

PRESTIGE CAVIAR NOURISHING DAILY CREAM- glycerin, dimethicone cream
FW1 R&D_Branch

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.

Drug Facts

Glycerin 27.36%

Dimethicone 2.00%

Skin Protectant

Helps to prevent dehydration of skin

Apply liberally as needed onto skin

For external use only.

Do not use on damaged or broken skin.

When using this product, keep out of eyes. Rinse with water to remove

Stop using and ask a doctor if rash occurs.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Caviar Extract, Cyclopentasiloxane, Water, Dimethicone/Vinyl Dimethicone Crosspolymer, Butylene Glycol, Glycereth-26, Niacinamide, 1,2-Hexanediol, PEG/PPG-19/19 Dimethicone, Methyl Gluceth-20, Sodium Glutamate, Phenoxyethanol, PEG-7 Dimethicone, PEG/PPG-20/20 Dimethicone, Fragrance(Parfum), Dipotassium Glycyrrhizate, Adenosine, Iron Oxides (CI 77499), Synthetic Fluorphlogopite, Sodium Citrate, C12-14 Pareth-12, Titanium Dioxide (CI 77891), Disodium EDTA, Aqua, Polydecene, Saccharide Isomerate, Hydrolyzed Rice Protein, Caprylic/Capric Triglyceride, Sorbitan Laurate, Squalane, Hydrogenated Lecithin, Viscum Album (Mistletoe) Fruit Extract, Sodium Benzoate, Superoxide Dismutase, Glycine Soja (Soybean) Protein, Ceramide 3, Hydroxyethylcellulose, Acetyl Dipeptide-1 Cetyl Ester, Citric Acid, Sodium Dextran Sulfate, Potassium Sorbate, Prunus Persica (Peach) Flower Extract



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glycerin, dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70519-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	13.7 mg in 50 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength

CAVIAR, UNSPECIFIED (UNII: 020K6HLU0O)
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
WATER (UNII: 059QF0KO0R)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
GLYCERETH-26 (UNII: NNE56F2N14)
NIACINAMIDE (UNII: 25X51I8RD4)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
PEG/PPG-19/19 DIMETHICONE (UNII: EHH90CO7TL)
METHYL GLUCETH-20 (UNII: J3QD0LD11P)
MONOSODIUM GLUTAMATE (UNII: W81N5U6R6U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PEG/PPG-20/20 DIMETHICONE (UNII: BA94B7CK8K)
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)
ADENOSINE (UNII: K72T3FS567)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)
C12-14 PARETH-12 (UNII: M0LJS773XW)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
EDETATE DISODIUM (UNII: 7FLD91C86K)
HYDROGENATED DIDECENE (UNII: 048B98MT5O)
SACCHARIDE ISOMERATE (UNII: W8K377W98I)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)
SQUALANE (UNII: GW89575KF9)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
VISCUM ALBUM FRUIT (UNII: P83EQ521R3)
SODIUM BENZOATE (UNII: OJ245FE5EU)
LEDISMASE (UNII: 0786H5RV0T)
SOY PROTEIN (UNII: R44IWB3RN5)
CERAMIDE NP (UNII: 4370DF050B)
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)
ACETYL TYROSYLARGININE CETYL ESTER (UNII: 3M7W78X5IR)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
PRUNUS PERSICA FLOWER (UNII: 19GWB0JENH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70519-004-02	1 in 1 PACKAGE	06/27/2017	
1	NDC:70519-004-01	50 mL in 1 CONTAINER; 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	06/27/2017	

Labeler - FW1 R&D_Branch (689605458)

Registrant - FW1 R&D_Branch (689605458)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc		689049693	manufacture(70519-004)

Revised: 6/2017

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