

**CERAMIDE PREMIER INTENSE MOISTURE AND RENEWAL ACTIVATION BROAD SPECTRUM 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.

BC1145

DESCRIPTION

This rich, replenishing moisture cream with skin identical Ceramide Triple Complex hydrates deeply to restore skin's natural protective barrier and ease the look of fine lines and wrinkles. Nutrient rich sea minerals including calcium help support skin's natural processes to fortify thin, fragile looking skin. Our patented retinyl complex is clinically proven to optimize surface cell turnover to improve the appearance of age spots, discolorations and overall radiance.

DOSAGE AND ADMINISTRATION

To Use: Apply to cleansed face and throat.

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.

OTC - ACTIVE INGREDIENT

Active Ingredients: Octinoxate 7.5%, Octisalate 5.0%, Oxybenzone 4.0%, Octocrylene 3.0%, Avobenzone 2.0%.

INACTIVE INGREDIENT

Inactive Ingredients: Water/Aqua/Eau, Dimethicone, Glycerin, Hydrogenated Polyisobutene, Petrolatum, Glyceryl Stearate, Butylene Glycol, Butylolctyl Salicylate, Caprylic/Capric Triglyceride, Cetearyl Alcohol, PEG-100 Stearate, Butyrospermum Parkii (Shea Butter), Hydrogenated Lecithin, Dimethylcapramide, Ceramide 1, Ceramide 3, Ceramide 6 II, Fucus Serratus Extract, Yeast Extract/Faex/Extrait de Levure, Retinyl Lonoleate, Tocopheryl Acetate, Cetearyl Dimethicone Crosspolymer, PEG-40 Hydrogenated Castor Oil, Soy Amino Acids, 3-Aminopropane Sulfonic Acid, Calcium Hydroxymethionine, Hydrolyzed Soy Protein, Methyl Methacrylate Crosspolymer, Phytosphingosine, Ammonium Acryloyldimethyltaurate/VP Copolymer, Cholesterol, Sodium Lauroyl Lactylate, PEG-8 Laurate, Polysorbate 20, Sodium Dodecylbenzenesulfonate, Styrene/Acrylates Copolymer, Behenyl Alcohol, Pentylene Glycol, Carbomer, Hydroxyethylcellulose, Polyethylene, Xanthan Gum, EDTA, Sodium Hydroxide, BHT, Disodium EDTA, Mica, Tin Oxide, Aminopropyl Dimethicone, Fragrance/Parfum, Alpha-Isomethyl Ionone, Butylpheyyl Methylpropional, Citronellol, Hydroxycitronellal, Ethylparaben, Methylparaben, Phenoxyethanol, Potassium Sorbate, Propylparaben, Sodium Benzoate, Titanium Dioxide (CI 77891).

INDICATIONS AND USAGE

Apply to face and throat.

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.

WARNINGS

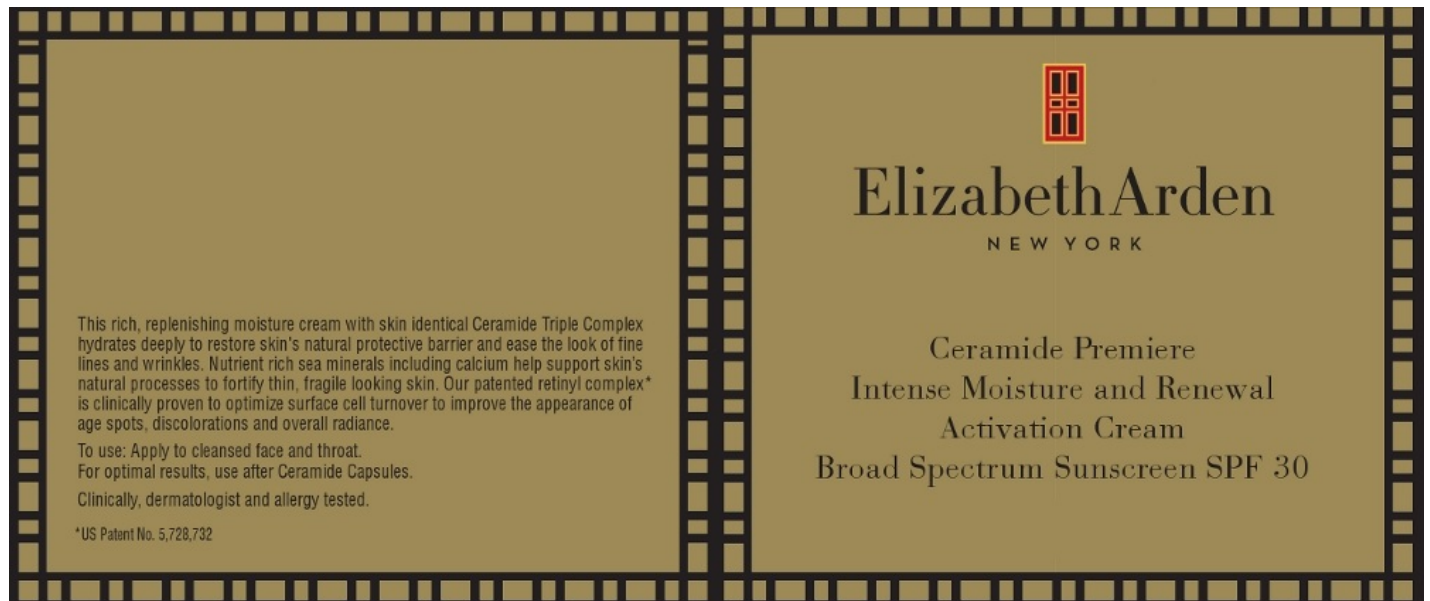
Warnings:

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.



