

PRESTIGE CAVIAR ESSENTIAL BARRIER EYE CREAM- 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

Dimethicone 5.00%

Skin Protectant

An eye treatment that moisturizes and helps minimize the look of dark circles, shadows, and puffiness

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, Petrolatum, Glycerin, Butyrospermum Parkii (Shea) Butter, Ceresin, Phenyl Trimethicone, Water, Polyglyceryl-2 Dipolyhydroxystearate, Cetyl PEG/PPG-10/1 Dimethicone, Butylene Glycol, Niacinamide, Pentylene Glycol, Beeswax, Sodium Chloride, 1,2-Hexanediol, Silica, PEG-7 Dimethicone, Hydroxystearic Acid, Phenoxyethanol, Fragrance(Parfum), Disodium EDTA, Adenosine, Iron Oxides (CI 77499), Aqua, Hydrolyzed Rice Protein, Sodium Benzoate, Superoxide Dismutase, Glycine Soja (Soybean) Protein, Polydecene, Saccharide Isomerate, Sodium Dextran Sulfate, Potassium Sorbate, Caprylic/Capric Triglyceride, Sorbitan Laurate, Squalane, Hydrogenated Lecithin, Viscum Album (Mistletoe) Fruit Extract, Ceramide 3, Hydroxyethylcellulose, Acetyl Dipeptide-1 Cetyl Ester, Sodium Citrate, Citric Acid, Prunus Persica (Peach) Flower Extract



PRESTIGE CAVIAR ESSENTIAL BARRIER EYE CREAM

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70519-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CAVIAR, UNSPECIFIED (UNII: 020K6HLU0O)	

PETROLATUM (UNII: 4T6H12BN9U)
GLYCERIN (UNII: PDC6A3C0OX)
SHEA BUTTER (UNII: K49155WL9Y)
CERESIN (UNII: Q1LS2UJO3A)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
WATER (UNII: 059QF0KO0R)
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
NIACINAMIDE (UNII: 25X51I8RD4)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
YELLOW WAX (UNII: 2ZA36H0S2V)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
12-HYDROXYSTEARIC ACID (UNII: 933ANU3H2S)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
EDETATE DISODIUM (UNII: 7FLD91C86K)
ADENOSINE (UNII: K72T3FS567)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
SODIUM BENZOATE (UNII: OJ245FE5EU)
LEDISMASE (UNII: 0786H5RV0T)
SOY PROTEIN (UNII: R44IWB3RN5)
HYDROGENATED DIDECENE (UNII: 048B98MT5O)
SACCHARIDE ISOMERATE (UNII: W8K377W98I)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)
SQUALANE (UNII: GW89575KF9)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
VISCUM ALBUM FRUIT (UNII: P83EQ521R3)
CERAMIDE NP (UNII: 4370DF050B)
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)
ACETYL TYROSYLARGININE CETYL ESTER (UNII: 3M7W78X5IR)
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
PRUNUS PERSICA FLOWER (UNII: 19GWB0JENH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70519-001-02	1 in 1 PACKAGE	06/27/2017	
1	NDC:70519-001-01	30 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(70519-001)

Revised: 6/2017

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