

**PREVAGE ANTI AGING TRIPLE DEFENSE SHIELD BROAD SPECTRUM SUNSCREEN  
SPF 50- octinoxate, oxybenzone, octisalate, octocrylene, and avobenzone 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.*

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**BB0990**

**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 daily defense shield for face with advanced Idebenone technology delivers triple environmental protection against the visible effects of free radical damage due to oxidative stress from sun, pollution and Infrared-A exposure. Provides broad spectrum sun protection from UVA and UVB rays. Helps to correct the appearance of existing sun damage like fine lines, wrinkles, age spots and discolorations and helps prevent future aging signs. Leaves a soft, matte finish and works well under makeup.

**INDICATIONS AND USAGE**

To Use: Turn brush head to "On" and squeeze gently to dispense product. Brush lightly across face. Turn brush head to "Off" to store. To clean, rinse brush with warm water and towel dry.

Directions For Sunscreen Use: Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: Limit time in the sun, especially from 10 a.m. – 2 p.m. Wear long-sleeve shirts, pants, hats, and sunglasses

**WARNINGS**

Warnings:

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 7.5%, Oxybenzone 6.0%, Octisalate 5.0%, Octocrylene 4.0%, Avobenzone 3.0%

**INACTIVE INGREDIENT**

Inactive Ingredients: Water/Aqua/Eau, Ethylhexyl Methoxycrylene, Nylon-12, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Butylene Glycol, Dimethicone, Propylene Glycol, Methyl Methacrylate Crosspolymer, Caprylic/Capric Triglyceride, Caprylyl Methicone, Isopropyl Isostearate, Ergothioneine, Hydroxydecyl Ubiquinoyl Dipalmitoyl Glycerate, Yeast Extract/Faex/Extrait de Levure,

Tocopheryl Acetate, Soy Amino Acids, Isohexadecane, PEG-40 Hydrogenated Castor Oil, BIS-Vinyl Dimethicone/Dimethicone Copolymer, Hydrolyzed Soy Protein, C20-22 Alcohols, C20-22 Alkyl Phosphate, Cetearyl Alcohol, Coco-Glucoside, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polysorbate 60, Isododecane EDTA, Triethanolamine, BHT, Disodium EDTA, Parfum/Fragrance, Alpha-Isomethyl Ionone, Linalool, Ethylparaben, Methylparaben, Phenoxyethanol, Potassium Sorbate, Propylparaben, Sodium Benzoate, Red 4 (CI 14700), Yellow 5 (CI 19140).

## **DOSAGE AND ADMINISTRATION**

Apply to skin.

## **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 50 Sun Protection.

## **OTC - WHEN USING**

Keep out of eyes.

## **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

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 daily defense shield for face with advanced (de)benzene technology delivers triple environmental protection against the visible effects of free radical damage due to oxidative stress from sun, pollution and infrared-A exposure. Provides broad spectrum sun protection from UVA and UVB rays. Helps to correct the appearance of existing sun damage like fine lines, wrinkles, age spots and discolorations and helps prevent future aging signs. Leaves a soft, matte finish and works well under makeup.

To use: Turn brush head to "On" and squeeze gently to dispense product. Brush lightly across face. Turn brush head to "Off" to store. To clean, rinse brush with warm water and towel dry. See insert or [elizabetharden.com](http://elizabetharden.com) for complete directions prior to first use.

## Drug Facts

Active Ingredients	Purpose
OCTINOXATE 7.5%	Sunscreen
OXYBENZONE 6.0%	Sunscreen
OCTISALATE 5.0%	Sunscreen
OCTOCRYLENE 4.0%	Sunscreen
AVOBENZONE 3.0%	Sunscreen

### Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

### Warnings

- 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
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
  - Limit time in the sun, especially from 10 a.m. – 2 p.m.
  - Wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor.

