

DOUBLE WEAR STAY IN PLACE HIGH COVER CONCEALER BROAD SPECTRUM SPF 35- octinoxate and titanium dioxide cream
ESTEE LAUDER 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.

DOUBLE WEAR
STAY IN PLACE HIGH COVER CONCEALER BROAD SPECTRUM SPF 35

Drug Facts

Active ingredients

Octinoxate 4.90%
Titanium Dioxide 1.90%

Purpose

Sunscreen

Use

helps prevent sunburn

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 product is 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 two 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

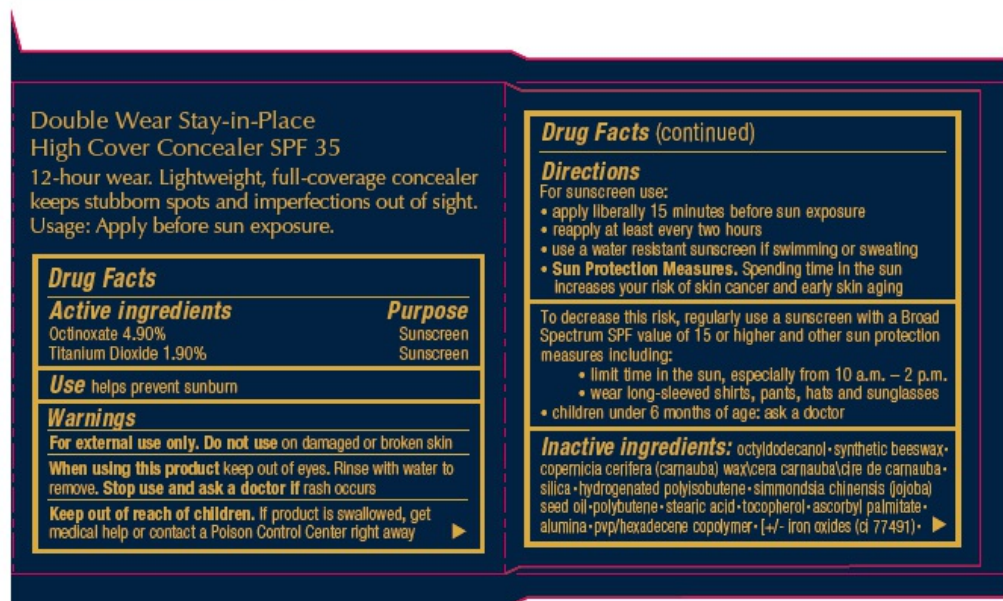
Inactive ingredients

octyldodecanol•synthetic beeswax•copernicia cerifera (carnauba) wax\cera carnauba\cire de carnauba•silica•hydrogenated polyisobutene•simmondsia chinensis (jojoba) seed oil•polybutene•stearic acid•tocopherol•ascorbyl palmitate•alumina•pvp/hexadecene copolymer•[+/- iron oxides (ci 77491)•iron oxides (ci 77492)•iron oxides (ci 77499)•titanium dioxide (ci 77891)•chromium oxide greens (ci 77288)•chromium hydroxide green (ci 77289)] <iln40218>

Other information

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

PRINCIPAL DISPLAY PANEL - 3g Jar Carton**ESTÉE LAUDER****Double Wear****Stay-in-Place****High Cover Concealer****Broad Spectrum SPF 35****NET WT. .1 OZ./3g**



DOUBLE WEAR STAY IN PLACE HIGH COVER CONCEALER BROAD SPECTRUM SPF 35

octinoxate and titanium dioxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11559-036

Route of Administration	TOPICAL
--------------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.9 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
octyldodecanol (UNII: 461N1O614Y)	
carnauba wax (UNII: R12CBM0EIZ)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
jojoba oil (UNII: 724GKU717M)	
stearic acid (UNII: 4ELV7Z65AP)	
tocopherol (UNII: R0ZB2556P8)	
ascorbyl palmitate (UNII: QN83US2B0N)	
aluminum oxide (UNII: LM26O6933)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferrosoferric oxide (UNII: XM0M87F357)	
chromic oxide (UNII: X5Z09SU859)	
chromium hydroxide green (UNII: RV8FT8XF5R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11559-036-01	1 in 1 CARTON	07/01/2013	
1		3 g 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	07/01/2013	

Labeler - ESTEE LAUDER INC (005914387)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(11559-036) , REPACK(11559-036)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(11559-036)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(11559-036)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(11559-036)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(11559-036)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(11559-036) , REPACK(11559-036)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(11559-036) , REPACK(11559-036)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(11559-036)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(11559-036)