

**LANCOME PARIS ABSOLUE PRECIOUS CELLS BROAD SPECTRUM SPF 15 SUNSCREEN
INTENSE REVITALIZING- avobenzone, homosalate, 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%

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 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, alcohol denat, dimethicone, bis-PEG-18 methyl ether dimethyl silane, hydrogenated polyisobutene, cetearyl alcohol, PEG-20, petrolatum, cetyl alcohol, octyldodecanol, c13-14 isoparaffin, zea mays (corn) oil, tocopheryl acetate, tocopherol, ascorbyl palmitate, hydroxypropyl tetrahydropyrantriol, hydrolyzed soy protein, hydrolyzed linseed extract, sodium hydroxide, sodium benzoate, red 4, phenoxyethanol, adenosine, PEG-100 stearate, trisodium ethylenediamine disuccinate, polyacrylamide, yellow 5, dimethiconol, limonene, xanthan gum, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, pentylene glycol, linalool, propylene glycol, caprylyl glycol, capryloyl salicylic acid, acrylates/c10-30 alkyl acrylate crosspolymer, geraniol, passiflora edulis seed oil, rosa damascena flower oil, butyrospermum parkii (shea) butter, cetearyl glucoside, citronellol, BHT, citral, citric acid, prunus armeniaca (apricot) kernel oil, laureth-7, coumarin, oryza sativa (rice) bran oil, glyceryl stearate

Questions or comments?

1-800-LANCOME (1-800-526-2663) Monday - Friday (9 am - 5 pm EST)

<p>Drug Facts (continued)</p> <p>Other information • protect the product in this container from excessive heat and direct sun.</p> <p>Inactive ingredients water, alcohol, dimethicone, bis-PEG-18 methyl ether dimethyl silane, hydrogenated polyisobutene, cetearyl alcohol, PEG-20, petrolatum, cetyl alcohol, octyldodecanol, c13-14 isoparaffin, zea mays (corn) oil, tocopheryl acetate, tocopherol, ascorbyl palmitate, hydroxypropyl tetrahydropyrantriol, hydrolyzed soy protein, hydrolyzed linseed extract, sodium hydroxide, sodium benzoate, red 4, phenoxyethanol, adenosine, PEG-100 stearate, trisodium ethylenediamine disuccinate, polyacrylamide, yellow 5, dimethiconol, limonene, xanthan gum, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, pentylene glycol, linalool, propylene glycol, caprylyl glycol, capryloyl salicylic acid, acrylates/c10-30 alkyl acrylate crosspolymer, geraniol, passiflora edulis seed oil, rosa damascena flower oil, butyrospermum parkii (shea) butter, cetearyl glucoside, citronellol, BHT, citral, citric acid, prunus armeniaca (apricot) kernel oil, laureth-7, coumarin, oryza sativa (rice) bran oil, glyceryl stearate.</p> <p>Questions or comments? 1-800-LANCOME (1-800-526-2663) Monday - Friday (9 a.m. - 5 p.m. EST)</p> <p><small>02079491 71436 13</small></p> <p>Absolue, an exceptional skincare collection, inspired by nature, refined by science. Absolue Precious Cells Day Cream SPF 15 is a light daily skincare cream, developed by L'Oréal Paris Skincare. At the heart of each of our Absolue skincare products is Pro-Xylane™, Absolue's iconic ingredient. This indulgent cream leaves skin feeling hydrated and softer with moisture. On the skin, visible signs of dryness, skin looks smoother and feel more plumped.</p> <p><small>Suitable for sensitive skin - Avoid eye area Tested under dermatological control</small></p> <p><small>LANCÔME LUXURY PRODUCTS S.L.L.C. 1400 AVENUE OF THE AMERICAS, 10TH FLOOR NEW YORK, NY 10101 IMP BY L'ORÉAL PARIS, 1000 AVENUE DE LA GARDIOLLE, 14011 HS TSA 75000, 93084 ST OMER (FRANCE) Made in France</small></p>	<p>LANCÔME PARIS</p> <p>ABSOLUE PRECIOUS CELLS</p> <p>SUNSCREEN BROAD SPECTRUM SPF 15 INTENSE REVITALIZING CREAM</p> <p>50 ml NET WT 1.7 OZ</p>	 <p><small>THIS PRODUCT CAN BE SOLD ONLY BY APPROVED DISTRIBUTORS LANCÔME PARIS 1400 AVENUE DE LA GARDIOLLE</small></p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Avobenzone 3%</td> <td>Sunscreen</td> </tr> <tr> <td>Homosalate 5%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate 4%</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 ask 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>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><small>LANCÔME.COM L4102 50</small></p>	Active ingredients	Purpose	Avobenzone 3%	Sunscreen	Homosalate 5%	Sunscreen	Octisalate 4%	Sunscreen	Octocrylene 7%	Sunscreen
Active ingredients	Purpose												
Avobenzone 3%	Sunscreen												
Homosalate 5%	Sunscreen												
Octisalate 4%	Sunscreen												
Octocrylene 7%	Sunscreen												

LANCÔME PARIS ABSOLUE PRECIOUS CELLS BROAD SPECTRUM SPF 15 SUNSCREEN INTENSE REVITALIZING avobenzone, homosalate, octisalate and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-667
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 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BIS-PEG-18 METHYL ETHER DIMETHYL SILANE (UNII: OEB4R3WW9C)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CORN OIL (UNII: 8470G57WFM)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
HYDROXYPROPYL TETRAHYDROPYRANTRIOIOL (UNII: 4U3GMG1OT1)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ADENOSINE (UNII: K72T3FS567)	
PEG-100 STEARATE (UNII: YD01N1999R)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22HB4H9Q)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
DIMETHICONOL (100000 CST) (UNII: OSA9UP217S)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAPRYLOYL SALICYLIC ACID (UNII: 5F7PJF6AA4)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

GERANIOL (UNII: L837108USY)
PASSIFLORA EDULIS SEED OIL (UNII: F3VOA31UHQ)
ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13)
SHEA BUTTER (UNII: K49155WL9Y)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CITRAL (UNII: T7EU0O9VPP)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
APRICOT KERNEL OIL (UNII: 54JB35T06A)
LAURETH-7 (UNII: Z95S6G8201)
COUMARIN (UNII: A4VZ22K1WT)
RICE BRAN OIL (UNII: LZO6K1506A)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-667-01	1 in 1 CARTON	08/01/2017	
1		50 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:49967-667-02	1 in 1 CARTON	08/01/2017	
2		75 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 not final	part352	08/01/2017	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-667)