

PREVAGE ANTI AGING MOISTURE BROAD SPECTRUM SUNSCREEN SPF 30- octinoxate, octisalate, oxybenzone, 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.

BB0904

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 high performance multi-defense moisturizer with advanced Idebenone technology, a powerful environmental protectant, and broad spectrum UVA/UVB sunscreens, helps protect against the visible signs of aging as it minimizes the appearance of existing sun damage – fine lines, wrinkles and discolorations. Locks in moisture to enhance the benefits of PREVAGE Anti-aging Daily Serum.

INDICATIONS AND USAGE

To Use: Massage onto cleansed face and neck daily after PREVAGE Anti-aging Daily Serum.

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.

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, 7.50% , Octisalate, 5.00%, Oxybenzone, 5.00%, Octocrylene, 2.20%, Avobenzone, 2.00%.

INACTIVE INGREDIENT

Other Ingredients: Water/Aqua/Eau, Glycerin, Dimethicone, Cetearyl Alcohol, C12-15 Alkyl Benzoate, Propylene Glycol, PEG-40 Hydrogenated Castor Oil, Potassium Cetyl Phosphate, Glyceryl Polyacrylate, Glyceryl Stearate, Butyrospermum Parkii (Shea Butter), Ergothioneine, Hydroxydecyl Ubiquinoyl Dipalmitoyl Glycerate, Sodium Hyaluronate, Hydrogenated Palm Glycerides, Sodium PCA, Trehalose, Urea, Polyquaternium-51, Carbomer, Sodium Hydroxide, Mica, Cyclohexasiloxane, Cyclopentasiloxane, Parfum/Fragrance, Alpha-Isomethyl Ionone, Linalool, Benzoic Acid, Methylparaben, Phenoxyethanol, Chlorphenesin, Iron Oxides (CI 77492), Red 4 (CI 14700), Titanium Dioxide (CI 77891), Yellow 5 (CI 19140).

DOSAGE & ADMINISTRATION

Massage on to face and neck.

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 30 Sun Protection.

OTC - WHEN USING

Keep out of eyes.

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 high performance multi-defense moisturizer with advanced Iobanone technology, a powerful environmental protectant, and broad spectrum UVA/UVB sunscreens, helps protect against the visible signs of aging as it minimizes the appearance of existing sun damage – fine lines, wrinkles and discolorations. Locks in moisture to enhance the benefits of PREVAGE® Anti-aging Daily Serum.

To use: Massage onto cleansed face and neck daily after PREVAGE® Anti-aging Daily Serum. See insert or elizabetharden.com for complete directions prior to first use.

Drug Facts

Active Ingredients	Purpose
OCTINOXATE 7.5%	Sunscreen
OCTISALATE 5.0%	Sunscreen
OXYBENZONE 5.0%	Sunscreen
OCTOCRYLENE 2.2%	Sunscreen
AVOBENZONE 2.0%	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, GLYCERIN, DIMETHICONE, CETEARYLALCOHOL, C12-15 ALKYL BENZOATE, PROPYLENE GLYCOL, PEG-40 HYDROGENATED CASTOR OIL, POTASSIUM CETYL PHOSPHATE, GLYCERYL POLYACRYLATE, GLYCERYL STEARATE, BUTYROSPERMUM PARKII (SHEA BUTTER), ERGOTHIONEINE, HYDROXYDECYL UBIQUINOL DIPALMITOYL GLYCERATE, SODIUM HYALURONATE, HYDROGENATED PALM GLYCERIDES, SODIUM PCA, TREHALOSE, UREA, POLYQUATERNIUM-51, CARBOMER, SODIUM HYDROXIDE, MICA, CYCLOHEXASILOXANE, CYCLOPENTASILOXANE, PARFUM/FRAGRANCE, ALPHA-ISOMETHYL IONONE, LINALDOL, BENZOIC ACID, METHYLPARABEN, PHENOXYETHANOL, CHLORPHENESIN, IRON OXIDES (CI 77492), RED 4 (CI 14700), TITANIUM DIOXIDE (CI 77891), 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 moisture lotion
broad spectrum
sunscreen SPF 30



Elizabeth Arden
NEW YORK



© Elizabeth Arden, Inc., Div., New York, NY 10022
elizabetharden.com
Made in U.S.A. No. PRW00702
U.S. Patent 6,756,045 and other pending/issued
U.S. and international patents.

PREVAGE®

anti-aging moisture
lotion broad spectrum
sunscreen SPF 30

Elizabeth Arden

To use: Massage onto cleansed face and neck daily after PREVAGE® Face Advanced Anti-aging Daily Serum. **See or elizabetharden.com for complete directions prior to first use.**

ACTIVE INGREDIENTS:

OCTINOXATE 7.50% W/W
OCTISALATE 5.00% W/W
OXYBENZONE 5.00% W/W
OCTOCRYLENE 2.20% W/W
AVOBENZONE 2.00% 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.

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.

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. PRVN00102

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

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octinoxate, octisalate, oxybenzone, octocrylene, and avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-0904
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	35 mg in 50 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	25 mg in 50 mL

OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	25 mg in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	11 mg in 50 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	10 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
MICA (UNII: V8A1AW0880)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
UREA (UNII: 8W8T17847W)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TREHALOSE (UNII: B8WCK70T7I)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-0904-1	1 in 1 BOX		
1	NDC:67938-0904-2	50 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/04/2009	

Labeler - Elizabeth Arden, Inc (849222187)