

**LOREAL PARIS REVITALIFT ANTI WRINKLE FIRMING MOISTURIZER SPF 25-
avobenzone, octisalate and octocrylene lotion
L'Oreal USA Products Inc**

Drug Facts

Active ingredients

Avobenzone 3%

Octisalate 5%

Octocrylene 7%

Purpose

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 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 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

Other information

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

Inactive ingredients

water, glycerin, dimethicone, alcohol denat., propanediol, PTFE, isopropyl isostearate, behenyl alcohol, octyldodecanol, phenoxyethanol, cetyl alcohol, polyacrylamide, ammonium acryloyldimethyltaurate/stearate-25 methacrylate crosspolymer, disodium stearyl glutamate, vinyl dimethicone/methicone silsequioxane crosspolymer, hydrolyzed soy protein, dimethicone/vinyl dimethicone crosspolymer, C13-14 isoparaffin, PEG-100 stearate, glycine soja (soybean) protein, fragrance, cetearyl alcohol, dimethiconol, tocopheryl acetate, panthenol, retinyl palmitate, laureth-7, capryloyl salicylic acid, acetyl trifluoromethylphenyl valylglycine, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, disodium EDTA, carbomer, caprylyl glycol, cetearyl glucoside, calcium PCA, sodium cocoyl glutamate, pentylene glycol, ethylhexylglycerin, sodium benzoate, benzyl salicylate, benzyl alcohol, yeast extract, benzyl benzoate, potassium sorbate, linalool, centella asiatica extract, hexyl cinnamal, citronellol, limonene, geraniol, alpha-isomethyl ionone, salicyloyl phytosphingosine, tocopherol

SPF 25

avobenzone, octisalate and octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-287
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		30 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		70 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
PROPANEDIOL (UNII: 5965N8W85T)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
ISOPROPYL ISOSTEARATE (UNII: C67IXB9Y7T)	
DOCOSANOL (UNII: 9G1OE216XY)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE7O)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SOY PROTEIN (UNII: R44IWB3RN5)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WW9CM0O67Z)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
LAURETH-7 (UNII: Z95S6G8201)	
CAPRYLOYL SALICYLIC ACID (UNII: 5F7PJF6AA4)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CALCIUM PIDOLATE (UNII: 7Y2LVU5EKK)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	

PENTYLENE GLYCOL (UNII: 50C1307PZG)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
BENZYL BENZOATE (UNII: N863NB338G)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
CENTELLA ASIATICA WHOLE (UNII: 7M867G6T1U)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
GERANIOL (UNII: L837108USY)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-287-01	1 in 1 CARTON	10/02/2017	
1		50 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:49967-287-02	1 in 1 CARTON	10/02/2017	12/01/2023
2		70 mL in 1 JAR; Type 0: Not a Combination Product		
3	NDC:49967-287-03	1 in 1 CARTON	10/02/2017	12/01/2023
3		48 mL in 1 JAR; Type 0: Not a Combination Product		
4	NDC:49967-287-04	1 in 1 CARTON	10/02/2017	12/01/2023
4		72 mL in 1 JAR; Type 0: Not a Combination Product		
5	NDC:49967-287-05	1 in 1 CARTON	10/02/2017	
5		100 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/02/2017	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment			
Name	Address	ID/FEI	Business Operations
L'Oreal USA, Inc.		624244349	manufacture(49967-287)

Revised: 12/2023

L'Oreal USA Products Inc