

THE RADIANT CONCEALER BROAD SPECTRUM SPF 25- titanium dioxide cream
MAX HUBER RESEARCH LAB 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.

THE RADIANT CONCEALER BROAD SPECTRUM SPF 25

Drug Facts

Active ingredient

Titanium Dioxide 4.65%

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 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 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

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 • aluminum hydroxide • polyethylene • tocopherol • tocopheryl acetate • rosmarinus officinalis (rosemary) extract • glycine soja (soybean) oil • phaeodactylum tricornotum extract • santalum album seed extract • poria cocos sclerotium extract • sodium rna • tourmaline • dimethicone silylate • dimethicone • calcium carbonate • malachite • phytosphingosine • caprylic/capric triglyceride • allyl methacrylates crosspolymer • bisabolol • pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate • isopropyl titanium triisostearate • hydrogenated cottonseed oil • tin oxide • alumina • silica • [+/-mica • titanium dioxide (ci 77891) • iron oxides (ci 77491, ci 77492, ci 77499)] <iln34940>

Other information

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

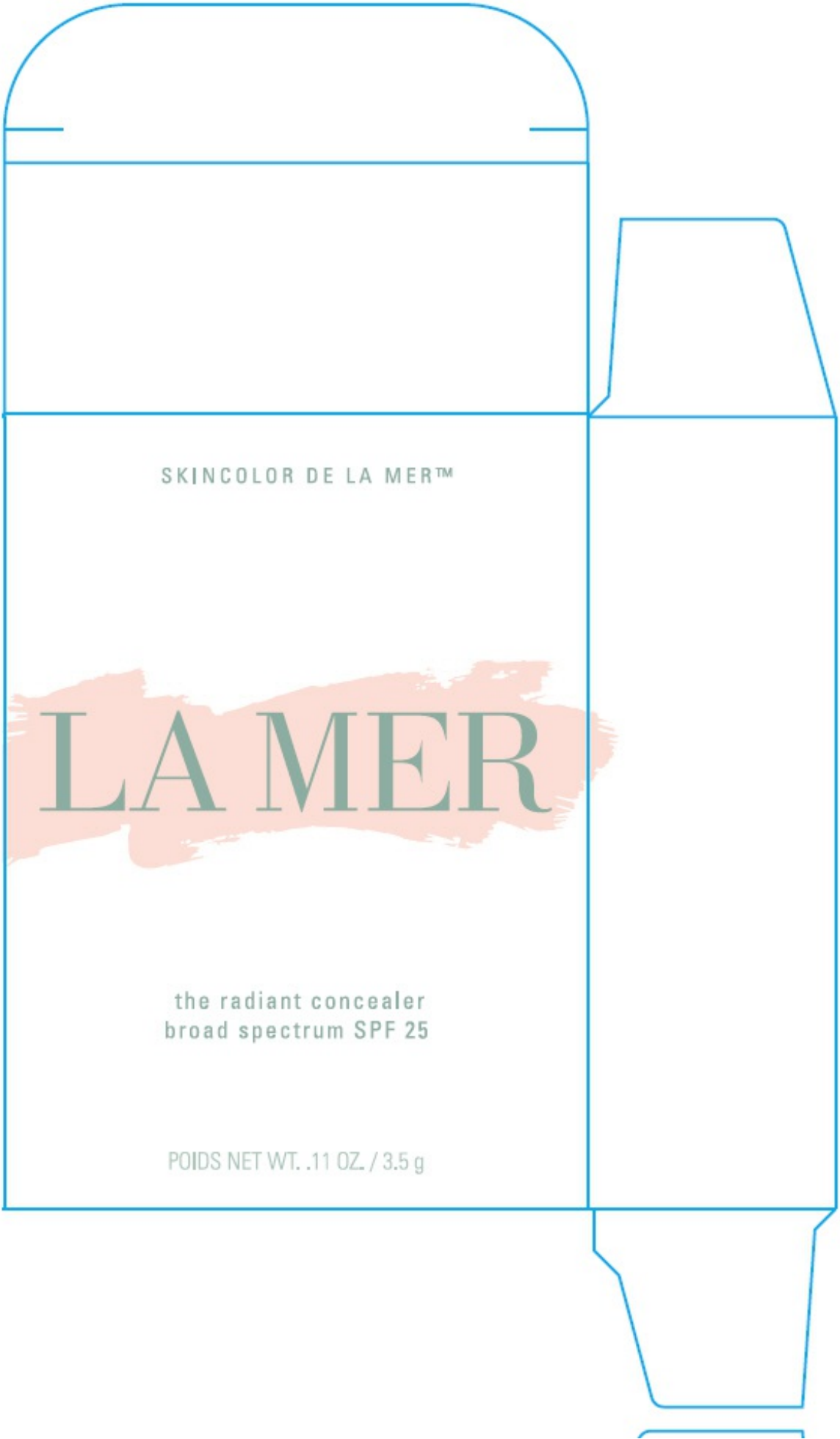
PRINCIPAL DISPLAY PANEL - 3.5 g Container Carton

