

CLE DE PEAU BEAUTE CORRECTING VEIL N- ensulizole, octinoxate, and titanium dioxide cream

SHISEIDO AMERICAS CORPORATION

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.

CLÉ DE PEAU BEAUTÉ CORRECTING CREAM VEIL n

Drug Facts

Active ingredients	Purpose
Ensulizole 1.0%	Sunscreen
Octinoxate 2.9%	Sunscreen
Titanium Dioxide 2.4	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
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- **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 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-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: ask a doctor

Inactive Ingredients

WATER•DIMETHICONE•BUTYLENE GLYCOL•GLYCERIN•ISOHEXADECANE•SD ALCOHOL 40-B•POLYMETHYLSILSESQUIOXANE•PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE•NYLON-12•TRIISOSTEARIN•DISTEARDIMONIUM HECTORITE•ERYTHRITOL•CETYL ETHYLHEXANOATE•XYLITOL•SILICA•ISODECYL

NEOPENTANOATE▪TRIMETHYLSILOXYSILICATE▪TREHALOSE▪GLYCINE▪PEG/PPG-14/7
DIMETHYL ETHER▪ROSA ROXBURGHII FRUIT EXTRACT▪ANGELICA ACUTILOBA ROOT
EXTRACT▪HYDROLYZED CONCHIOLIN PROTEIN▪HYDROLYZED
SILK▪DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER▪PERILLA OCYMOIDES LEAF
EXTRACT▪TRIETHANOLAMINE▪ISOSTEARIC ACID▪ALUMINUM HYDROXIDE▪STEARIC
ACID▪DISODIUM EDTA▪BHT▪POLYSILICONE-
2▪TOCOPHEROL▪TRIETHOXYCAPRYLYLSILANE▪SODIUM CITRATE▪BARIUM
SULFATE▪THEANINE▪CITRIC ACID▪METHYL METHACRYLATE
CROSSPOLYMER▪PHENOXYETHANOL▪FRAGRANCE▪TITANIUM DIOXIDE▪IRON
OXIDES▪MICA▪

Other information

Protect this product in this container from excessive heat and direct sun.

Questions or comments?

Call toll free 1-800-906-7503

PRINCIPAL DISPLAY PANEL - 37 mL Bottle Carton

clé de peau

BEAUTÉ

CORRECTING
CREAM VEIL n

BROAD SPECTRUM
SPF 21
SUNSCREEN

37mL NET WT. 1.4 OZ.

CORRECTING CREAM VEIL n



clé de peau
BEAUTÉ

CORRECTING
CREAM VEIL n
BROAD SPECTRUM
SPF 21
SUNSCREEN

Drug Facts
(continued)

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours

■ **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 of 15 or higher and other sun protection measures including:

- limit time in the sun, especially

Drug Facts
(continued)

Inactive Ingredients

ISODECYL NEOPENTANOATE-TRIMETHYLSILOXYLICATE-TREHALOSE-GLYCINE-PEG/PPG-14/7 DIMETHYL ETHER-ROSA ROXBURGHII FRUIT EXTRACT-ANGELICA ACUTILOBA ROOT EXTRACT-HYDROLYZED CONCHILIN PROTEIN-HYDROLYZED SILK-DIMETHICONE/VINYL DIMETHICONE-CROSSPOLYMER-PERILLA OCYMOIDES LEAF EXTRACT-TRIETHANOLAMINE-ISOSTEARIC ACID-ALUMINUM HYDROXIDE-STEARIC ACID-DISODIUM EDTA-BHT-POLYSILICONE-2-TOCOPHEROL-TRIETHOXYCAPRYLYLSILANE-SODIUM CITRATE-BARIUM SULFATE-THIAMINE-CITRIC ACID-METHYL METHACRYLATE

sun, especially
from 10 a.m. -2
p.m.

• wear
long-sleeve
shirts, pants,
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sunglasses

■ children under 6
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doctor

Inactive Ingredients

WATER • DIMETHICONE •
BUTYLENE GLYCOL •
GLYCERIN • ISOHEXADECANE •
SD ALCOHOL 40-B •
POLYMETHYLSILSESQUOX-
ANE •
PEG-9
POLYDIMETHYLSILOXYETH-
YL DIMETHICONE •
NYLON-12 • TRIISOSTEARIN •
DISTEARDIMONIUM
HECTORITE •
ERYTHRITOL •
CETYL ETHYLHEXANOATE •
XYLITOL • SILICA ▶

CROSSPOLYMER •
PHENOXYETHANOL •
FRAGRANCE •
TITANIUM DIOXIDE •
IRON OXIDES • MICA

Other Information

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and direct sun.

Questions or Comments?

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QRコード

<http://cpb1982.com/16182CP>

See our website
for more information.

37mL NET WT. 1.4 OZ.

7 30852 16182 5

縮小サイズ0.85倍 6mm/片
12mm×33mm

16182-41-5040
AAA



CLÉ DE PEAU
BEAUTÉ
CORRECTING CREAM VEIL n
BROAD SPECTRUM SPF 21
SUNSCREEN

**Define your most radiant,
most colorful life.**

A universal skincare primer that instantly diffuses dullness and blurs skin's imperfections for a smooth, refreshed finish.

- A hybrid of makeup and skincare, exclusive **Light-Empowering Enhancer** amplifies your radiant finish.
- Formulated with **Skin-Empowering Illuminator**, our exclusive skincare ingredient.
- Reducing the quantity of application will lower the level of sunscreen protection significantly.
- NON-COMEDOGENIC.
DERMATOLOGIST-TESTED.

Drug Facts

Active Ingredients Purpose

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OCTINOXATE 2.9%	Sunscreen
TITANIUM DIOXIDE 2.4%	Sunscreen

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CLE DE PEAU BEAUTE CORRECTING VEIL N

ensulizole, octinoxate, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-483
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	0.386 g in 37 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.119 g in 37 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.9264 g in 37 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X10UF1E)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
NYLON-12 (UNII: 446U8J075B)	
TRIISOSTEARIN (UNII: 71503RH8KG)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ERYTHRITOL (UNII: RA96B954X6)	
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)	
XYLITOL (UNII: VCQ006KQ1E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
TREHALOSE (UNII: B8WCK70T7I)	
GLYCINE (UNII: TE7660XO1C)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	

ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)
ANGELICA ACUTILOBA ROOT (UNII: 3W51R3EK30)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
PERILLA FRUTESCENS LEAF (UNII: T4L5881Y68)
TROLAMINE (UNII: 9O3K93S3TK)
ISO STEARIC ACID (UNII: X33R8U0062)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
STEARIC ACID (UNII: 4ELV7Z65AP)
EDETATE DISODIUM (UNII: 7FLD91C86K)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)
BARIUM SULFATE (UNII: 25BB7EKE2E)
THEANINE (UNII: 8021PR16QO)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: 657L0NC5MT)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-483-10	1 in 1 CARTON	03/01/2020	
1		37 mL in 1 BOTTLE; 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	03/01/2020	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICAS INC.		782677132	MANUFACTURE(58411-483) , ANALYSIS(58411-483)