

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

BC1144

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, concentrated moisturizing cream for dry to very dry skin helps nourish skin's natural moisture defenses and reverse dryness. Diminishes the appearance of aging signs and existing sun damage – fine lines, wrinkles and discolorations. Advanced Idebenone technology provides powerful environmental protection while broad spectrum UVA/UVB sunscreens help shield from the sun. Skin feels ultra soft and smooth, looks healthy, radiant - younger than ever.

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

Inactive Ingredients: Water/Aqua/Eau, Dimethicone, C12-15 Alkyl Benzoate, Butylene Glycol, Cyclopentasiloxane, Isostearyl Neopentanoate, Dimethicone/Vinyl Dimethicone Crosspolymer, Butyrospermum Parii (Shea Butter) Extract, Theobroma Cacao (Cocoa) Seed Butter, Propylene Glycol, PPG-2 Isoceteth-20 Acetate, Glycerin, Caprylic/Capric Triglyceride, Ergothioneine, Hydroxydecyl

Ubiquinoyl Dipalmitoyl Glycerate, Hibiscus Abelmoschus Seed Extract, Sodium Hyaluronate, Retinyl Linoleate, Cetearyl Dimethicone Crosspolymer, Isohexadecane, Sodium PCA, Trehalose, Urea, Hydrogenated Lecithin, Phospholipids, Polyphosphorylcholine Glycol Acrylate, Sucrose, Cetearyl Alcohol, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polysorbate 60, Trideceth-6, Acrylamide/Sodium Acrylate Copolymer, Polyquaternium-51, PEG-8, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Xanthan Gum, Sodium Hydroxide, BHT, Mica, Mineral Oil/Paraffinum Liquidum/Huile Minerale, Dimethiconol, Phenyl Trimethicone, Parfum/Fragrance, Alpha-Isomethyl Ionone, Linalool, Benzoic Acid, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Propylparaben, Chlorphenesin, Iron Oxides (CI 77492), Red 4 (CI 14700), Titanium Dioxide (CI 77891), Yellow 5 (CI 19140).

DOSAGE AND ADMINISTRATION

Massage onto 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.

Drug Facts	
Active Ingredients	Purpose
OCTYLATE 7.1%	Sunscreen
OCTYLATE 5.0%	Sunscreen
OXYBENZONE 5.0%	Sunscreen
OCTOXYLENE 2.2%	Sunscreen
AVOBENZONE 3.1%	Sunscreen
Uses	
<ul style="list-style-type: none"> Helps prevent sunburn 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	
<ul style="list-style-type: none"> 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:	
<ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure Reapply At least every 2 hours 	

Drug Facts (continued)	
<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Limit time in the sun, especially from 10 a.m. – 2 p.m. Wear long-sleeve shirts, pants, hats, and sunglasses Shade your eyes Children under 6 months: Ask a doctor 	
Inactive Ingredients	
WATER/EAU, DIMETHICONE, C12-18 ALKYL BENZOATE, BUTYLENE GLYCOL, CYCLOPENTASILOXANE, ISOSTEARYL NEOPENTANOATE, DIMETHICONE/VINYL DIMETHICONE COPOLYMER, BUTYROSPERMUM PARKII (SHEA BUTTER) EXTRACT, THEOBROMA CACAO (COCOA) SEED BUTTER, PROPYLENE GLYCOL, PPG-2, ISOCETETH-20 ACETATE, GLYCERIN, CARNYLOLIPIC ACID, ERGOTHIONEINE, HYDROXYDECYL UBQUINOLYLDIPALMITOYL GLYCERATE, HIBISCUS ABELMOSCHUS SEED EXTRACT, SODIUM HYALURONATE, RETINYL LINOLEATE, CETEARYL DIMETHICONE CROSSPOLYMER, ISOHXADECANE, SODIUM PCA, TREHALOSE, UREA, HYDROGENATED LECITHIN	

prevage[®]

anti-aging moisture cream
broad spectrum
sunscreen SPF 30

Elizabeth Arden
NEW YORK

Drug Facts (continued)	
PHOSPHOLIPID, POLYPHOSPHORYLCHOLINE GLYCOL ACRYLATE, SUCROSE, CETEARYL ALCOHOL, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, POLYSORBATE 60, TRIDECETH-6, ACRYLAMIDE/SODIUM ACRYLATE COPOLYMER, POLYQUATERNIUM-51, PEG-8, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, XANTHAN GUM, SODIUM HYDROXIDE, BHT, MICA, MINERAL OIL/PARAFFINUM LIQUIDUM/HUILE MINERALE, DIMETHICONOL, PHENYL TRIMETHICONE, PARFUM/FRAGRANCE, ALPHA-ISOMETHYL IONONE, LINALOOL, BENZOIC ACID, BUTYLPARABEN, ETHYLPARABEN, ISOBUTYLPARABEN, METHYLPARABEN, PHENOXYETHANOL, PROPYLPARABEN, CHLORPHENESIN, IRON OXIDES (CI 77492), RED 4 (CI 14700), TITANIUM DIOXIDE (CI 77891), YELLOW 5 (CI 19140)	
Other Information	
<ul style="list-style-type: none"> Protect this product from excessive heat and direct sun 	
Questions or comments?	
<ul style="list-style-type: none"> Call toll free 1-800-325-7337 	

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 elizabetharden.com
 Made in U.S.A. No. 7690001
 U.S. Patent 8,758,000 and other patents pending
 U.S. and elsewhere patents



prevage[®]

anti-aging moisture cream
broad spectrum sunscreen SPF 30

Elizabeth Arden

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

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

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

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 ©Elizabeth Arden, Inc.
 New York, NY 10003

Made in U.S.A.

No. PRVN00101

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 cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-9144
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.75 g in 50 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2.5 g in 50 g
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	2.5 g in 50 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	1.1 g in 50 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PPG-2 ISO CETETH-20 ACETATE (UNII: B16C7YO419)	
GLYCERIN (UNII: PDC6A3C0OX)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
TREHALOSE (UNII: B8WCK70T7I)	
SUCROSE (UNII: C151H8M554)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MICA (UNII: V8A1AW0880)	
MINERAL OIL (UNII: T5L8T28FGP)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLPARABEN (UNII: 3QPIU3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-9144-1	1 in 1 BOX		
1	NDC:67938-9144-2	50 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/22/2011	

