

INTERVENE DAILY MOISTURE SPF 15 OIL FREE- octinoxate and oxybenzone lotion
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.

BB0577

DESCRIPTION

This lightweight, oil free moisturizing lotion, powered by alpha and beta hydroxy compounds, refines, clarifies and retexturizes skin for a naturally radiant appearance. SPF 15 UVA/UVB sunscreens and antioxidant vitamins C and E protect skin from sun and pollution while an advanced hydrating system helps keep skin soft, smooth, and healthy looking all day long. Sensitive skin tested. Oil Free. Clinically, dermatologist and allergy tested.

INDICATIONS AND USAGE

To Use: Apply daily to face and throat before sun exposure.

WARNINGS

Warning: Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown to prevent sunburn not skin cancer or early skin aging. For external use only.

OTC - ACTIVE INGREDIENT

Active Ingredients: Octinoxate 6.0% w/w, Oxybenzone 3.0% w/w.

INACTIVE INGREDIENT

Other Ingredients:

WATER/AQUA/EAU, DIMETHICONE, ISONONYL ISONONANOATE, GLYCERIN, TRIDECYL SALICYLATE, STEARETH-21, ISOSTEARIC ACID, OCTYLDODECYL NEOPENTANOATE, ALUMINUM STARCH OCTENYLSUCCINATE, SALVIA OFFICINALIS (SAGE) LEAF EXTRACT, HYDROLYZED GLYCOSAMINOGLYCANS, SODIUM HYALURONATE, SODIUM LACTATE, RETINYL LINOLEATE, TETRAHEXYLDECYL ASCORBATE, TOCOPHEROL, GLYCERYL STEARATE, PROPYLENE GLYCOL, PANTHENOL, C12-20 ACID PEG-8 ESTER, CETYL ALCOHOL, PEG-100 STEARATE, TRILAURETH-4 PHOSPHATE, STEARETH-2, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, ETHYLENE/VA COPOLYMER, SCLEROTIUM GUM, TRIETHANOLAMINE, BHT, DISODIUM EDTA, PARFUM/FRAGRANCE, BENZYL SALICYLATE, BUTYLPHENYL METHYLPROPIONAL, CITRONELLOL, HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE, LIMONENE, LINALOOL, DMDM HYDANTOIN, METHYLPARABEN, PHENOXYETHANOL, PROPYLPARABEN.

DOSAGE & ADMINISTRATION

Apply liberally 15 minutes before sun exposure. Reapply: at least every 2 hours.

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

OTC - PURPOSE

SPF 15 UVA/UVB sunscreens protect skin from sun.

OTC - WHEN USING

Avoid contact with eyes.

The image shows the back of the product packaging for Elizabeth Arden INTERVENE DAILY MOISTURE LOTION SUNSCREEN SPF 15 OIL FREE. The packaging is divided into several sections:

- Top Left:** A paragraph describing the product's benefits, mentioning that it is free of parabens, contains alpha and beta hydroxy compounds, retinol, vitamin E, and antioxidants, and provides SPF 15 UVA/UVB protection.
- Top Center:** The Elizabeth Arden logo and the product name "INTERVENE DAILY MOISTURE LOTION SUNSCREEN SPF 15 OIL FREE".
- Top Right:** A barcode and a QR code, along with contact information for Elizabeth Arden, Inc. (New York, NY 10003) and a toll-free number (1-800-526-7337).
- Bottom Left:** "Drug Facts" section, including "Active Ingredients" (Octinoxate 6.0%, Oxybenzone 3.0%), "Uses" (Helps prevent sunburn), "Warnings" (Skin Cancer/Skin Aging Alert), and "Directions for Use" (Apply liberally 15 minutes before sun exposure).
- Bottom Center:** "Inactive Ingredients" list, including Water, Dimethicone, Isononyl Isononanoate, Glycerin, Steareth-21, Isostearic Acid, Octyldecyl Neopentanoate, Aluminum Starch Octenylsuccinate, Salvia Officinalis (Sage) Leaf Extract, Hydrolyzed Glycosaminoglycans, Sodium Hyaluronate, Sodium Lactate, Retinyl Linoleate, Tetrahexyldecyl Ascorbate, Tocopherol, Glyceryl Stearate, Propylene Glycol, Panthenol, C12-20 Acid Peg-8 Ester, Cetyl Alcohol, PEG-100 Stearate, Tri Laureth-4 Phosphate, Steareth-2 Acrylates Copolymer, Alkyl Acrylate Crosspolymer, Ethylene Glycol Copolymer, Sclerotium Gum, Triethanolamine, BHT, Disodium EDTA, Parfumerie Fragrance, Benzyl Salicylate, Butylphenyl Methylpropional, Citronellol, Hydroxyisohexyl Cyclohexene Carboxaldehyde, Limonene, Linalool, Dimethylsiloxane, Methylparaben, Phenoxyethanol, Propylparaben.
- Bottom Right:** "Drug Facts (continued)" section, including "Other Information" (Avoids product from excessive heat and direct sun) and "Questions or comments?" (Call toll free 1-800-526-7337).

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-0577
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3600 mg in 50 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1800 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
STEARETH-21 (UNII: 53J3F32P58)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	

PEG-100 STEARATE (UNII: YD01N1999R)
CETYL ALCOHOL (UNII: 936JST6JCN)
PANTHENOL (UNII: WV9CM0O67Z)
SODIUM LACTATE (UNII: TU7HW0W0QT)
STEARETH-2 (UNII: V56DFE46J5)
C12-20 ACID PEG-8 ESTER (UNII: 9M7A3K4339)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)
HYDROLYZED GLYCOSAMINOGLYCANS (BOVINE; 50000 MW) (UNII: 997385V0VV)
DMDM HYDANTOIN (UNII: BYR0546TOW)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
TOCOPHEROL (UNII: R0ZB2556P8)
RETINYL LINOLEATE (UNII: 61911N8D6W)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
BENZYL SALICYLATE (UNII: WAO5MKN9TU)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-0577-1	1 in 1 BOX		
1	NDC:67938-0577-2	50 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/24/2013	

Labeler - Elizabeth Arden, Inc (849222187)

Revised: 12/2013

Elizabeth Arden, Inc