

INTERVENE MAKEUP SPF 15 SOFT SHELL- 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.

BC1075

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, 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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ElizabethArden.com
Made in Italy

Elizabeth Arden
INTERVENE
MAKEUP
SPF 15

1 FL.OZ. 30 ml

INTERVENE MAKEUP SPF 15 SOFT SHELL

octinoxate cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67938-1075 |
| 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 | PINK (Soft Shell) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------|----------------------|--------------------|
| 1 | NDC:67938-1075-1 | 1 in 1 BOX | | |
| 1 | NDC:67938-1075-2 | 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