

**PREVAGE ANTI AGING EYE SUNSCREEN SPF 15- octinoxate and oxybenzone 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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**BC1126**

**DESCRIPTION**

PREVAGE Anti-aging Skincare helps protect and correct skin's appearance from environmental threats, a leading cause of visible aging signs, for younger-looking, more beautiful skin. This multi-defense cream specially designed for the delicate eye area with advanced Idebenone technology provides serious environmental protection, all day intensive moisture and encapsulated sunscreens. Helps smooth the appearance of fine lines, crow's feet and crepiness and helps prevent future aging signs. Eyes instantly appear smoother and brighter. Ophthalmologist tested.

**INDICATIONS AND USAGE**

To Use: Gently pat a small amount around eye area after PREVAGE Anti-aging Daily Serum.

Directions For Sunscreen Use: Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours. Children under 6 months: Ask a doctor.

**WARNINGS**

Warnings

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 only to prevent sunburn, not skin cancer or early skin aging.

For external use only.

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

**OTC - ACTIVE INGREDIENT**

Active Ingredients: Octinoxate, 4.09%, Oxybenzone, 1.40%.

**INACTIVE INGREDIENT**

Other Ingredients: Water/Aqua/Eau, Butyrospermum Parkii (Shea Butter), Phytosteryl Macadamiate, Glycerin, Butylene Glycol, Dimethicone, Cetearyl Glucoside, Synthetic Beeswax, Theobroma Cacao (Cocoa) Seed Butter, C12-15 Alkyl Benzoate, Stearyl Dimethicone, Dipentaerythrityl Hexacaprylate/Hexacaprate, Tridecyl Trimellitate, Copernicia Cerifera (Carnauba) Wax/Cera Carnauba/Cire De Carnauba, Peg-100 Stearate, Hydroxydecyl Ubiquinoyl Dipalmitoyl Glycerate, Beeswax/Cera Alba/Cire D'Abeille, Rabdosia Rubescens Extract, Sigesbeckia Orientalis Extract, Sodium Hyaluronate, Caprylic/Capric Triglyceride, Caprylyl Methicone, BIS-PEG-12 Dimethicone, Caprylyl Glycol, Glyceryl Stearate, Neopentyl Glycol Dicaprylate/Dicaprate, Tridecyl Stearate, Propylene Glycol, Sodium PCA, Trehalose, Urea, Ethylhexylglycerin, Hydrogenated Lecithin, Lecithin, Polyphosphorylcholine Glycol Acrylate, Glycerophosphoinositol Lysine, Acetyl

Tetrapeptide-5, Cetearyl Alcohol, PEG-20, Sorbitan Tristearate, Steareth-100, Polyquaternium-51, Sodium Acrylates Copolymer, Hexylene Glycol, Carbomer, PVP, VP/Eicosene Copolymer, Xanthan Gum, Sodium Hydroxide, Disodium EDTA, Mica, Silica, Sodium Citrate, Dimethicone Crosspolymer, Benzoic Acid, Diazolidinyl Urea, Methyparaben, Phenoxyethanol, Potassium Sorbate, Propylparaben, Sorbic Acid, Triacetin, Cetrimonium Chloride, Chlorphenesis, Iron Oxides (CI 77492), Red 40 (CI 16035), Titanium Dioxide (CI 77891).

## DOSAGE & ADMINISTRATION

Pat around eye area.

## OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

## OTC - PURPOSE

Provides SPF 15 Sun Protection.

## OTC - WHEN USING

Keep out of eyes.