SKINCOLOR DE LA MER™

LA MER

the radiant concealer
broad spectrum SPF 25

POIDS NET WT. .11 OZ. / 3.5 g



SKINCOLOR DE LA MER™

LA MER

the radiant concealer
broad spectrum SPF 25

POIDS NET WT. .11 OZ. / 3.5 g

2HML-01-1112
CN#B0479X1

The Radiant Concealer A treatment cream concealer that optically corrects dark circles and blemishes to create a naturally flawless finish.

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Drug Facts (continued)

polyethylene • tocopherol • tocopheryl acetate • rosmarinus officinalis (rosemary) extract • glycine soja (soybean) oil • phaeodactylum tricornutum extract • santalum album seed extract • poria cocos sclerotium extract • sodium ma • tourmaline • dimethicone silylate • dimethicone • calcium carbonate • malachite • phytosphingosine • caprylic/capric triglyceride • allyl methacrylates crosspolymer • bisabolol • pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate • isopropyl titanium triisostearate • hydrogenated cottonseed oil • tin oxide • alumina • silica • [+/- mica • titanium dioxide (ci 77891) • iron oxides (ci 77491, ci 77492, ci 77499)] <ln34940>

Other information

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MAX HUBER RESEARCH LABS INC., DIST.
NEW YORK, N.Y. 10022
LONDON W1K 3BQ • PARIS • MILANO
MADE IN JAPAN 2HML
www.LaMer.com



UPC/FPO

THE RADIANT CONCEALER BROAD SPECTRUM SPF 25

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65966-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	3.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
isocetyl myristate (UNII: 69AX3BRR5N)	
diisostearyl malate (UNII: QBS8A3XZGQ)	
carnauba wax (UNII: R12CBM0EIZ)	
candelilla wax (UNII: WL0328HX19)	
aluminum hydroxide (UNII: 5QB0T2IUN0)	
high density polyethylene (UNII: UG00KM4WR7)	
tocopherol (UNII: R0ZB2556P8)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
rosemary (UNII: IJ67X351P9)	
soybean oil (UNII: 241ATL177A)	
phaeodactylum tricornutum (UNII: Y5W63E7HLV)	
santalum album seed (UNII: 7RZT0U509Y)	
dimethicone (UNII: 92RU3N3Y1O)	
calcium carbonate (UNII: H0G9379FGK)	
phytosphingosine (UNII: GIN46U9Q2Q)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
levomenol (UNII: 24WE03BX2T)	
pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (UNII: 255PIF62MS)	
isopropyl titanium triisostearate (UNII: 949E3KBJ1I)	
hydrogenated cottonseed oil (UNII: Z82Y2C65EA)	
stannic oxide (UNII: KM7N50LOS6)	
aluminum oxide (UNII: LM26O6933)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
mica (UNII: V8A1AW0880)	
ferric oxide red (UNII: 1K09F3G675)	
ferric oxide yellow (UNII: EX438O2MRT)	
ferrosoferric oxide (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65966-015-01	1 in 1 CARTON		

1	3.5 g in 1 CONTAINER; 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	05/01/2014	

Labeler - MAX HUBER RESEARCH LAB INC (926708694)

Establishment			
Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(65966-015) , REPACK(65966-015)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(65966-015) , REPACK(65966-015)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(65966-015)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(65966-015)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(65966-015)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(65966-015)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(65966-015) , REPACK(65966-015)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC LLC		959338336	MANUFACTURE(65966-015)

Establishment			
Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(65966-015) , REPACK(65966-015)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(65966-015)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(65966-015)

Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center (PALC)		078364654	REPACK(65966-015) , RELABEL(65966-015)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(65966-015)

Establishment

Name	Address	ID/FEI	Business Operations
Toshiki Pigment Company Limited		716140285	MANUFACTURE(65966-015)

Revised: 5/2015

MAX HUBER RESEARCHLAB INC