

**PRESTIGE CAVIAR FULL MOISTURIZING EMULSION- dimethicone emulsion
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 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, Water, Glycerin, Butylene Glycol, Niacinamide, Pentaerythrityl Tetraethylhexanoate, 1,2-Hexanediol, Cyclopentasiloxane, Glyceryl Stearate, Limnanthes Alba (Meadowfoam) Seed Oil, Pentylene Glycol, Hydrogenated Poly(C6-14 Olefin), Cetearyl Alcohol, Polyglyceryl-3 Methylglucose Distearate, PEG-40 Stearate, Phenoxyethanol, Ammonium Acryloyldimethyltaurate/VP Copolymer, Caprylyl Glycol, Fragrance(Parfum), Carbomer, Tromethamine, Dimethicone/Vinyl Dimethicone Crosspolymer, Xanthan Gum, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate, Squalane, Adenosine, Dextrin, Theobroma Cacao (Cocoa) Extract, Disodium EDTA, Polysorbate 60, Imperata Cylindrica Root Extract, Sorbitan Isostearate, Polydecene, Gardenia Florida Fruit Extract, Saccharide Isomerate, Monascus Extract, PEG-8, Maltodextrin, Caprylic/Capric Triglyceride, Sorbitan Laurate, Hydrogenated Lecithin, Viscum Album (Mistletoe) Fruit Extract, Carthamus Tinctorius (Safflower) Flower Extract, Hydrolyzed Viola Tricolor Extract, Cassia Angustifolia Seed Polysaccharide, Ceramide 3, Hydroxyethylcellulose, Acetyl Dipeptide-1 Cetyl Ester, Sodium Citrate





PRESTIGE CAVIAR FULL MOISTURIZING EMULSION

dimethicone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70519-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2.6 mg in 130 mL

Inactive Ingredients

Ingredient Name	Strength
CAVIAR, UNSPECIFIED (UNII: 020K6HLU0O)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HYDROGENATED POLY(C6-14 OLEFIN; 2 CST) (UNII: P0TX083987)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
TROMETHAMINE (UNII: 023C2WHX2V)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
ADENOSINE (UNII: K72T3FS567)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	
COCOA (UNII: D9108TZ9KG)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
IMPERATA CYLINDRICA ROOT (UNII: VYT2JA85NH)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
HYDROGENATED DIDECENE (UNII: 048B98MT5O)	
GARDENIA JASMINOIDES FRUIT (UNII: 7CTH8MD549)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
VISCUM ALBUM FRUIT (UNII: P83EQ521R3)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
VIOLA TRICOLOR (UNII: 9Q24RAI43V)	
CERAMIDE NP (UNII: 4370DF050B)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
ACETYL TYROSYLARGININE CETYL ESTER (UNII: 3M7W78X5IR)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70519-003-02	1 in 1 PACKAGE	06/27/2017	
1	NDC:70519-003-01	130 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(70519-003)

Revised: 6/2017

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