<p><b>Drug Facts</b></p> <p><b>Active Ingredients</b></p> <p>OCTINOXATE 4.09%          DIBENZONE 1.40%</p> <p><b>Purpose</b></p> <p>Sunscreen          Sunscreen</p> <p><b>Uses</b></p> <p>Helps prevent sunburn</p> <p><b>Warnings</b></p> <p><b>Skin Cancer/Skin Aging Alert:</b> Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.</p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions For Sunscreen Use:</b></p> <p>Apply liberally 15 minutes before sun exposure</p> <p>Reapply</p> <ul style="list-style-type: none"> <li>at least every 2 hours</li> <li>Children under 6 months: Ask a doctor.</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Inactive Ingredients</b></p> <p>WATER/AQUAEAU, BUTYROSPERMUM PARKII (SHEA BUTTER), PHYTOSTERYL MACADAMATE, GLYCERIN, BUTYLENE GLYCOL, DIMETHICONE, CETEARYL GLUCOSIDE, SYNTHETIC BEESWAX, THEOBROMA CACAO (COCOA) SEED BUTTER, C12-15 ALKYL BENZOATE, STEARYL DIMETHICONE, DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE, TRIDECYL TRIMELLITATE, COPERNICIA CERIFERA (CARNAUBA) WAX/CERA CARNAUBACIRE DE CARNAUBA, PEG-100 STEARATE, HYDROXYDECYLUBQUINOLYL DIPALMITOYL GLYCERATE, BEESWAX/CERA ALBACIRE D'ABELLE, RABDOSIA RUBESCENS EXTRACT, SIGESBECKIA ORIENTALIS EXTRACT, SODIUM HYALURONATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, CAPRYLYL METHICONE, BIS-PEG-12 DIMETHICONE, CAPRYLYL GLYCOL, GLYCERYL STEARATE, NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE, TRIDECYL STEARATE, PROPYLENE GLYCOL, SODIUM PCA, TREHALOSE UREA, ETHYLHEXYLGLYCERIN, HYDROGENATED LECITHIN, LECITHIN, POLYPHOSPHORYLCHOLINE GLYCOL ACRYLATE, GLYCEROPHOSPHODIBIS(OL)YSINE ACETYL, TETRAPEPTIDE-5, CETEARYL ALCOHOL, PEG-20, SORBITAN TRISTEARATE, STEARETH-100, POLYQUATERNIUM-51, SODIUM ACRYLATES COPOLYMER.</p>	<p><b>PREVAGE®</b> Anti-aging. Delicate helps protect and correct skin's appearance from environmental threats. A soothing array of visible aging signs, for younger looking, more beautiful skin.</p> <p>This multi defense cream specially designed for the delicate eye area with advanced defense technology provides serious environmental protection, all day intensive moisture and encapsulated sunscreens. Helps smooth the appearance of fine lines, crows feet and creases and helps prevent future aging signs. Even instantly appear smoother and brighter. Sunscreen/SPF 15.</p> <p>To use: Gently pat a small amount around eye area after PREVAGE® Anti-aging Daily Serum. Replace seal after use. See insert or <a href="http://elizabetharden.com">elizabetharden.com</a> for complete directions prior to first usage.</p> <p><b>prevage®</b></p> <p>anti-aging eye cream          sunscreen SPF 15</p> <p><b>Elizabeth Arden</b>          NEW YORK</p>
<p><b>Drug Facts (continued)</b></p> <p>HEXYLENE GLYCOL, CARBOMER, PVP, VP/EICOSENE COPOLYMER, XANTHAN GUM, SODIUM HYDROXIDE, DISODIUM EDTA, MICA, SILICA, SODIUM CITRATE, DIMETHICONE CROSSPOLYMER, BENZOIC ACID, DIAZOLIDINYL UREA, METHYLPARABEN, PHENOXYETHANOL, POTASSIUM SORBATE, PROPYLPARABEN, SORBIC ACID, TRIACETIN, CETRIMONIUM CHLORIDE, CHLORPHENESIN, IRON OXIDES (CI 77492), RED 40 (CI 16035), TITANIUM DIOXIDE (CI 77891).</p> <p><b>Other Information</b></p> <p>Protect this product from excessive heat and direct sun</p> <p><b>Questions or comments?</b></p> <p>Call toll free 1-800-326-7337</p>	<p>No. PRV00103</p>	<p>© 2008 Elizabeth Arden, Inc., Div., New York, NY 10020  <a href="http://elizabetharden.com">elizabetharden.com</a>          Made in U.S.A.          U.S. Patent 4,736,045 and other pending/issued U.S. and international patents.</p>

# prevage®

anti-aging eye cream  
sunscreen SPF 15

Elizabeth Arden

**To use:** Gently pat a small amount around eye area. Replace seal after each use. **See insert or elizabetharden.com for complete directions prior to first usage.**

ACTIVE INGREDIENTS:

OCTINOXATE 4.09 % W/W, OXYBENZONE 1.40 % W/W

**USES:** Helps prevent sunburn.

**WARNINGS: 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 ONLY TO

PREVENT SUNBURN,  
**NOT SKIN CANCER OR EARLY SKIN AGING. FOR EXTERNAL USE ONLY. DO NOT USE ON DAMAGED OR BROKEN SKIN. WHEN USING THIS PRODUCT KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE. STOP USE AND ASK A DOCTOR IF RASH OCCURS. KEEP OUT OF REACH OF CHILDREN. IF PRODUCT IS SWALLOWED, GET MEDICAL HELP OR**

**CONTACT A POISON CONTROL CENTER RIGHT AWAY. Directions for Sunscreen use:** apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours. Children under 6 months: Ask a doctor. **Other information:** protect this product from excessive heat and direct sun. **Questions or comments?** Call toll free 1-800-326-7337

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Made in U.S.A. No. PRV100103  
U.S. Patent 6,756,045 and other pending/issued U.S. and international patents.

## PREVAGE ANTI AGING EYE SUNSCREEN SPF 15

octinoxate and oxybenzone cream

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67938-1126

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.613 g in 15 g
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.21 g in 15 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)	
<b>DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE</b> (UNII: 554N82UWVW)	
<b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	
<b>TRIDECYL STEARATE</b> (UNII: A8OE252M6L)	
<b>UREA</b> (UNII: 8W8T17847W)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>POLYETHYLENE GLYCOL 1000</b> (UNII: U076Q6Q621)	
<b>SORBITAN TRISTEARATE</b> (UNII: 6LUM696811)	
<b>STEARETH-100</b> (UNII: 4OH5W9UM87)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128MIS)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>TREHALOSE</b> (UNII: B8WCK70T7I)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	

CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-1126-1	1 in 1 BOX		
1	NDC:67938-1126-2	15 g in 1 JAR		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/14/2011	

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

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Elizabeth Arden, Inc