

LANCOME PARIS ABSOLUE PREMIUM BX REPLENISHING AND REJUVENATING DAY-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 2%

Octisalate 5%

Octocrylene 8%

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, hydrogenated polyisobutene, alcohol denat., bis-PEG-18 methyl ether dimethyl silane, glycerin, cyclohexasiloxane, cetearyl alcohol, dimethicone, PEG-20, prunus armeniaca (apricot) kernel oil, petrolatum, C13-14 isoparaffin, tocopheryl acetate, hydroxypropyl tetrahydropyrantriol, hydrolyzed malt extract, sodium hyaluronate, pedia prepone extract, sodium hydroxide, hydrolyzed soy protein, adenosine, PEG-100 stearate, polyacrylamide, calcium pantothenate, dimethyl isosorbide, dimethiconol, limonene, xanthan gum, linalool, dioscorea villosa (wild yam) root extract, iron oxides, caprylyl glycol, capryloyl salicylic acid, paraffin, acrylates/C10-30 alkyl acrylate, crosspolymer, disodium EDTA, butyrospermum parkii (shea butter), butylene glycol, cetyl alcohol, cetearyl glucoside, octyldodecanol, citronellol, laureth-7, hexyldecanol, glyceryl stearate, fragrance

Questions or comments?

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

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-952
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	20 mg in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	80 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-952-01	1 in 1 CARTON	06/01/2010	
1		50 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:49967-952-02	1 in 1 CARTON	06/01/2010	
2		75 g in 1 JAR; Type 0: Not a Combination Product		
3	NDC:49967-952-03	1 in 1 CARTON	06/01/2010	
3		15 g in 1 JAR; Type 0: Not a Combination Product		
4	NDC:49967-952-04	2 g in 1 PACKET; Type 0: Not a Combination Product	06/01/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2010	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-952)

Establishment

Name	Address	ID/FEI	Business Operations
L'Oreal USA, Inc.		185931458	manufacture(49967-952)

