

## **INTERVENE MAKEUP SPF 15- 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.*

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**BT0091**

### **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.



• 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, NAROSSUS 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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**Elizabeth Arden**  
**INTERVENE**  
MAKEUP  
SPF 15

**1 FL.OZ. 30 ml**

### INTERVENE MAKEUP SPF 15

octinoxate cream

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67938-091
<b>Route of Administration</b>	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: 3QP1I3FV8)	
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)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-091-01	1 in 1 BOX		
1	NDC:67938-091-02	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	

