

GIORGIO ARMANI POWER FABRIC LONG WEAR HIGH COVER FOUNDATION BROAD SPECTRUM SPF 25 SUNSCREEN- octinoxate lotion

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 ingredient

Octinoxate 6.7%

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

Flammable until dry.

Do not use near fire, flame, or heat.

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 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

cyclohexasiloxane, water, dimethicone, vinyl dimethicone/methicone silsesquioxane crosspolymer, propanediol, alcohol denat., butylene glycol, phenyl trimethicone, cetyl PEG/PPG-10/1 dimethicone, synthetic fluorophlogopite, tocopherol, phenoxyethanol, magnesium sulfate, PEG/PPG-18 dimethicone, polyglyceryl-4 isostearate, dimethicone/vinyl dimethicone crosspolymer, limonene, benzyl salicylate, benzyl alcohol, linalool, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, isobutane, acrylonitrile/methylmethacrylate/vinylidene chloride copolymer, disodium stearyl glutamate, BHT, butylphenyl methylpropional, aluminum hydroxide, hexyl cinnamal, fragrance; may contain: iron oxides, titanium dioxide

Questions or comments?

CONTACT: GIORGIO ARMANI PARFUMS

LUXURY PRODUCTS LLC

10 HUDSON YARDS, NEW YORK, NY 10001

Drug Facts (continued)

Other information
 • protect the product in this container from excessive heat and direct sun

Inactive ingredients
 cyclohexasiloxane, water, dimethicone, vinyl dimethicone / methicone silsesquioxane crosspolymer, propanediol, alcohol denat., butylene glycol, phenyl trimethicone, cetyl PEG / PPG-10 / 1 dimethicone, synthetic fluorophlogopite, tocopherol, phenoxysthianol, magnesium sulfate, PEG / PPG-18 / 18 dimethicone, polyglyceryl-4 isostearate, dimethicone / vinyl dimethicone crosspolymer, limonene, benzyl salicylate, benzyl alcohol, linalool, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, isobutene, acrylonitrile / methyl methacrylate / vinylidene chloride copolymer, disodium stearyl glutamate, BHT, butylphenyl methylpropional, aluminum hydroxide, hexyl cinnamal, fragrance; may contain: iron oxides, titanium dioxide

power fabric

longwear high cover foundation

octinoxate sunscreen

broad spectrum SPF 25

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Drug Facts

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Octinoxate 6.7%	Sunscreen

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Warnings
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 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 liberally 15 minutes before sun exposure ▼

G992011 - FIL: B190915/1

DERMATOLOGICALLY TESTED. NON-COMEDOGENIC.
 THIS PRODUCT CAN BE USED ONLY BY APPROVED DISTRIBUTORS: GIORGIO ARMANI PARFUMS S.R.L. PLACE VENDÔME 75001 PARIS. LUXURY PRODUCTS LLC 10 HUDSON YARDS, NEW YORK, NY 10001. IMP. BY DESIGNER FRAGRANCES, MONTREAL, CANADA. HT 105. TSA 75001 95694 SP OLIN COLEX FR. MADE IN FRANCE.

QUESTIONS OR COMMENTS?
 CONTACT OUR GIORGIO ARMANI PARFUMS LUXURY PRODUCTS LLC 10 HUDSON YARDS, NEW YORK, NY 10001 FOR MORE INFORMATION ON THIS: ARMANIBEAUTY.COM





GIORGIO ARMANI

30 ml 1.01 FL.OZ.

Drug Facts (continued)

- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- Sun Protection Measure: 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:
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GIORGIO ARMANI POWER FABRIC LONG WEAR HIGH COVER FOUNDATION BROAD SPECTRUM SPF 25 SUNSCREEN

octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-349
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	67 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
TOCOPHEROL (UNII: R0ZB2556P8)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL SALICYLATE (UNII: WAO5MKN9TU)
BENZYL ALCOHOL (UNII: LKG8494WBH)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
ISOBUTANE (UNII: BXR49TP611)
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-349-01	1 in 1 CARTON	08/10/2016	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-349-02	1 in 1 CARTON	08/10/2016	
2		18 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:49967-349-03	1 in 1 CARTON	08/10/2016	
3		5 mL in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:49967-349-04	1 mL in 1 PACKET; Type 0: Not a Combination Product	08/10/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/10/2016	

Labeler - L'Oreal USA Products Inc. (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-349) , pack(49967-349)

Establishment

Name	Address	ID/FEI	Business Operations
Socoplan		276221405	pack(49967-349)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoires Biocosm SARL		288479491	pack(49967-349)

Revised: 12/2017

L'Oreal USA Products Inc.