

**LANCOME PARIS VISIONNAIRE BROAD SPECTRUM SPF 20 SUNSCREEN ADVANCED
MULTI CORRECTING ALL SKIN TYPES- 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 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 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, alcohol denat., isopropyl isostearate, behenyl alcohol, synthetic wax, octyldodecanol, C13-14 isoparaffin, yeast extract, tocopheryl acetate, tocopherol, hydrolyzed soy protein, sodium cocoyl glutamate, sodium benzoate, phenoxyethanol, acetyl trifluoromethylphenyl valylglycine, PEG-100 stearate, ethylhexylglycerin, polyacrylamide, calcium PCA, salicyloyl phytosphingosine, ammonium acryloyldimethyltaurate/stearate-25 methacrylate crosspolymer, dimethicone/vinyl dimethicone crosspolymer, dimethiconol, limonene, vinyl dimethicone/methicone silsesquioxane crosspolymer, panthenol, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, pentylene glycol, linalool, caprylyl glycol, capryloyl salicylic acid, carbomer, disodium stearyl glutamate, disodium EDTA, cetyl alcohol, methyl dihydrojasmonate, cetearyl alcohol, retinyl palmitate, cetearyl glucoside, potassium sorbate, citronellol, BHT, laureth-7, glycine soja (soybean) protein

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>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:</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</p> <p>water, glycerin, dimethicone, PTFE, alcohol denat., isopropyl isostearate, behenyl alcohol, synthetic wax, octyldodecanol, C13-14 isoparaffin, yeast extract, tocopheryl acetate, tocopherol, hydrolyzed soy protein, sodium cocoyl glutamate, sodium benzoate, phenoxyethanol, acetyl trifluoromethylphenyl valylglycine, PEG-100 stearate, ethylhexylglycerin, polyacrylamide, calcium PCA, salicyloyl phytosphingosine, ammonium acryloyldimethyltaurate/stearate-25 methacrylate crosspolymer, dimethicone/vinyl dimethicone crosspolymer, dimethiconol, limonene, vinyl dimethicone/methicone silsesquioxane crosspolymer, panthenol, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, pentylene glycol, linalool, caprylyl glycol, capryloyl salicylic acid, carbomer, disodium stearyl glutamate, disodium EDTA, cetyl alcohol, methyl dihydrojasmonate, cetearyl alcohol, retinyl palmitate, cetearyl glucoside, potassium sorbate, citronellol, BHT, laureth-7, glycine soja (soybean) protein, fragrance</p> <p>Questions or comments? 1-800-LANCOME (1-800-526-2663) Monday - Friday (9 a.m. - 5 p.m. EST)</p>	<p>LANCÔME PARIS</p> <p>VISIONNAIRE</p> <p>SUNSCREEN BROAD SPECTRUM SPF 20</p> <p>ADVANCED MULTI-CORRECTING CREAM ALL SKIN TYPES</p> <p>50 g NET WT. 1.7 OZ.</p>	<p>Advanced Multi-Correcting Cream - SPF 20 Wrinkles - Bounce - Luminosity</p> <p>"Future-Proof" your skin's appearance. Visionnaire SPF 20 Cream visibly corrects and helps prevent the appearance of unwanted wrinkles and lack of suppleness. Formulated with broad spectrum UVA/UVB protection, this lightweight texture helps visibly correct and shield skin against outdoor sun. See visible results.</p> <p>Immediately: skin feels fresh and moisturized</p> <p>After one week: skin feels softer, replenished with moisture and appears younger</p> <p>In four weeks: skin feels suppler and wrinkles appear significantly reduced. Visible correcting effect for beautiful skin today and every day after use. Look forward to your skin's future.</p> <p>MDK Paraben free Fragrance free PHO 000000</p> <p>THIS PRODUCT CAN BE SOLD ONLY BY APPROVED DISTRIBUTORS LANCÔME PARIS 20 rue du Faubourg St Honoré 75008 Paris LANCÔME LOUVEUR PRODUCTS LLC 10 HUDSON YARDS, NEW YORK, NY 10001 IMP BY LANCÔME CANADA, MONTREAL, H4T 1W6 USA 1200/00004 ST-OUEN CEDEX 03</p> <p>Made in France</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Azobenzene 5%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate 5%</td> <td>Sunscreen</td> </tr> <tr> <td>Octocrylene 7%</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 <p>LANCÔME L6818 30</p>	Active ingredients	Purpose	Azobenzene 5%	Sunscreen	Octisalate 5%	Sunscreen	Octocrylene 7%	Sunscreen
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LANCÔME PARIS VISIONNAIRE BROAD SPECTRUM SPF 20 SUNSCREEN ADVANCED MULTI CORRECTING ALL SKIN TYPES

avobenzone, octisalate and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-194
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	70 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ISOSTEARATE (UNII: C67IXB9Y7T)	
DOCOSANOL (UNII: 9G1OE216XY)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ACETYL TRIFLUOROMETHYLPHENYL VALYLGLYCINE, DL- (UNII: 95SP8380V9)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
CALCIUM PIDOLATE (UNII: 7Y2LVU5EKK)	
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
DIMETHICONOL (100000 CST) (UNII: OSA9UP217S)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
PANTHENOL (UNII: WV9CM0O67Z)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAPRYLOYL SALICYLIC ACID (UNII: 5F7PJF6AA4)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYL DIHYDROJASMONATE (SYNTHETIC) (UNII: 3GW44CIE3Y)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)

LAURETH-7 (UNII: Z95S6G8201)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-194-01	1 in 1 CARTON	05/01/2017	
1		50 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:49967-194-02	1 in 1 CARTON	05/01/2017	
2		5 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:49967-194-04	1 in 1 CARTON	12/10/2018	
3		15 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:49967-194-03	2 g in 1 PACKET; Type 0: Not a Combination Product	05/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/01/2017	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-194) , pack(49967-194)

Establishment

Name	Address	ID/FEI	Business Operations
Socoplan		276221405	pack(49967-194)

Establishment

Name	Address	ID/FEI	Business Operations
L'Oreal USA, Inc.		185931458	manufacture(49967-194)

Revised: 12/2018

L'Oreal USA Products Inc