### Inactive Ingredients

WATER/AQUA/EAU, ETHYLHEXYL METHOXYCRYLENE, NYLON-12, BUTYLOCTYL SALICYLATE, C12-15 ALKYL BENZOATE, BUTYLENE GLYCOL, DIMETHICONE, PROPYLENE GLYCOL, METHYL METHACRYLATE COPOLYMER, CAPRYLIC/CAPRIC TRIGLYCERIDE, CAPRYLYL METHICONE, ISOPROPYL ISOSTEARATE, ERGOTHIONEINE, HYDROXYDECYL UBQUINOYL DIPALMITYL GLYCERATE, YEAST EXTRACT/FAEX/EXTRAIT DE LEVURE, TOCOPHERYL ACETATE, SOY AMINO ACIDS, ISOHXADECANE, PEG-40 HYDROGENATED CASTOR OIL, BIS-VINYL DIMETHICONE/DIMETHICONE COPOLYMER, HYDROLYZED SOY PROTEIN, C20-22 ALCOHOLS, C20-22 ALKYL PHOSPHATE, CETEARYLALCOHOL, COCO-GLUCOSIDE, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, POLYSORBATE 60, ISODODECANE, EDTA, TRIETHANOLAMINE, BHT, DISODIUM EDTA, PARFUM/FRAGRANCE, ALPHA-ISOMETHYL IONONE, LINALOOL, ETHYLPARABEN, METHYLPARABEN, PHENOXYETHANOL, POTASSIUM SORBATE, PROPYLPARABEN, SODIUM BENZOATE, RED 4 (CI 14700), YELLOW 5 (CI 19140).

### Other Information

- Protect this product from excessive heat and direct sun

### Questions or comments?

- Call toll free 1-800-326-7337

# prevage®

anti-aging triple defense  
shield broad spectrum  
sunscreen SPF 50



Elizabeth Arden

NEW YORK

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**TO USE:** Turn brush head to "On" and squeeze gently to dispense product. Brush lightly across face. Turn brush head to "Off" to store. To clean, rinse brush with warm water. **See insert or [elizabetharden.com](http://elizabetharden.com) for complete directions prior to first use.**

**ACTIVE INGREDIENTS:**

OCTINOXATE 7.5 % W/W, OXYBENZONE 6.0 % W/W,  
OCTISALATE 5.0 % W/W, OCTOCRYLENE 4.0 % W/W,  
AVOBENZONE 3.0 % W/W

**USES:** Helps prevent sunburn. If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

**WARNING: 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. **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m. – 2 p.m., wear long-sleeve shirts, pants, hats, and sunglasses. 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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[elizabetharden.com](http://elizabetharden.com)

Made in U.S.A. No. PRVN00104

U.S. Patent 6,756,045 and other pending/issued

U.S. and international patents.



## PREVAGE ANTI AGING TRIPLE DEFENSE SHIELD BROAD SPECTRUM SUNSCREEN SPF 50

octinoxate, oxybenzone, octisalate, octocrylene, and avobenzone lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67938-0990
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 50 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 50 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 50 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	40 mg in 50 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 50 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>NYLON-12</b> (UNII: 446U8J075B)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>ISOPROPYL ISOSTEARATE</b> (UNII: C67IXB9Y7T)	
<b>ERGOTHIONEINE</b> (UNII: BDZ3DQM98W)	
<b>YEAST</b> (UNII: 3NY3SM6B8U)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
<b>C20-22 ALCOHOLS</b> (UNII: O4M0347C6A)	
<b>C20-22 ALKYL PHOSPHATE</b> (UNII: L4VKP0Y7RP)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>EDETIC ACID</b> (UNII: 9G34HU7RV0)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ISOMETHYL-.ALPHA.-IONONE</b> (UNII: 9XP4LC555B)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-0990-1	1 in 1 BOX		
1	NDC:67938-0990-2	50 mL in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/14/2011	

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

Revised: 5/2013

Elizabeth Arden, Inc