

PRESCRIPTIVES SITE UNSEEN BRIGHTENING CONCEALER BROAD SPECTRUM SPF 15- octinoxate, titanium dioxide, and zinc oxide liquid
PRESCRIPTIVES 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.

PRESCRIPTIVES
Site Unseen Brightening Concealer Broad Spectrum SPF 15

Drug Facts

Active ingredients

Octinoxate 4.10%
Titanium Dioxide 1.40%
Zinc Oxide 1.50%

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

water/aqua/eau • cyclopentasiloxane • dimethicone • phenyl trimethicone • dimethicone silylate • butylene glycol • peg/ppg-18/18 dimethicone • silica • yeast extract/faex/extrait de levure • ethylhexylglycerin • octyldodecyl neopentanoate • tocopheryl acetate • triethoxycaprylylsilane • glycerin • polysilicone-11 • magnesium sulfate • disteardimonium hectorite • dipeptide-2 • palmitoyl tetrapeptide-7 • sorbitan sesquioleate • acetyl hexapeptide-8 • polyglyceryl-6 polyricinoleate • laureth-7 • isopropyl titanium triisostearate • propylene carbonate • chamomilla recutita (matricaria) • hesperidin methyl chalcone • steareth-20 • alumina • chloroxylenol • phenoxyethanol • [+/- titanium dioxide (ci 77891)] • mica • iron oxides (ci 77491, ci 77492, ci 77499)] <iln32488>

Other information

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

DIST. NEW YORK, N.Y. 10022

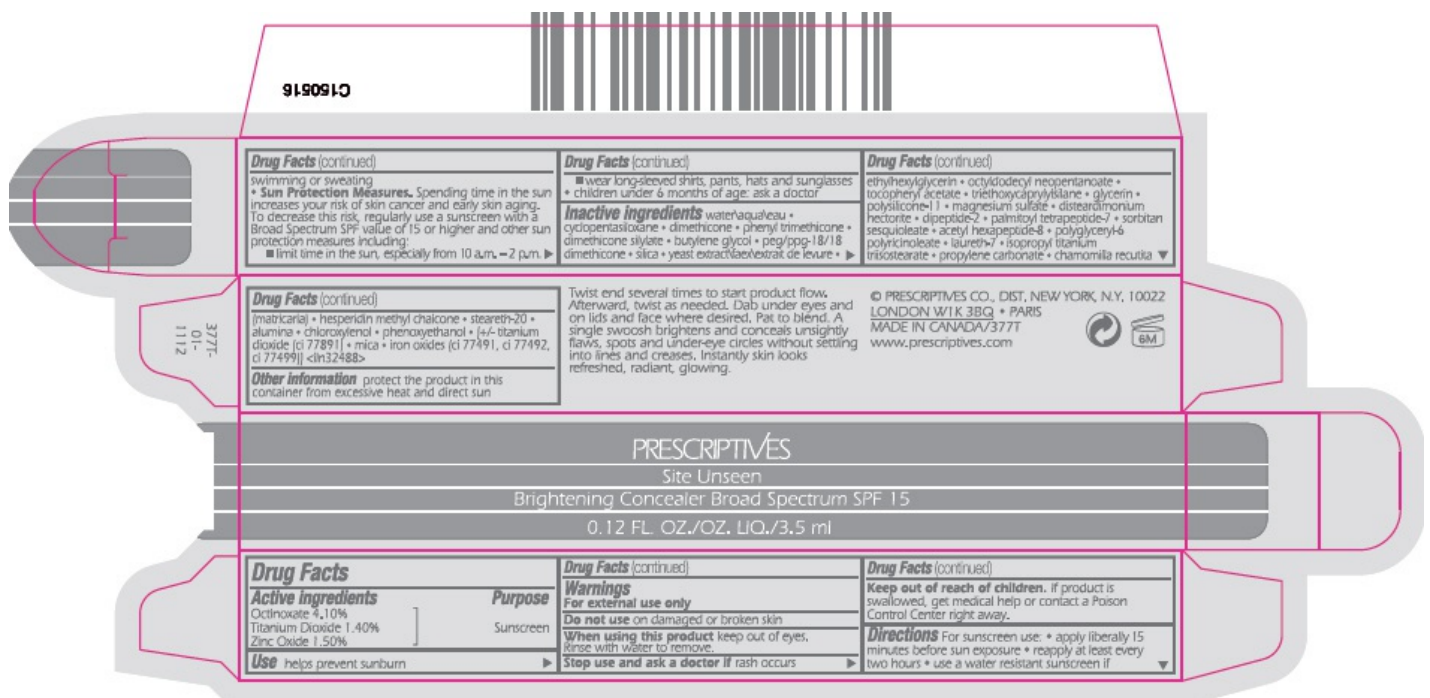
PRINCIPAL DISPLAY PANEL - 3.5 ml Carton

PRESCRIPTIVES

Site Unseen

Brightening Concealer Broad Spectrum SPF 15

0.12 FL. OZ./OZ. LIQ./3.5 ml



PRESCRIPTIVES SITE UNSEEN BRIGHTENING CONCEALER BROAD SPECTRUM SPF 15

octinoxate, titanium dioxide, and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59 158-9 13
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	.04551 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	.01554 g in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.01665 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
YEAST (UNII: 3NY3SM6B8U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
VALYLTRYPTOPHAN (UNII: 3G64B4AFQN)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWIL)	
LAURETH-7 (UNII: Z95S6G8201)	
ISOPROPYL TITANIUM TRIISO STEARATE (UNII: 949E3KBJ1I)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ)	
HESPERIDIN METHYLCHALCONE (UNII: 4T2GVA922X)	
STEARETH-20 (UNII: L0Q8IK9E08)	
ALUMINUM OXIDE (UNII: LM26O6933)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59158-913-01	1 in 1 CARTON		
1		3.5 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	11/16/2006	

Labeler - PRESCRIPTIVES INC. (151701588)

Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(59 158-9 13) , REPACK(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(59 158-9 13) , RELABEL(59 158-9 13) , REPACK(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Inc.		042918826	MANUFACTURE(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(59 158-9 13) , RELABEL(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
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NORTEC KEYSTONE		943871157	MANUFACTURE(59 158-9 13) , RELABEL(59 158-9 13) , REPACK(59 158-9 13)
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Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(59 158-9 13) , RELABEL(59 158-9 13) , REPACK(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(59 158-9 13) , RELABEL(59 158-9 13) , REPACK(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(59 158-9 13)

Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(59 158-9 13) , RELABEL(59 158-9 13)

Revised: 11/2012

PRESCRIPTIVES INC.