

**FLAWLESS SKIN TOTAL PROTECTION CONCEALER SPF 25- titanium dioxide paste
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.

FLAWLESS SKIN TOTAL PROTECTION CONCEALER SPF 25

Usage

Apply before sun exposure.

WARNING

Keep out of eyes.

Stop use if irritation occurs.

Keep out of reach of children.

ACTIVE INGREDIENT

TITANIUM DIOXIDE 4.20%

INGREDIENTS

ISOCETYL MYRISTATE • METHYL METHACRYLATE CROSSPOLYMER • DIISOSTEARYL MALATE • COPERNICIA CERIFERA (CARNAUBA) WAX\CERA CARNAUBA\CIRE DE CARNAUBA • POLYGLYCERYL-2 OLEATE • EUPHORBIA CERIFERA (CANDELILLA) WAX\CANDELILLA CERA\CIRE DE CANDELILLA • POLYETHYLENE • GLYCINE SOJA (SOYBEAN) OIL • TOCOPHERYL ACETATE • PORIA COCOS SCLEROTIUM EXTRACT • ISOPROPYL TITANIUM TRIISOSTEARATE • ROSMARINUS OFFICINALIS (ROSEMARY) EXTRACT • SODIUM RNA • PHYTOSPHINGOSINE • SANTALUM ALBUM SEED EXTRACT • HYDROGENATED COTTONSEED OIL • ALLYL METHACRYLATES CROSSPOLYMER • SILICA • DIMETHICONE • DIMETHICONE SILYLATE • ALUMINA • TIN OXIDE • BHT • [+/- MICA • TITANIUM DIOXIDE (CI 77891) • IRON OXIDES (CI 77491, CI 77492, CI 77499)] <ILN33642>

PRESCRIPTIVES CO., DIST.
NEW YORK, N.Y. 10022

PRINCIPAL DISPLAY PANEL - 3.5g Container Carton

PX

PRESCRIPTIVES

Flawless Skin

**Total Protection Concealer
UVA/UVB SPF 25**

Net Wt./Poids Net . 11 Oz. / 3.5g e

Px
PRESCRIPTIVES

Flawless Skin

Total Protection Concealer
UVA/UVB SPF 25

Cache-Cernes Protection Totale

Net Wt./Poids Net .11 Oz. / 3.5g e

36H1-
01-
1113

This seamless, long-wearing formula includes the complete protection benefits of broad spectrum UVA/UVB SPF 25 and advanced anti-aging ingredients, which help reduce the appearance of dark circles, puffiness, and redness. Skin looks beautiful, healthy...truly flawless. Waterproof.



Usage: Apply before sun exposure.

WARNING: Keep out of eyes. Stop use if irritation occurs. Keep out of reach of children.

Cette formule longue tenue impeccable allie un écran solaire FPS 25 UVA / UVB à large spectre doté d'une protection complète à des ingrédients anti-âge évolués qui aident à atténuer l'apparence des cernes, des poches et des rougeurs. La peau respire d'un éclat sain... et parfaitement unifié. Résistant à l'eau.

Mode d'emploi : Appliquer avant l'exposition au soleil.

AVERTISSEMENT : Éviter tout contact avec les yeux. Cesser l'emploi en cas d'irritation. Garder hors de la portée des enfants.

ACTIVE INGREDIENT: TITANIUM DIOXIDE 4.20%

INGREDIENTS: ISOCETYL MYRISTATE ▪ METHYL METHACRYLATE CROSSPOLYMER ▪ DIISOSTEARYL MALATE ▪ COPERNICIA CERIFERA (CARNAUBA) WAX ▪ CERA CARNAUBA CIRE DE CARNAUBA ▪ POLYGLYCERYL-2 OLEATE ▪ EUPHORBIA CERIFERA (CANDELILLA) WAX ▪ CANDELILLA CERACIRE DE CANDELILLA ▪ POLYETHYLENE ▪ GLYCINE SOJA (SOYBEAN) OIL ▪ TOCOPHERYL ACETATE ▪ PORIA COCOS SCLEROTIUM EXTRACT ▪ ISOPROPYL TITANIUM TRIISOSTEARATE ▪ ROSMARINUS OFFICINALIS (ROSEMARY) EXTRACT ▪ SODIUM RNA ▪ PHYTOSPHINGOSINE ▪ SANTALUM ALBUM SEED EXTRACT ▪ HYDROGENATED COTTONSEED OIL ▪ ALLYL METHACRYLATES CROSSPOLYMER ▪ SILICA ▪ DIMETHICONE ▪ DIMETHICONE SILYLATE ▪ ALUMINA ▪ TIN OXIDE ▪ BHT ▪ [+/- MICA ▪ TITANIUM DIOXIDE (CI 77891) ▪ IRON OXIDES (CI 77491, CI 77492, CI 77499)] <ILN33642>

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NEW YORK, N.Y. 10022
LONDON W1K 3BQ ▪ PARIS ▪ MILANO
MADE IN JAPAN / 36H1
www.prescriptives.com



FLAWLESS SKIN TOTAL PROTECTION CONCEALER SPF 25

titanium dioxide paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59 158-9 14
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	4.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ISOCETYL MYRISTATE (UNII: 69 AX3BRR5N)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	

CARNAUBA WAX (UNII: R12CBM0EIZ)
CANDELILLA WAX (UNII: WL0328HX19)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
SOYBEAN OIL (UNII: 241ATL177A)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ISOPROPYL TITANIUM TRIISO STEARATE (UNII: 949E3KBJ1I)
ROSEMARY (UNII: IJ67X351P9)
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)
SANTALUM ALBUM SEED (UNII: 7RZT0U509Y)
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
DIMETHICONE (UNII: 92RU3N3Y1O)
ALUMINUM OXIDE (UNII: LM26O6933)
STANNIC OXIDE (UNII: KM7N50LOS6)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
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:59158-914-01	1 in 1 CARTON		
1		3.5 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	11/01/2005	

Labeler - PRESCRIPTIVES INC (151701588)

Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(59158-914) , REPACK(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(59158-914) , RELABEL(59158-914) , REPACK(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Inc.		042918826	MANUFACTURE(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(59158-914) , RELABEL(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(59158-914) , RELABEL(59158-914) , REPACK(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(59158-914) , RELABEL(59158-914) , REPACK(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(59158-914) , RELABEL(59158-914) , REPACK(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(59158-914)

Establishment

Name	Address	ID/FEI	Business Operations
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Pennsylvania Logistics Center		078364654	REPACK(59158-914) , RELABEL(59158-914)
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Establishment

Name	Address	ID/FEI	Business Operations
Toshiki Pigment Company Limited		690723812	MANUFACTURE(59158-914)

Revised: 9/2012

PRESCRIPTIVES INC