

ELIZABETH ARDEN, GREAT 8, MOISTURIZER SPF 35- avobenzone, octisalate, homosalate emulsion
Revlon

Elizabeth Arden Great 8, Eight Hour Daily Defense Moisturizer Broad Spectrum Sunscreen SPF35

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures decreases the risk of cancer and early skin aging caused by the sun

When using this product

keep out of eyes. Rinse with water to remove.

Stop using 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

use water resistant sunscreen if swimming or sweating

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 10am-2pm

wear long-sleeved shirts, pants, hats, and sunglasses

children under 6 months: ask a doctor

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 using 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

As needed

Sunscreen

Aqua/water/eau, dipropylene glycol, glycerin, thermus thermophilus ferment, butylene glycol, imperata cylindrica root extract, enantia chlorantha bark extract, marrubium vulgare extract, acrylates/C10-30 alkyl acrylate crosspolymer, ammonium acryloyldimethyltaurate/beheneth-25 methacrylate crosspolymer, caprylyl glycol, carbomer, dimethylmethoxy chromanol disodium EDTA, hydroxyacetophenone, oleanolic acid, sclareolide, triethanolamine, parfum (fragrance), geraniol, hexyl cinnamal, limonene, linalool, chlorphenesin.



1 step, 8 great benefits! Protects and perfects for a healthy, radiant glow. Defends skin from damaging effects of sun, pollution, infrared rays and even blue light. Designed to hydrate, purify, brighten and with regular use, fight excess oil. Additive, translucent formula for all skin types and tones. No white cast or residue.

To use: Apply daily to face after cleansing. Can be used as a primer before makeup.



Drug Facts

Active Ingredient	Purpose
Avobenzone 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	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 using 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.


Elizabeth Arden
 NEW YORK

GREAT 8™
Eight Hour®
Daily Defense
Moisturizer
Broad Spectrum
Sunscreen
SPF 35

1.5 FL. OZ. 45 ml

Drug Facts (continued)

Directions

For Sunscreen Use:

- Apply liberally 15 minutes before sun exposure
- reapply:
 - at least every 2 hours
 - use a water resistant sunscreen if swimming or sweating.
- 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

AQUAMATERIAL, DIPROPYLENE GLYCOL, GLYCERIN, THERMOPHILLUS FERMENT, BUTYLENE GLYCOL, IMPERATA CYLINDRICA ROOT EXTRACT, ENANTIA CHLORANTHA BARK EXTRACT, MARRUBIUM VULGARE EXTRACT, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, AMMONIUM ACRYLOYLDIMETHYLTAURATE/EGENETH-25 METHACRYLATE CROSSPOLYMER, CAPRYLYL GLYCOL, CARBOMER, DIMETHYLMETHOXY CHROMANOL, DISODIUM EDTA, HYDROXYACETOPHENONE, OLEANOIC ACID, SOLARELIDE, TRIETHANOLAMINE, PARFUM (FRAGRANCE), GERANIOL, HEXYL CINNAMAL, LIMONENE, LINALOOL, CHLORPHENESIN.

Other Information

- Protect this product from excessive heat and direct sun
- Store at room temperature

Questions or comments?
Call toll free 1-800-326-7337

Clinically and dermatologist tested.

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No. A0118283



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ELIZABETH ARDEN, GREAT 8, MOISTURIZER SPF 35

avobenzone, octisalate, homosalate emulsion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10967-665
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 1 mL	

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE (UNII: KBC00G95HI)	
2'-HYDROXYACETOPHENONE (UNII: 3E533Z76W0)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
IMPERATA CYLINDRICA ROOT (UNII: VYT2JA85NH)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
THERMUS THERMOPHILUS LYSATE (UNII: 775R692494)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
OLEANOLIC ACID (UNII: 6SMK8R7TGJ)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
ANNICKIA CHLORANTHA BARK (UNII: H70115MP4A)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SCLAREOLIDE (UNII: 37W4O006E6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10967-665-15	45 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/01/2018	

Labeler - Revlon (788820165)

Establishment

Name	Address	ID/FEI	Business Operations
Revlon, INC		809725570	manufacture(10967-665)