

**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.*

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**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

## RECOMMENDED FOR ALL TYPES OF HAIR

- NORMAL HAIR
- OILY HAIR
- DRY HAIR

## TREATMENTS

### Important, BIG SIZE format ampoules:

Each ampoule can be used 2 or 3 times.

For severe hair problems, it is recommended starting with an intensive 2-month treatment (see directions below). Once completed, it is recommended to continue with a maintenance treatment (see directions below).

### INTENSIVE TREATMENT:

Use one ampoule 2 or 3 times per week for at least two months.

### MAINTENANCE TREATMENT:

Apply ½ ampoule once a week continuously. The dose may be increased if desired, which will improve the results.

## PRESENTATION

0.338 Fl.Oz/10 ml ampoules, with lid, nozzle and dispenser.  
Each ampoule can be used 2 or 3 times.

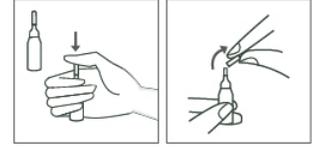
## READ BEFORE USE

- It can be applied on dry or wet hair.
- Does not make hair dirty or greasy.
- No need to wash your hair every day during the duration of the treatment.
- Onion-free smell. It leaves a pleasant smell of hay and lemon.
- It can be applied both at night before going to bed and during the day.
- It is recommended to apply the treatment after washing the hair.
- It is recommended always to wash the hair with Nuggela & Sulé Premium Shampoo during the treatment for better results. If necessary, use Nuggela & Sulé Extreme Conditioner for easier combing and to continue the hair treatment.

## DIRECTIONS

### ON DRY HAIR:

1. When using the ampoule for the first time, press down on the lid to pierce the nozzle.
2. Once you hear a click sound indicating that the ampoule is open, remove the lid by pulling it off.
3. Once the ampoule is open, press lightly and apply 6-8 parallel lines from the forehead to the nape, covering the entire head.
4. Then massage your scalp with your fingertips for two minutes to spread the liquid, facilitate the penetration of the active ingredients into the scalp and stimulate blood flow.
5. Once the massage is over, you can comb your hair normally.
6. Do not wash the hair for at least 6 hours after application.



### ON WET HAIR:

7. Perform steps 1 to 4 and wait around 5 to 7 minutes for the full absorption of the active ingredients before drying the hair.
8. Once this time has elapsed, you can dry and comb your hair normally.



## IMPORTANCE OF SCALP MASSAGE

Massaging the scalp is key to enhancing treatment results. Its function is to stimulate blood flow to benefit hair nourishment and improve the penetration of active ingredients. Massaging the scalp is always recommended when using both Nuggela & Sulé Hair Strengthen Ampoules and Premium Shampoo.

- 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 strength 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 strength 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:71578-004
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: 0B44BS5IJS)	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:71578-004-02	1 in 1 BOX	07/27/2017	
1	NDC:71578-004-01	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(71578-004)

Revised: 7/2017

NUGGELA & SULE SL