LANCOME PARIS RENERGIE LIFT MULTIACTION ULTRA FIRMING AND DARK SPOT CORRECTING MOISTURIZER BROAD SPECTRUM SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate and octocrylene lotion L'Oreal USA Products 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.

Drug Facts

Active ingredients

Avobenzone 3%

Homosalate 5%

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 generously and evenly 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 of 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, silica, PEG-100 stearate, glyceryl stearate, glycolic acid, guanosine, cyathea medullaris leaf extract, t-butyl alcohol, dicaprylyl carbonate, mica, tocopherol, ascorbyl glycoside, sodium hydroxide, sodium hyaluronate, hydrolyzed linseed extract, sodium benzoate, sodium levulinate, stearic acid, phenoxyethanol, steareth-100, phenylethyl resorcinol, palmitic acid, ammonium polyacryloyldimethyl taurate, dimethicone/vinyl dimethicone crosspolymer, limonene, xanthan gum, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, benzyl alcohol, tin oxide, cinnamic acid, leontopodium alpinum extract, caprylyl glycol, myristic acid, geraniol, disodium EDTA, titanium dioxide, retinyl palmitate, citric acid, potassium sorbate, levulinic acid, glyceryl pacrylate, fragrance

Questions or comments?

1-800-LANCOME (1-800-526-2663) Monday - Friday (9 a.m. - 5 p.m. EST)

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Drug Facts (continued) Other information

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For 25 years, Renergie has been Lancôme's

For 25 years, Renergie has been Lancome's best-selling anti-aging face cream that firms, lifts and tightens skin.

Lancome now introduces an oil-free moisturizer that helps target the multiple signs of aging. Formulated with linen extract, known for its capacity to grow even in the most extreme loonditions - this lotion helps to visibly lift, firm, and improve the elasticity of your skin. In addition, the appearance of skin tone irregularities is diminished and the look of dark spots is visibly reduced. Ispots is visibly reduced

Discover a lightweight texture that fits to all skin types: it delicately melts after application for more beautiful, younger-looking skin. Apply morning, face, neck and décolleté.

NEW

RÉNERGIE LIFT MULTI-ACTION ULTRA

BROAD SPECTRUM SPF 30

e 50 ml 1.69 FL, OZ,

THIS PRODUCT CAN BE SOLD ONLY BY APPROVED DISTRIBUTORS LANCOME PARIS 14 rue Royale 75008 PARIS LANCÔME, LUXURY PRODUCTS LLC, 10 HUDSON YARDS, NEW YORK, NY 10001 IMP. BY LANCÔME CANADA, MONTRÉAL, H4T 1K5

TSA 75000 93584 ST OUEN CEDEX FR Made in France

LANCOME PARIS RENERGIE LIFT MULTIACTION ULTRA FIRMING AND DARK SPOT CORRECTING MOISTURIZER BROAD SPECTRUM SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate and octocrylene lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49967-768

Route of Administration TOPICAL

Active Ingredient/Active Maiet

ı	Active ingredient/Active wrotety			
I	Ingredient Name	Basis of Strength	Strength	
l	Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 mL	
l	HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 mL	

	Octisalate (UNII: 4X49 Y0596W) (Octisalate - UNII:4X49 Y0596W)	Octisalate	50 mg in 1 mL
ı	Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	70 mg in 1 mL

Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
DIMETHICO NE (UNII: 92RU3N3Y10)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
PEG-100 STEARATE (UNII: YD01N1999R)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
GLYCOLIC ACID (UNII: 0WT12SX38S)		
GUANO SINE (UNII: 12133JR80S)		
CYATHEA MEDULLARIS LEAF (UNII: G65ROR2RKA)		
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)		
DICAPRYLYL CARBONATE (UNII: 609 A3V1SUA)		
MICA (UNII: V8A1AW0880)		
TOCOPHEROL (UNII: R0 ZB2556P8)		
ASCORBYL GLUCOSIDE (UNII: 2V52R0 NHXW)		
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)		
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM LEVULINATE (UNII: VK44E1MQU8)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
STEARETH-100 (UNII: 4OH5W9UM87)		
PHENYLETHYL RESORCINOL (UNII: G37UFG162O)		
PALMITIC ACID (UNII: 2V16EO95H1)		
DIMETHICO NE/VINYL DIMETHICO NE CROSSPO LYMER (HARD PARTICLE) (UNII: H895X08VNQ)		
LIMO NENE, (+)- (UNII: GFD7C86Q1W)		
XANTHAN GUM (UNII: TTV12P4NEE)		
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
STANNIC O XIDE (UNII: KM7N50LOS6)		
CINNAMIC ACID (UNII: U14A832J8D)		
LEONTO PODIUM NIVALE SUBSP. ALPINUM ROOT (UNII: SDW6SS1K61)		
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)		
MYRISTIC ACID (UNII: 0 BV7S25AW)		
GERANIOL (UNII: L837108USY)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
LEVULINIC ACID (UNII: RYX5QG61EI)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:49967-768-01	1 in 1 CARTON	09/01/2017		
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:49967-768-02	OC:49967-768-02 1 in 1 CARTON			
2		5 mL in 1 TUBE; Type 0: Not a Combination Product			
3	NDC:49967-768-03	1.5 mL in 1 PACKET; Type 0: Not a Combination Product	09/01/2017		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part352	09/01/2017			

Labeler - L'Oreal USA Products Inc (002136794)

Establishment			
Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-768), pack(49967-768)

Establishment			
Name	Address	ID/FEI	Business Operations
Socoplan		276221405	pack(49967-768)

Revised: 12/2017 L'Oreal USA Products Inc