

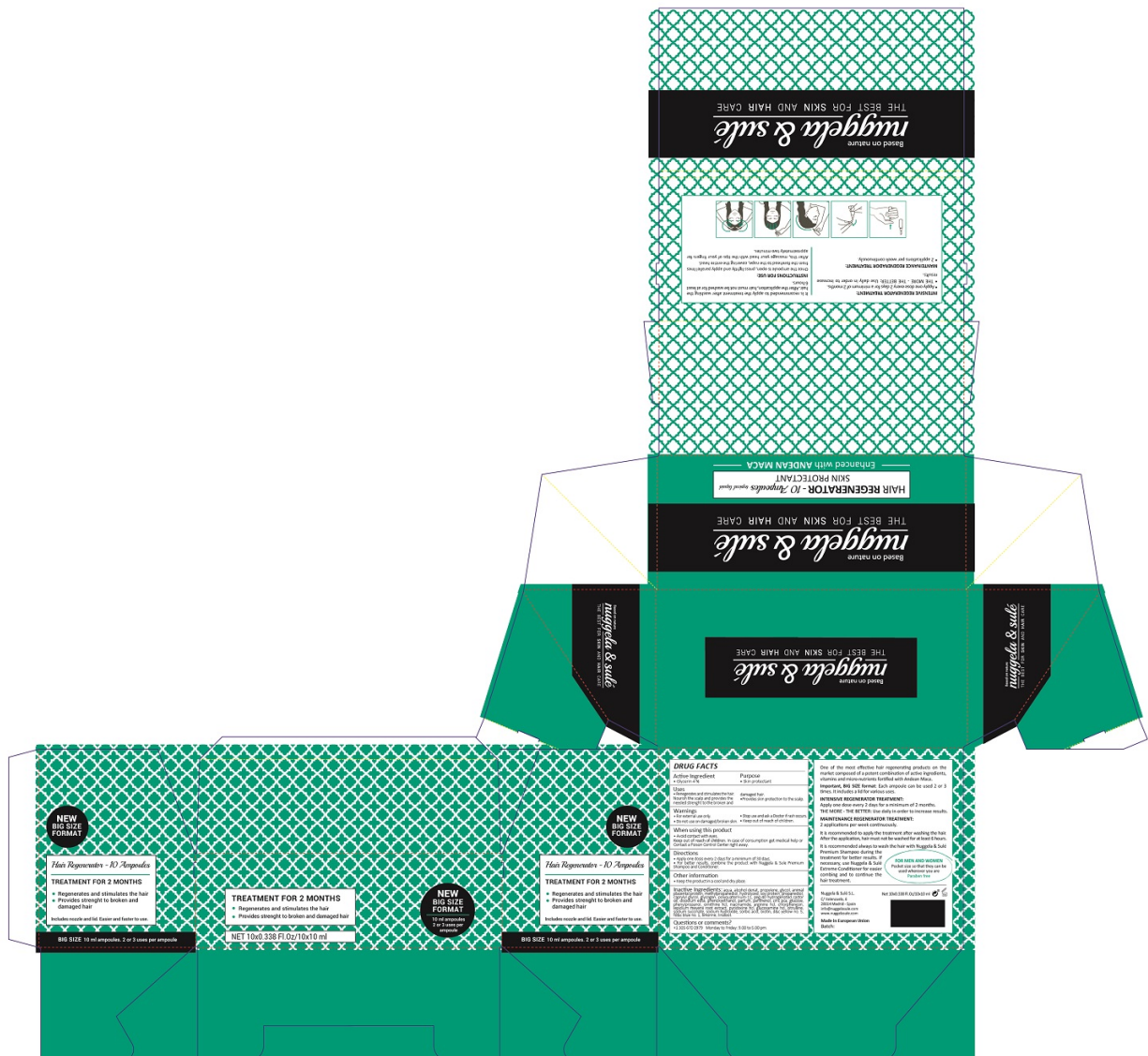
HAIR REGENERATOR- glycerin solution NUGGELA & SULE SL

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.

