

LANCÔME PARIS HIGH RESOLUTION REFILL 3X TRIPLE ACTION RENEWAL ANTI WRINKLE BROAD SPECTRUM SPF 15 SUNSCREEN- avobenzone, octisalate and octocrylene cream

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%

Octisalate 5%

Octocrylene 3%

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 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, PTFE, octyldodecanol, alcohol denat., isopropyl isostearate, methylsilanol/silicate crosspolymer, arachidyl alcohol, tocopheryl acetate, medicago sativa (alfalfa) extract, hydrolyzed rice protein, sodium chloride, sodium hyaluronate, phenoxyethanol, acetyl trifluoromethylphenyl valylglycine, adenosine, PEG-100 stearate, behenyl alcohol, polysorbate 80, silica, cellulose acetate butyrate, polyphosphorylcholine glycol acrylate, polyvinyl alcohol, dimethicone/vinyl dimethicone crosspolymer, ammonium acryloyldimethyltaurate/stearate-25 methacrylate crosspolymer, dimethiconol, limonene, ammonium polyacryloyldimethyl taurate, manganese gluconate, linalool, benzyl alcohol, isohexadecane, capryloyl salicylic acid, alpha-isomethyl ionone, acrylamide/sodium acryloyldimethyltaurate copolymer, carbomer, geraniol, disodium stearyl glutamate, disodium EDTA, cetyl alcohol, cetearyl alcohol, methylparaen, cetearyl glucoside, butylphenyl methylpropional, methylisothiazolinone, citronellol, butylene glycol, coumarin, fragrance

Questions or comments?

1-800-LANCOME (1-800-526-2663)

Monday - Friday (9 a.m. - 5 p.m. EST)

<p>Drug Facts (continued)</p> <p>Spectrum SPF value of 15 or higher and other sun protection measures including:</p> <ul style="list-style-type: none"> • 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 <p>Other information</p> <ul style="list-style-type: none"> • protect the product in this container from excessive heat and direct sun <p>Inactive ingredients water, glycerin, dimethicone, PTFE, octyldodecanol, alcohol denat., isopropyl isostearate, arachidyl alcohol, isopropyl isostearate, medicago sativa (alfalfa) extract, hydrolyzed rice protein, sodium chloride, sodium hyaluronate, phenoxyethanol, acetyl trifluoromethylphenyl valylglycine, adenosine, PEG-100 stearate, behenyl alcohol, polysorbate 80, cellulose acetate butyrate, polyphosphorylcholine glycol acrylate, polyvinyl alcohol, ammonium acryloyldimethyltaurate/stearate-25 methacrylate crosspolymer, dimethiconol, limonene, ammonium polyacryloyldimethyl taurate, manganese gluconate, linalool, benzyl alcohol, isohexadecane, capryloyl salicylic acid, alpha-isomethyl ionone, acrylamide/sodium acryloyldimethyltaurate copolymer, carbomer, geraniol, disodium stearyl glutamate, disodium EDTA, cetyl alcohol, cetearyl alcohol, methylparaen, cetearyl glucoside, butylphenyl methylpropional, methylisothiazolinone, citronellol, butylene glycol, coumarin, fragrance</p> <p>Questions or comments? 1-800-LANCOME (1-800-526-2663) Monday-Friday (9am – 5pm EST)</p>	<p style="text-align: center;">LANCÔME PARIS</p> <p style="text-align: center;">HIGH RÉOLUTION REFILL-3X™</p> <p style="text-align: center;">SUNSCREEN BROAD SPECTRUM SPF 15</p> <p style="text-align: center;">TRIPLE ACTION RENEWAL ANTI-WRINKLE CREAM</p> <p style="text-align: center;">2.6 OZ. (75g)</p>	<p style="text-align: center;">Triple Action Renewal Anti-Wrinkle Cream</p> <p>For all skin types</p> <p>LANCÔME introduces High-Resolution Refill-3X™ for visibly smoother, younger-looking skin. Lines and wrinkles are visibly reduced. Skin recaptures its youthful beauty.</p> <p>Visible anti-wrinkle results</p> <p>Immediately, skin feels significantly softer. In 4 weeks, the number and size of wrinkles are significantly reduced. Like any anti-wrinkle cream, this is not equivalent to a permanent wrinkle filler.</p> <p>Non-comedogenic. Dermatologist-tested for safety.</p> <p style="text-align: right;">lancome.com LANCÔME LABOR PRODUCTS, LLC NEW YORK, NY 10001 MADE IN U.S.A. OF U.S. AND/OR IMPORTED INGREDIENTS</p>	<p style="text-align: right;">U.S.P.T.</p> <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Azobenzene 3%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate 5%</td> <td>Sunscreen</td> </tr> <tr> <td>Octocrylene 8%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> • 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 <p>Warnings</p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and seek a doctor if rash occurs</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <p>For sunscreen use:</p> <ul style="list-style-type: none"> • 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 	Active ingredients	Purpose	Azobenzene 3%	Sunscreen	Octisalate 5%	Sunscreen	Octocrylene 8%	Sunscreen
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avobenzone, octisalate and octocrylene cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-502
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Avobenzene (UNII: G63QQF2NOX) (Avobenzene - UNII:G63QQF2NOX)	Avobenzene	30 mg in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	30 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ISOSTEARATE (UNII: C67IXB9Y7T)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ACETYL TRIFLUOROMETHYLPHENYL VALYLGLYCINE, DL- (UNII: 95SP8380V9)	
ADENOSINE (UNII: K72T3FS567)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DOCOSANOL (UNII: 9G1OE216XY)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CELLABURATE (MW 12000, 32% BUTYRYL, 18% ACETYL) (UNII: I94M7L124G)	
POLYVINYL ALCOHOL (100000 MW) (UNII: 949E52Z6MY)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
DIMETHICONOL (100000 CST) (UNII: OSA9UP217S)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
MANGANESE (UNII: 42Z2K6ZL8P)	
GLUCONATE ION (UNII: W552L9Y4VZ)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
CAPRYLOYL SALICYLIC ACID (UNII: 5F7PJF6AA4)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
GERANIOL (UNII: L837108USY)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)

COUMARIN (UNII: A4VZ22K1WT)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-502-01	1 in 1 CARTON	08/01/2013	
1		75 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:49967-502-02	1 in 1 CARTON	08/01/2013	
2		50 g in 1 JAR; Type 0: Not a Combination Product		
3	NDC:49967-502-03	1 in 1 CARTON	08/01/2013	
3		15 g 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 not final	part352	08/01/2013	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-502)

Establishment

Name	Address	ID/FEI	Business Operations
L'Oreal USA, Inc.		185931458	manufacture(49967-502)

Revised: 1/2020

L'Oreal USA Products Inc