PROPYLENE GLYCOL, GLYCERIN, METHYLPROPANEDIOL, CAPRYLYL GLYCOL, GLYCOGEN, POLYQUATERNIUM-11, PEG-40 HYDROGENATED CASTOR OIL, DISODIUM EDTA , PARFUM, PHENOXYETHANOL, PHENYLPROPANOL, ALLIUM CEPA BULB EXTRACT, SODIUM SUCCINATE, POTASSIUM SORBATE, SODIUM BENZOATE, SODIUM HYDROXIDE, LINALOOL, CITRAL, HEXYL CINNAMAL, LIMONENE

Uses

- regenerates and stimulates the hair
- nourish the scalp and provides the needed strenght to the broken and damaged hair
- provides skin protection to the scalp

Package Label



Treatment for two months
 Stimulate and strengthen the hair
 With onion extract and Glycoenergizer hair

| EFFECTIVE HAIR STRENGTHEN | | | |
|--|--|--------------------------|-----------------|
| glycerin solution | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71578-003 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX) | GLYCERIN | 4.97 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-------------------|
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | 0.0001 mg in 1 mL |
| CITRAL (UNII: T7EU0O9VPP) | 0.0001 mg in 1 mL |
| LINALOOL, (-)- (UNII: 3U21E3V8I2) | 0.0001 mg in 1 mL |
| WATER (UNII: 059QF0KO0R) | 84.31 mg in 1 mL |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | 0.52 mg in 1 mL |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | 0.15 mg in 1 mL |
| GLYCOGEN (UNII: 309GSC92U1) | 0.5 mg in 1 mL |
| POLYQUATERNIUM-11 (100000 MW) (UNII: 0B44BS5JS) | 0.4 mg in 1 mL |
| PEG-40 CASTOR OIL (UNII: 4ERD2076EF) | 0.25 mg in 1 mL |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | 0.2 mg in 1 mL |
| PROPANEDIOL (UNII: 5965N8W85T) | 6 mg in 1 mL |
| PHENYLPROPANOL (UNII: 0F897O3O4M) | 0.07 mg in 1 mL |
| ONION (UNII: 492225Q21H) | 0.04 mg in 1 mL |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | 0.005 mg in 1 mL |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | 0.005 mg in 1 mL |
| .ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I) | 0.0001 mg in 1 mL |
| SODIUM SUCCINATE HEXAHYDRATE (UNII: U16QOD6C4E) | 0.01 mg in 1 mL |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | 0.004 mg in 1 mL |
| METHYLPROPANEDIOL (UNII: N8F53B3R4R) | 2.4 mg in 1 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71578-003-02 | 1 in 1 BOX | 07/27/2017 | |
| 1 | NDC:71578-003-01 | 10 mL in 1 AMPULE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 07/27/2017 | |

Labeler - NUGGELA & SULE SL (466134663)

Registrant - NUGGELA & SULE SL (466134663)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|------------------------|
| NUGGELA & SULE SL | | 466134663 | manufacture(71578-003) |