

**EIGHT HOUR CREAM INTENSIVE DAILY MOISTURIZER FOR FACE 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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**BB0866**

**DESCRIPTION**

This daily hydrating lotion leaves skin feeling soft, smooth, and moisturized for up to 8 hours. Protects skin from the effects of extreme weather and climate changes while SPF 15 shields from the harmful effects of the sun.

**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 6.0% W/W, Oxybenzone 3.0% W/W, Avobenzone 2.0% W/W.

**INACTIVE INGREDIENT**

Other Ingredients: Water/Aqua/Eau, Cyclopentasiloxane, Glycerin, Dimethicone, Butyloctyl Salicylate, Steareth-2, Methylheptyl Isostearate, Butyrospermum Parkii (Shea Butter), Petrolatum, Cetearyl Glucoside, Aluminum Starch Octenylsuccinate, Butylene Glycol, Aloe Barbadensis Leaf Juice, Sodium Hyaluronate, Tocopheryl Acetate, Sodium PCA, Trehalose, Urea, Allantoin, C10-30 Cholesterol/Lanosterol Esters, Panthenol, Phospholipids, Stearyl Alcohol, PEG/PPG-20/15 Dimethicone, Seareth-21, Polyquaternium-51, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polyethylene, Triethanolamine, Disodium EDTA, Dimethicone Crosspolymer Phenyl Methicone, Parfum/Fragrance, Citral, Citronellol, Geraniol, Limonene, Linalool, Benzoic Acid, Methyparaben, Phenoxyethanol, Chlorphenesin.

**DOSAGE & ADMINISTRATION**

Smooth on to face.

**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.

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ACTIVE INGREDIENTS:  
OCTINOXATE 6.0% W/W,  
OXYBENZONE 3.0% W/W,  
AVOBENZONE 2.0% W/W

OTHER INGREDIENTS: WATER/AQUA/EAU, CYCLOPENTASILOXANE, GLYCERIN, DIMETHICONE, BUTYLOCTYL SALICYLATE, STEARETH-2, METHYLHEPTYL ISOSTEARATE, BUTYROSPERMUM PARKII (SHEA BUTTER), PETROLATUM, CETEARYL GLUCOSIDE, ALUMINUM STARCH OCTENYLSUCCINATE, BUTYLENE GLYCOL, ALOE BARBADENSIS LEAF JUICE, SODIUM HYALURONATE, TOCOPHERYL ACETATE, SODIUM PCA, TREHALOSE, UREA, ALLANTOIN, C10-30 CHOLESTEROL/LANOSTEROL ESTERS, PANTHENOL, PHOSPHOLIPIDS, STEARYL ALCOHOL, PEG/PPG-20/15 DIMETHICONE, STEARETH-21, POLYQUATERNIUM-51, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, POLYETHYLENE, TRIETHANOLAMINE, DISODIUM EDTA, DIMETHICONE CROSSPOLYMER, PHENYL METHICONE, PARFUM/FRAGRANCE, CITRAL, CITRONELLOL, GERANIOL, LIMONENE, LINALOOL, BENZOIC ACID, METHYLPARABEN, PHENOXYETHANOL, PROPYLPARABEN, CHLORPHENESIN.

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Made in U.S.A.



## Elizabeth Arden



### **Eight Hour Cream**

**Intensive Daily Moisturizer  
for Face SPF 15  
Sunscreen PA++**

**NET WT. 1.7 OZ. 49 g**

Elizabeth Arden



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NET WT. 1.7 OZ. 49 g

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No. EIGN00017



**Eight Hour Cream**  
Intensive Daily Moisturizer  
for Face SPF 15  
Sunscreen PA++

7mm

## EIGHT HOUR CREAM INTENSIVE DAILY MOISTURIZER FOR FACE SPF 15

octinoxate cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-0866
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.94 g in 49 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1.47 g in 49 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.98 g in 49 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
STEARETH-2 (UNII: V56DFE46J5)	
SHEA BUTTER (UNII: K49155WL9Y)	

<b>PETROLATUM</b> (UNII: 4T6H12BN9U)
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ0O6294)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>TREHALOSE</b> (UNII: B8WCK70T7I)
<b>UREA</b> (UNII: 8W8T17847W)
<b>ALLANTOIN</b> (UNII: 344S277G0Z)
<b>C10-30 CHOLESTEROL/LANOSTEROL ESTERS</b> (UNII: 137SL7IL0Y)
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4HIY)
<b>STEARETH-21</b> (UNII: 53J3F32P58)
<b>CITRAL</b> (UNII: T7EU0O9VPP)
<b>GERANIOL</b> (UNII: L837108USY)
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-0866-1	1 in 1 BOX		
1	NDC:67938-0866-2	49 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/06/2008	

**Labeler** - Elizabeth Arden, Inc (849222187)

Revised: 7/2011

Elizabeth Arden, Inc