Drug Facts (continued)

CROSSPOLYMER, PHYTOSPHINGOSINE, AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, CHOLESTEROL, SODIUM LAUROYL LACTYLATE, PEG-8 LAURATE, POLYSORBATE 20, SODIUM DODECYLBENZENESULFONATE, STYRENE/ACRYLATES COPOLYMER, BEHENYL ALCOHOL, PENTYLENE GLYCOL, CARBOMER, HYDROXYETHYLCELLULOSE, POLYETHYLENE, XANTHAN GUM, EDTA, SODIUM HYDROXIDE, BHT, DISODIUM EDTA, MICA, TIN OXIDE, AMINOPROPYL DIMETHICONE, FRAGRANCE/PARFUM.

Drug Facts (continued)

ALPHA-ISOMETHYL IONONE, BUTYLPHENYL METHYLPROPIONAL, CITRONELLOL, HYDROXYCITRONELLAL, ETHYLPARABEN, METHYLPARABEN, PHENOXYETHANOL, POTASSIUM SORBATE, PROPYLPARABEN, SODIUM BENZOATE, TITANIUM DIOXIDE (CI 77891).

Other Information

■ Protect this product from excessive heat and direct sun

Questions or comments?

■ Call toll free 1-800-326-7337

Drug Facts**Active Ingredients Purpose**

OCTINOXATE 7.5%..... Sunscreen
 OCTISALATE 5.0%..... Sunscreen
 OXYBENZONE 4.0%... Sunscreen
 OCTOCRYLENE 3.0% 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

Drug Facts (continued)**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.

Drug Facts (continued)**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:

Drug Facts (continued)

- 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, DIMETHICONE, GLYCERIN, HYDROGENATED POLYISOBUTENE, PETROLATUM, GLYCERYL STEARATE, BUTYLENE GLYCOL, BUTYLOCTYL SALICYLATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, CETEARYL ALCOHOL, PEG-100 STEARATE, BUTYROSPERMUM

Drug Facts (continued)

PARKII (SHEA BUTTER), HYDROGENATED LECITHIN, DIMETHYL CAPRAMIDE, CERAMIDE 1, CERAMIDE 3, CERAMIDE 6 II, FUCUS SERRATUS EXTRACT, YEAST EXTRACT/FAEX/EXTRAIT DE LEVURE, RETINYL LINOLEATE, TOCOPHERYLACETATE, CETEARYL DIMETHICONE CROSSPOLYMER, PEG-40 HYDROGENATED CASTOR OIL, SOY AMINO ACIDS, 3-AMINOPROPANE SULFONIC ACID, CALCIUM HYDROXYMETHIONINE, HYDROLYZED SOY PROTEIN, METHYL METHACRYLATE

Elizabeth Arden

Ceramide Premiere
Intense Moisture
and Renewal
Activation Cream
Broad Spectrum
Sunscreen SPF 30

ACTIVE INGREDIENTS:
OCTINOXATE 7.5 % W/W
OCTISALATE 5.0 % W/W
OXYBENZONE 4.0 % W/W
OCTOCRYLENE 3.0 % W/W
AVOBENZONE 2.0 % 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.

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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Dist., N.Y., NY 10003
elizabetharden.com
Made in U.S.A. No. 8046MP2200

CERAMIDE PREMIER INTENSE MOISTURE AND RENEWAL ACTIVATION BROAD SPECTRUM SPF 30

octinoxate, octisalate, oxybenzone, octocrylene, and avobenzon cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-1145
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.68 g in 49 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.45 g in 49 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	1.96 g in 49 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	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)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

GLYCERIN (UNII: PDC6A3C0OX)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SHEA BUTTER (UNII: K49155WL9Y)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
CERAMIDE 3 (UNII: 4370DF050B)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
FUCUS SERRATUS (UNII: V8K40WNW5B)	
YEAST (UNII: 3NY3SM6B8U)	
RETINYL LINOLEATE (UNII: 61911N8D6W)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
TRAMIPROSATE (UNII: 5K8EAX0G53)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
DOCOSANOL (UNII: 9G1OE216XY)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETIC ACID (UNII: 9G34HU7RV0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MICA (UNII: V8A1AW0880)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
ETHYLPARABEN (UNII: 14255EXE39)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:67938-1145-1	1 in 1 JAR		
1	NDC:67938-1145-2	49 g in 1 CARTON		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part352		12/22/2011	

Labeler - Elizabeth Arden, Inc (849222187)

Revised: 4/2013

Elizabeth Arden, Inc