Hair Regenerator topical solution

ACTIVE INGREDIENTS PURPOSE

Glycerin 4%..... 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

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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

- apply one dose every 2 days for a minimum of 30 days
- for better results, combine this product with Nuggela & Sule Premium shampoo and Conditioner

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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

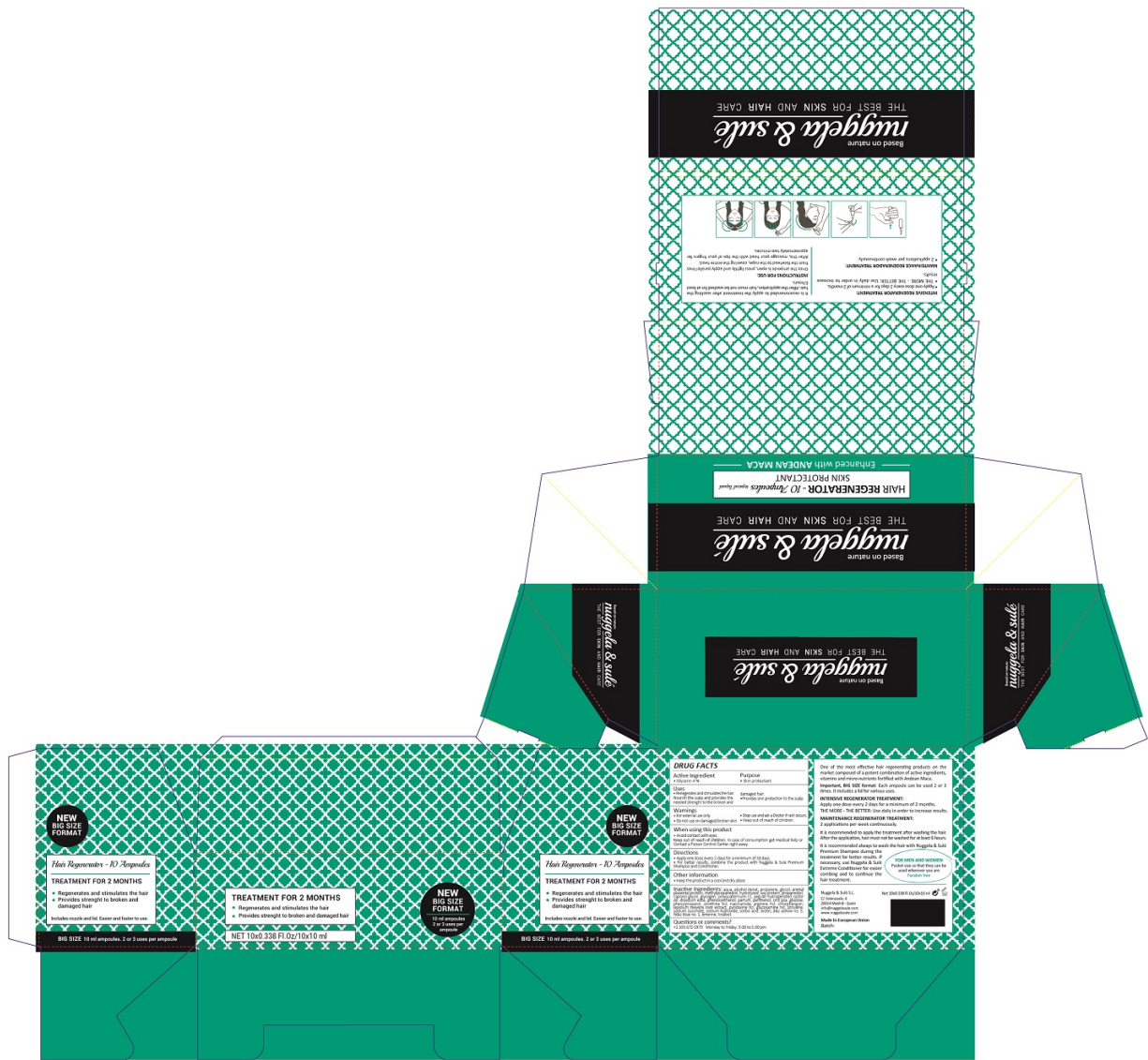
Inactive Ingredients

AQUA, ALCOHOL DENAT, PROPYLENE GLYCOL, PLACENTAL PROTEIN, METHYLPROPANEDIOL, HYDROLYZED SOY PROTEIN, PROPANEDIOL, CAPRYLYL GLYCOL, GLYCOGEN, POLYQUATERNIUM-11, PEG-40 HYDROGENATED CASTOR OIL DISODIUM EDTA, PHENOXYETHANOL, PARFUM, PANTHENOL, ZINC PCA, GLUCOSE, PHENYLPROPANOL, ORNITHINE HCL, NIACINAMIDE, ARGININE HCL, CHLORPHENESIN, LEPIDIUM MEYENII ROOT EXTRACT, PYRIDOXINE HCL, GLUCOSAMINE HCL, CITRULLINE, SODIUM SUCCINATE, SODIUM HYDROXIDE, SORBIC ACID, BIOTIN, D&C Yellow No. 5, FD&C Blue No.1, LIMONENE, LINALOOL

Uses

- regenerates and stimulates the hair
- nourish the scalp and provides the needed strength to the broken and damaged hair
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Package Label



HAIR REGENERATOR

glycerin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71578-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	0.0001 mg in 1 mL

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	0.0001 mg in 1 mL
BIOTIN (UNII: 6SO6U10H04)	0.002 mg in 1 mL
LINALOOL, (-) - (UNII: 3U21E3V8I2)	0.0001 mg in 1 mL
WATER (UNII: 059QF0K00R)	64.33 mg in 1 mL
