

**ADVANCED TIME ZONE AGE REVERSING LINE WRINKLE BROAD SPECTRUM SPF 15
NORMAL COMBO SKIN- avobenzone, octinoxate, and octisalate cream
ESTEE LAUDER 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.

**ADVANCED TIME ZONE AGE REVERSING / LINE WRINKLE CRÈME BROAD
SPECTRUM SPF 15 NORMAL /COMBO SKIN**

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Avobenzone 3.00%	Sunscreen
Octinoxate 7.50%	Sunscreen
Octisalate 5.00%	Sunscreen

Use

helps prevent sunburn

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 two 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 value 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-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

Inactive ingredients

water/aqua/eau • butylene glycol • glycerin • octyldodecyl myristate • neopentyl glycol diheptanoate • dimethicone • glyceryl stearate • citrullus vulgaris (watermelon) fruit extract • sigesbeckia orientalis (st. paul's wort) extract • pyrus malus (apple) fruit extract • lens esculenta (lentil) fruit extract • centaurium erythraea (centaury) extract • laminaria digitata extract • hordeum vulgare (barley) extract/extrait d'orge • cucumis sativus (cucumber) fruit extract • tamarindus indica seed extract •

salicornia herbacea extract • polygonum cuspidatum root extract • vitis vinifera (grape) seed extract • hydrolyzed rice extract • rosmarinus officinalis (rosemary) extract • selaginella tamariscina (spike moss) extract • humulus lupulus (hops) extract • citrus reticulata (tangerine) peel extract • yeast extract/faex\extrait de levure • limonium vulgare flower/leaf/stem extract • whey protein/lactis protein/proteine du petit-lait • thermus thermophilus ferment • cetyl alcohol • pentaerythrityl tetraethylhexanoate • hydrogenated lecithin • polyethylene • caprylic/capric/myristic/stearic triglyceride • punica granatum (pomegranate) fruit juice • cholesterol • sucrose • linoleic acid • caffeine • acetyl glucosamine • linolenic acid • adenosine phosphate • lactoperoxidase • phospholipids • acetyl hexapeptide-8 • glucose oxidase • peg-100 stearate • acrylamide/sodium acryloyldimethyltaurate copolymer • tocopheryl acetate • triolein • behenyl alcohol • phytantriol • trehalose • pvp/hexadecene copolymer • pentylene glycol • hdi/ppg/polycaprolactone crosspolymer • caprylic/capric triglyceride • polysilicone-11 • isohexadecane • caprylyl glycol • propylene glycol dicaprate • sodium pca • helianthus annuus (sunflower) seedcake • polysorbate 80 • glucose • sodium hyaluronate • sodium lactate • phytosteryl canola glycerides • oleic acid • palmitic acid • stearic acid • potassium sulfate • decarboxy carnosine hcl • nordihydroguaiaretic acid • cyclodextrin • carbomer • hexylene glycol • potassium hydroxide • fragrance (parfum) • silica • ethylbisiminomethylguaicol manganese chloride • disodium edta • bht • phenoxyethanol <iln38899>

Other information

protect the product in this container from excessive heat and direct sun

ESTÉE LAUDER, DIST., NEW YORK, N.Y. 10022

PRINCIPAL DISPLAY PANEL - 50 ml Jar Carton

EL

ESTÉE LAUDER

Advanced Time Zone

Age Reversing Line/Wrinkle Creme

Broad Spectrum SPF 15

Normal/Combination Skin

POIDS NET WT. 1.7 OZ./50 ml e



ESTÉE LAUDER

Advanced Time Zone
Age Reversing Line/Wrinkle Creme
Broad Spectrum SPF 15

■
Normal/Combination Skin

POIDS NET WT. 1.7 OZ./50ml e

Age Reversing Line/Wrinkle Creme
Broad Spectrum SPF 15

■ For Normal/Combination Skin

"Reprogram" your skin's future and reverse the look of aging with this advanced moisturizer—clinically proven to take years off your appearance. Our revolutionary Tri-HA Cell Signaling Complex™ actively helps skin boost its natural support structure to visibly—and dramatically—reduce the look of lines and wrinkles. Instantly plumps skin's surface and enhances your natural radiance. For skin that looks smoother, less lined, years younger. Dermatologist-tested. Non-acnegenic.

