

LANCOME PARIS CITY MIRACLE BROAD SPECTRUM SPF 50 SUNSCREEN CC-homosalate, octisalate, octocrylene and titanium dioxide 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

Homosalate 10%

Octisalate 5%

Octocrylene 5%

Titanium dioxide 1.6%

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:

- shake well

- apply liberally 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., dicaprylyl ether, polyglyceryl-4 isostearate, ascorbyl glucoside, silica, nylon-12, tribehenin, disteardimonium hectorite, butylene glycol, rosa canina fruit oil, PEG-30 dipolyhydroxystearate, saccharomyces/xylinum/black tea ferment, sodium chloride, aluminum hydroxide, adenosine, disodium stearyl glutamate, butyrospermum parkii (shea butter) seedcake extract, phenoxyethanol, fragrance, linalool, geraniol, limonene, hydroxyisohexyl 3-cyclohexene carboxaldehyde, citronellol, butylphenyl methylpropional, hexyl cinnamal, benzyl alcohol; may contain: titanium dioxide, iron oxides

Questions or comments?

1-800-LANCOME

(1-800-526-2663)

Monday - Friday

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

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01 BEIGE DRAGEE

e 30 ml L5719 60



Drug Facts (continued)

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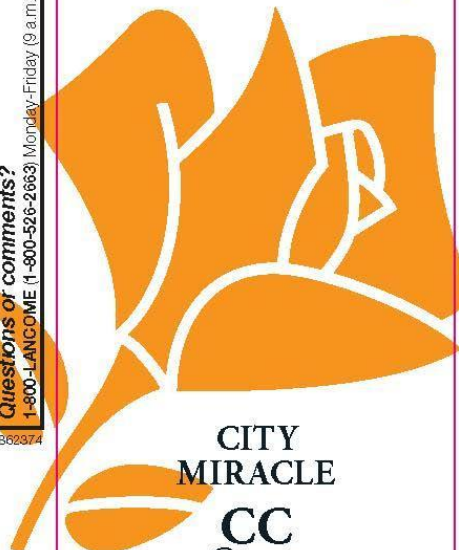
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LANCÔME

PARIS



**CITY
MIRACLE
CC
Cream**

**SUNSCREEN
BROAD SPECTRUM
SPF 50**

CORRECT & CARE
DAILY ANTI-OXIDANT PROTECTION

01

1.0 FL. OZ. (30ml)

Correct & Care
Daily Anti-oxidant Protection
Broad Spectrum SPF 50

City Miracle is the 1st CC Cream by Lancôme, tested in some of the most polluted cities of the world and recognized by women to protect against daily aggressions. The best of makeup and skincare united to correct imperfections and naturally beautify complexion. PERFECTS like a foundation BEAUTIFIES like an illuminator HYDRATES like a moisturizer PROTECTS with Broad Spectrum SPF 50 Sunscreen Unique healthy glow shades specifically formulated to defy dullness and fatigue. Choose your Miracle for tailor-made natural results: finish, lightness, perfection.

City tested - Shine-free finish
Suitable for sensitive skin
Dermatologically tested.

LANCÔME,
LUXURY PRODUCTS LLC,
NEW YORK, NY 10017
IMP. BY LANCÔME CANADA
MONTREAL, H4T 1K5
TSA 10007
F 92667 ASNIERES CEDEX
Made in France

LANCÔME PARIS CITY MIRACLE BROAD SPECTRUM SPF 50 SUNSCREEN CC

homosalate, octisalate, octocrylene and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-578
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	16 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C00X)	

ALCOHOL (UNII: 3K9958V90M)
DICAPRYLYL ETHER (UNII: 77JZM5516Z)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
NYLON-12 (UNII: 446U8J075B)
TRIBEHENIN (UNII: 8OC9U7TQZ0)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ADENOSINE (UNII: K72T3FS567)
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)
SHEA BUTTER (UNII: K49155WL9Y)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
GERANIOL (UNII: L837108USY)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
BENZYL ALCOHOL (UNII: LKG8494WBH)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-578-01	1 in 1 CARTON	01/01/2015	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-578-02	1 in 1 CARTON	01/01/2015	
2		10 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:49967-578-03	1 in 1 CARTON	01/01/2015	
3		5 mL in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:49967-578-04	1 mL in 1 PACKET; Type 0: Not a Combination Product	01/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2015	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-578)

