

INTERVENE RADIANCE BOOSTING MOISTURE 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.

BC1044

DESCRIPTION

This multi-benefit moisturizer immediately boosts skin's appearance for a radiant, clear, natural looking glow. With continued use, naturally-derived Biodormin technology supports skin's natural cell metabolism rate to help fight the visible aging effects caused by stress. Helps minimize the look of fine lines and combat the appearance of new ones. Provides deep hydration so skin stays younger looking longer. Clinically, dermatologist and allergy tested.

INDICATIONS AND USAGE

To Use: Smooth on to cleansed face and throat daily before sun exposure.

WARNINGS

Warning: For external use only. Avoid contact with eyes. Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor. Keep out of reach of children.

OTC - ACTIVE INGREDIENT

Active Ingredients: Octinoxate 7.5% w/w, Avobenzone 3.0% w/w, Oxybenzone 3.0% w/w.

INACTIVE INGREDIENT

Other Ingredients: Water/Aqua/Eau, Ethylhexyl Methoxycinnamate, Glycerin, Butylene Glycol, Isononyl Isononanoate, Dimethicone, Cetearyl Glucoside, Benzophenone-3, Butyl Methoxydibenzoylmethane, Pentylene Glycol, Butyl Stearate, Tidecyl Salicylate, Cetyl Ricinoleate, Cyclopentasiloxane, Narcissus Tazetta Bulb Extract, Triolium Pratense (Clover) Flower Extract, Sodium Hyaluronate, Tocopherol, Tocopheryl Acetate, Caprylyl Glycol, Cetearyl Dimethicone Crosspolymer, Ethylhexyl Palmitate, Glyceryl Stearate, Sodium PCA, Trehalose, Urea, Hydrolyzed Soy Protein, Lecithin, Palmitoyl Tetrapeptide-7, Phospholipids, Polyphosphorylcholine Glycol Acrylate, Ammonium Acryloyldimethyltaurate/VP Copolymer, PEG-100 Stearate, PEG-8 Laurate, Steareth-20, PEG-60 Hydrogenated Castor Oil, Sodium Dodecylbenzenesulfonate, Polyquaternium-51, Styrene/Acrylates Copolymer, Hexylene Glycol, Isododecane, PEG-8, Zanthan Gum, Nylon-12, Disodium EDTA, Mica, Tin Oxide, Silica Dimethyl Silylate, Parfum/Fragrance, Butylphenyl Methylpropional, Citronellol, Limonene, Linalool, Benzoic Acid, Methylparaben, Phenoxyethanol, Potassium Sorbate, Propylparaben, Sorbic Acid, Chlorhexidine Digluconate, Chlorphenesin, Titanium Dioxide (CI 77891).

DOSAGE & ADMINISTRATION

Smooth on to face and throat.

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

OTC - PURPOSE

Provides SPF 15 sun protection.

OTC - WHEN USING

Avoid contact with eyes.

This multi-benefit moisturizer immediately boosts skin's appearance for a radiant, clear, natural looking glow. With continued use, naturally-derived Biotinmin™ technology supports skin's natural cell metabolism rate to help fight the visible aging effects caused by stress. Helps minimize the look of fine lines and combat the appearance of new ones. Provides deep hydration so skin stays younger looking longer.

To use: Smooth onto cleansed face and throat daily before sun exposure.

WARNING: For external use only. Avoid contact with eyes. Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor. Keep out of reach of children. Clinically, dermatologist and allergy tested.

ACTIVE INGREDIENTS: OCTINOXATE .5 % W/W
AVOBENZONE 3.0 % W/W, OXYBENZONE 3.0 % W/W

OTHER INGREDIENTS: WATER/AQUA/EAU, GLYCERIN, BUTYLENE GLYCOL, ISONONYL ISONONANOATE, DIMETHICONE, CETEARYL GLUCOSIDE, PENTYLENE GLYCOL, BUTYL STEARATE, DIMETHYL SILYLATE, CETEYL RICINOLEATE, CYCLOPENTASILOXANE, NIGELLSA SEED BULB EXTRACT, TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT, SODIUM HYALURONATE, TOCOPHERYL ACETATE, CAPRYLYL GLYCOL, CETEARYL DIMETHICONE CROSSPOLYMER, ETHYLHEXYL PALMITATE, GLYCERYL STEARATE, SODIUM PCA, TRIHAIKOSYL UREA, HYDROLYZED SOY PROTEIN, LECITHIN, PALMITOYL TETRAPEPTIDE-7, PHOSPHOLIPIDS, POLYPHOSPHORYLCHOLINE GLYCOL ACRYLATE, AMMONIUM ACRYLOYLDIMETHYL TAURATE/VP COPOLYMER, PEG-100 STEARATE, PEG-8 LAURATE, STEARETH-20, PEG-60 HYDROGENATED CASTOR OIL, SODIUM DODECYLBENZENE SULFONATE, POLYQUATERNIUM-51, STYRENE ACRYLATES COPOLYMER, HEXYLENE GLYCOL, ISODODICANE, PEG-8, XANTHAN GUM, NYLON-12, DISODIUM EDTA, SILICA DIMETHYL SILYLATE, PARFUM/FRAGRANCE, BUTYLPHENYL METHYLPROPIONAL, CITRONELLOL, LIMONENE, LINALOOL, BENZOIC ACID, METHYLPARABEN, PHENOXYETHANOL, POTASSIUM SORBATE, SORBIC ACID, CHLORHEXIDINE DIGLUCONATE, CHLORPHENESIN, MICA, TITANIUM DIOXIDE.

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Elizabeth Arden
INTERVENE

RADIANCE BOOSTING
MOISTURE CREAM SPF 15

NET WT. 1.7 OZ. 50 g

To use: Smooth onto
cleansed face and throat daily
before sun exposure.

**WARNING: FOR EXTERNAL
USE ONLY. AVOID CONTACT
WITH EYES. DISCONTINUE USE IF
SIGNS OF IRRITATION OR RASH
APPEAR. IF IRRITATION OR RASH
PERSISTS, CONSULT A DOCTOR. KEEP
OUT OF REACH OF CHILDREN.**

Active Ingredients:
OCTINOXATE .5 % W/W
AVOBENZONE 3.0 % W/W
OXYBENZONE 3.0 % W/W

NET WT. 1.7 OZ. 48 g

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New York, NY 10003
ElizabethArden.com
Made in U.S.A.
No. LIGN00001

INTERVENE RADIANCE BOOSTING MOISTURE SPF 15

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-1044
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.75 g in 50 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 g in 50 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1.5 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
BUTYL STEARATE (UNII: 6Y0AI5605C)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ISODODECANE (UNII: A8289P68Y2)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MICA (UNII: V8A1AW0880)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
UREA (UNII: 8W8T17847W)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POLYOXYL 60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)	
NARCISSUS TAZETTA BULB (UNII: K17762966S)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TREHALOSE (UNII: B8WCK70T7I)	
STEARETH-20 (UNII: L0Q8IK9E08)	
SORBIC ACID (UNII: X045WJ989B)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	

TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-1044-1	1 in 1 BOX		
1	NDC:67938-1044-2	50 g in 1 JAR		
2	NDC:67938-1044-3	1 in 1 BOX		
2	NDC:67938-1044-4	15 g in 1 TUBE		
3	NDC:67938-1044-5	1 in 1 BOX		
3	NDC:67938-1044-6	7 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/27/2009	

Labeler - Elizabeth Arden, Inc (849222187)

Revised: 1/2011

Elizabeth Arden, Inc