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NEW YORK • LONDON W1K 3BO • PARIS • MILANO
MADE IN U.S.A. Y6NF
esteeauder.com



COATING
FREE AREA
Y6NF0111



SDHC 321931202
EDHC 321931202

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Y6NF-01-1111

SPECTRUM SPF 15 NORMAL COMBO SKIN

avobenzone, octinoxate, and octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11559-021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
butylene glycol (UNII: 3XUS85K0RA)	
glycerin (UNII: PDC6A3C0OX)	
octyldodecyl myristate (UNII: S013N99GR8)	
neopentyl glycol diheptanoate (UNII: 5LKW3C543X)	
dimethicone (UNII: 92RU3N3Y1O)	
glyceryl monostearate (UNII: 230OU9XXE4)	
watermelon (UNII: 231473QB6R)	
apple (UNII: B423VGH5S9)	
lens culinaris fruit (UNII: ZYZ076G9JH)	
centaurium erythraea (UNII: 57X4TSH58S)	
laminaria digitata (UNII: 15E7C67EE8)	
barley (UNII: 5PWM7YLI7R)	
cucumber (UNII: YY7C30VXJT)	
tamarind seed (UNII: 6AHP8A7OML)	
salicornia europaea (UNII: 6ADL50JAKW)	
polygonum cuspidatum root (UNII: 7TRV45YZF7)	
vitis vinifera seed (UNII: C34U15ICXA)	
rosemary (UNII: IJ67X351P9)	
selaginella tamariscina (UNII: GP370KXK6M)	
hops (UNII: 01G73H6H83)	
tangerine peel (UNII: JU3D414057)	
yeast (UNII: 3NY3SM6B8U)	
limonium vulgare flowering top (UNII: 840Y01ZC0M)	
cetyl alcohol (UNII: 936JST6JCN)	
pentaerythrityl tetraethylhexanoate (UNII: XJ7052W897)	
high density polyethylene (UNII: UG00KM4WR7)	
pomegranate juice (UNII: 99S671U9KB)	
cholesterol (UNII: 97C5T2UQ7J)	
sucrose (UNII: C151H8M554)	
linoleic acid (UNII: 9KJL21T0QJ)	

caffeine (UNII: 3G6A5W338E)	
n-acetylglucosamine (UNII: V956696549)	
linolenic acid (UNII: 0RBV727H71)	
adenosine phosphate (UNII: 415SHH325A)	
acetyl hexapeptide-8 (UNII: L4EL31FWIL)	
glucose oxidase (UNII: 0T8392U5N1)	
peg-100 stearate (UNII: YD01N1999R)	
glyceryl trioleate (UNII: O05EC62663)	
phytantriol (UNII: 8LVI07A72W)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
trehalose (UNII: B8WCK70T7I)	
pentylene glycol (UNII: 50C1307PZG)	
docosanol (UNII: 9G1OE216XY)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
isohexadecane (UNII: 918X1OUF1E)	
caprylyl glycol (UNII: 00YIU5438U)	
propylene glycol dicaprato (UNII: U783H9JHWY)	
sodium pyrrolidone carboxylate (UNII: 469OTG57A2)	
helianthus annuus seedcake (UNII: 482WYF7XLC)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
dextrose (UNII: IY9XDZ35W2)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
sodium lactate (UNII: TU7HW0W0QT)	
oleic acid (UNII: 2UMI9U37CP)	
palmitic acid (UNII: 2V16EO95H1)	
stearic acid (UNII: 4ELV7Z65AP)	
potassium sulfate (UNII: 1K573LC5TV)	
decarboxy carnosine hydrochloride (UNII: 6X7K9I5QR7)	
masoprocol (UNII: 7BO8G1BYQU)	
hexylene glycol (UNII: KEH0A3F75J)	
potassium hydroxide (UNII: WZHBC48M4T)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
edetate disodium (UNII: 7FLD91C86K)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
phenoxyethanol (UNII: HIE492ZZ3T)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11559-021-01	1 in 1 CARTON		
1		50 mL in 1 CONTAINER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/01/2012	

Labeler - ESTEE LAUDER INC (005914387)

Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(11559-021) , REPACK(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(11559-021) , RELABEL(11559-021) , REPACK(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Inc.		042918826	MANUFACTURE(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(11559-021) , RELABEL(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(11559-021) , RELABEL(11559-021) , REPACK(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(11559-021) , RELABEL(11559-021) , REPACK(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(11559-021) , RELABEL(11559-021) , REPACK(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(11559-021)

Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(11559-021) , RELABEL(11559-021)

Revised: 9/2012

ESTEE LAUDER INC