DIPROPYLENE GLYCOL (UNII: E107L85C40)	6.82 mg in 1 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.17 mg in 1 mL
HYDROLYZED PLACENTAL PROTEIN (BOVINE) (UNII: KR5CS6RBH9)	6.53 mg in 1 mL
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	2.4 mg in 1 mL
SOY PROTEIN (UNII: R44IWB3RN5)	1.97 mg in 1 mL
PROPANEDIOL (UNII: 5965N8W85T)	0.98 mg in 1 mL
LIMONENE, (+) - (UNII: GFD7C86Q1W)	0.01 mg in 1 mL
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	0.52 mg in 1 mL
GLYCOGEN (UNII: 309GSC92U1)	0.5 mg in 1 mL
POLYQUATERNIUM-11 (1000000 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
ZINC PIDOLATE (UNII: C32PQ86DH4)	0.1 mg in 1 mL
DEXTROSE (UNII: IY9XDZ35W2)	0.1 mg in 1 mL
PHENYLPROPANOL (UNII: 0F897O3O4M)	0.07 mg in 1 mL
ORNITHINE HYDROCHLORIDE (UNII: HBK84K66XH)	0.07 mg in 1 mL
NIACINAMIDE (UNII: 25X51I8RD4)	0.07 mg in 1 mL
ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y)	0.07 mg in 1 mL
CHLORPHENESIN (UNII: I670DAL4SZ)	0.03 mg in 1 mL
PANTHENOL (UNII: WV9CM0O67Z)	0.106 mg in 1 mL
LEPIDIUM MEYENII ROOT (UNII: HP7119212T)	0.03 mg in 1 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	0.02 mg in 1 mL
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)	0.02 mg in 1 mL
CITRULLINE (UNII: 29VT07BGDA)	0.02 mg in 1 mL
SODIUM SUCCINATE HEXAHYDRATE (UNII: U16QOD6C4E)	0.01 mg in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.0044 mg in 1 mL
SORBIC ACID (UNII: X045WJ989B)	0.002 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M)	10 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71578-001-02	1 in 1 BOX	07/27/2017	
1	NDC:71578-001-01	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(71578-001)

Revised: 5/2020

NUGGELA & SULE SL