

INTERVENE MAKEUP SPF 15 SOFT WHEAT- octinoxate cream

Elizabeth Arden, Inc

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.

BC1082

DESCRIPTION

For normal skin. Medium/full coverage. Soft natural finish. This innovative liquid makeup with Biodormin technology helps delay the appearance of new lines and wrinkles as it firms the look of skin. Micro-mineral pigment technology smoothes imperfections, evens out skin tone and creates a soft natural finish that lasts all day. Provides SPF 15 sun protection. Clinically, dermatologist, and allergy tested.

INDICATIONS AND USAGE

To Use: Smooth on to face before sun exposure.

WARNINGS

Warning: For external use only. Keep out of eyes. Stop use and see a doctor if rash or irritation develops and lasts. Keep out of reach of children.

OTC - ACTIVE INGREDIENT

Active Ingredient: Octinoxate 5% w/w.

INACTIVE INGREDIENT

Other Ingredients: Cyclopentasiloxane, Water/Aqua/Eau, Isododecane, Butylene Glycol, Ethylhexyl Methoxycinnamate, Talc, Mica, Polymethyl Methacrylate, Silica Silylate, Sorbitan Tristearate, PEG/PPG-18/18 Dimethicone, Silica, Trimethylsiloxysilicate, Palmitoyl Tetrapeptide-7, Narcissus Tazetta Bulb Extract, Trifolium Pratense (Clover) Flower Extract, Ascorbyl Palmitate, Tocopherol, Lecithin, Glycerin, Hydrolyzed Soy Protein, Laureth-4, Laureth-7, Steareth-20, Distearidimonium Hectorite, Dimethicone/Vinyl Dimethicone Crosspolymer, Propylene Carbonate, BHT, Sodium Chloride, Dimethicone, Dimethiconol, Fragrance/Parfum, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Propylparaben, Sodium Dehydroacetate, Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI77891).

DOSAGE & ADMINISTRATION

Smooth on to face.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.


OTC - PURPOSE

Provides SPF 15 sun protection.

OTC - WHEN USING

Keep out of eyes.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



• For normal skin.
• Medium/full coverage.
Soft natural finish.
• This innovative liquid makeup with Biodormin™ technology helps delay the appearance of new lines and wrinkles as it firms the look of skin. Micro-mineral pigment technology smoothes imperfections, evens out skin tone and creates a soft natural finish that lasts all day. Provides SPF 15 sun protection.

Clinically, dermatologist and allergy tested.
To use: Smooth onto face before sun exposure.

WARNING: For external use only. Keep out of eyes. Stop use and see a doctor if rash or irritation develops and lasts. Keep out of reach of children.

ACTIVE INGREDIENT:
OCTINOXATE 5.0 % W/W

OTHER INGREDIENTS:
CYCLOPENTASILOXANE, WATER/AQUA/EAU, ISODODECANE, BUTYLENE GLYCOL, TALC, MICA, POLYMETHYL METHACRYLATE, SILICA Silylate, SORBITAN TRISTEARATE, PEG/PPG-18/18 DIMETHICONE, SILICA, TRIMETHYLSILOXYSILICATE, PALMITOYL TETRAPEPTIDE-7, NARCISSUS TAZETTA BULB EXTRACT, TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT, ASCORBYL PALMITATE, TOCOPHEROL, LECITHIN, GLYCERIN, HYDROLYZED SOY PROTEIN, LAURETH-4, LAURETH-7, STEARETH-20, DISTEARDIMONIUM HECTORITE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, PROPYLENE CARBONATE, BHT, SODIUM CHLORIDE, DIMETHICONE, DIMETHICONOL, FRAGRANCE/PARFUM, BUTYLPARABEN, ETHYLPARABEN, ISOBUTYLPARABEN, METHYLPARABEN, PHENOXYETHANOL, PROPYLPARABEN, SODIUM DEHYDROACETATE, IRON OXIDES (CI 77491, CI 77492, CI 77499), TITANIUM DIOXIDE (CI 77891).

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ElizabethArden.com
Made in Italy

Elizabeth Arden
INTERVENE
MAKEUP
SPF 15

1 FL.OZ. 30 ml

INTERVENE MAKEUP SPF 15 SOFT WHEAT

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-1082
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.5 mL in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TALC (UNII: 7SEV7J4R1U)	
SORBITAN TRISTEARATE (UNII: 6LUM696811)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
LAURETH-7 (UNII: Z95S6G8201)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ETHYL PARABEN (UNII: 14255EXE39)	
BUTYL PARABEN (UNII: 3QPII03FV8)	
NARCISSUS TAZETTA BULB (UNII: K17762966S)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
LAURETH-4 (UNII: 6HQ855798J)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
STEARETH-20 (UNII: L0Q8IK9E08)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	

Product Characteristics

Color	BROWN (Soft Wheat)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-1082-1	1 in 1 BOX		
1	NDC:67938-1082-2	30 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/06/2010	

Labeler - Elizabeth Arden, Inc (849222187)

Revised: 1/2011

Elizabeth Arden, Inc