

JUNGSAEMMOOL ESSENTIAL SKIN NUDER CUSHION MEDIUM DEEP- titanium dioxide, octinoxate, octisalate cream

Jungsaemmoool Beauty Co., Ltd.

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.

71261-003_JUNGSAEMMOOL Essential Skin Nuder Cushion Medium Deep

Titanium Dioxide 13.19%

Octinoxate 6.70%

Octisalate 4.00%

Sunscreen

Helps prevent sunburn

Apply liberally 15 minutes before sun exposure. Reapply at least every two 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: 1) Limited time in the sun, especially from 10 am to 2 pm. 2) Wear long-sleeve shirts, pants, hats, and sunglasses

Wear long-sleeve shirts, pants, hats, and sunglasses

Ask a doctor to use for children under 6 months

For external use only

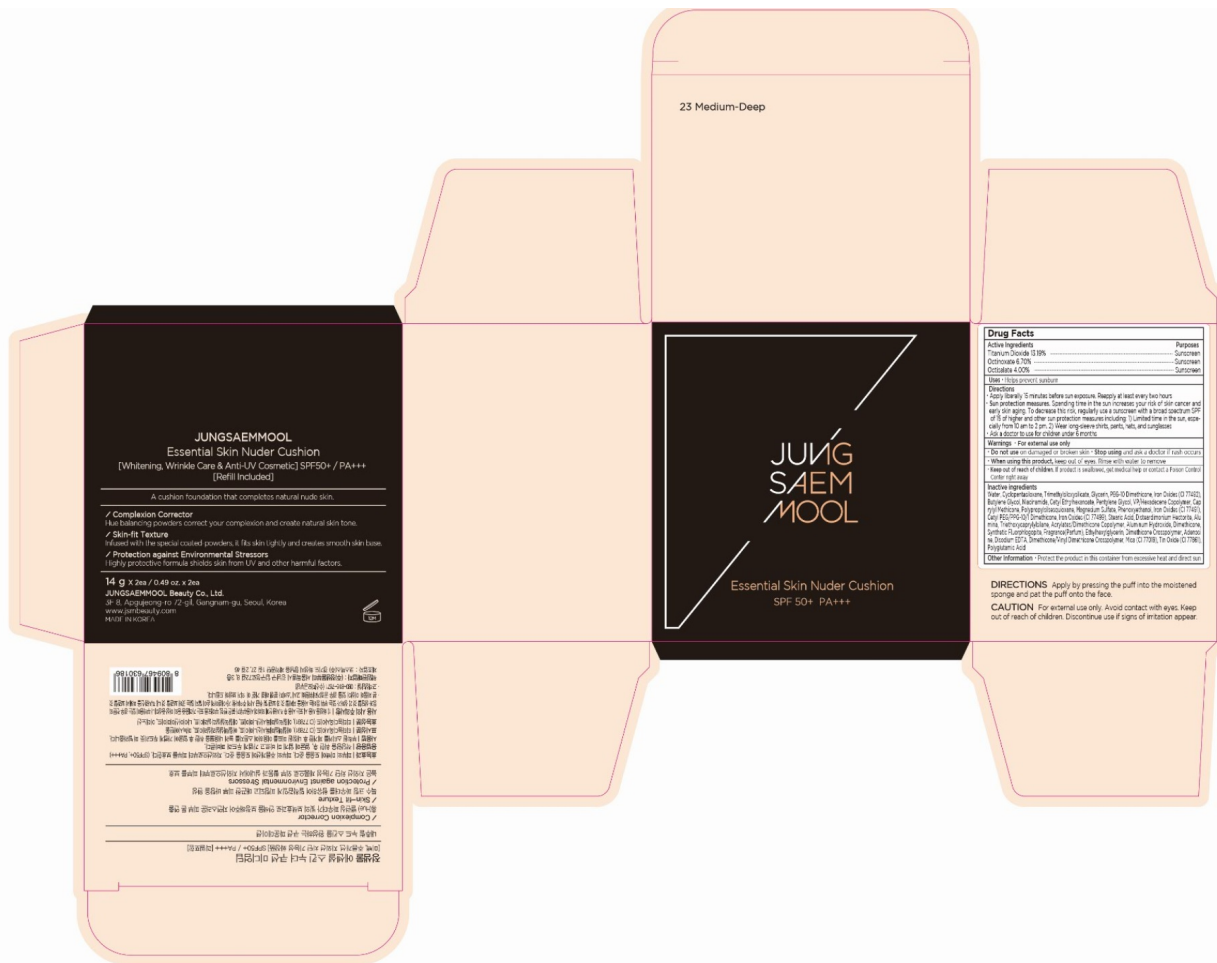
Do not use on damaged or broken skin

When using this product, keep out of eyes. Rinse with water to remove.

Stop using and ask a doctor if rash occurs.

Water, Cyclopentasiloxane, Trimethylsiloxysilicate, Glycerin, PEG-10 Dimethicone, Iron Oxides (CI 77492), Butylene Glycol, Niacinamide, Cetyl Ethylhexanoate, Pentylene Glycol, VP/Hexadecene Copolymer, Caprylyl Methicone, Polypropylsilsesquioxane, Magnesium Sulfate, Phenoxyethanol, Iron Oxides (CI 77491), Cetyl PEG/PPG-10/1 Dimethicone, Iron Oxides (CI 77499), Stearic Acid, Disteardimonium Hectorite, Alumina, Triethoxycaprylylsilane, Acrylates/Dimethicone Copolymer, Aluminum Hydroxide, Dimethicone, Synthetic Fluorphlogopite, Fragrance(Parfum), Ethylhexylglycerin, Dimethicone Crosspolymer, Adenosine, Disodium EDTA, Dimethicone/Vinyl Dimethicone Crosspolymer, Mica (CI 77019), Tin Oxide (CI 77861), Polyglutamic Acid

Protect the product in the container from excessive heat and direct sun



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titanium dioxide, octinoxate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71261-003
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	131.9 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	67 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	

GLYCERIN (UNII: PDC6A3C0OX)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
NIACINAMIDE (UNII: 25X51I8RD4)
CETYL ETHYLHEXANO ATE (UNII: 134647WMX4)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)
CAPRYL YL TRISILOXANE (UNII: Q95M2P1KJL)
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
STEARIC ACID (UNII: 4ELV7Z65AP)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
ALUMINUM OXIDE (UNII: LM26O6933)
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
DIMETHICONE (UNII: 92RU3N3Y1O)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
DIMETHICONE CROSSPOLYMER (45000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
ADENOSINE (UNII: K72T3FS567)
EDETATE DISODIUM (UNII: 7FLD91C86K)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)
MICA (UNII: V8A1AW0880)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71261-003-02	1 in 1 CARTON	10/16/2020	
1	NDC:71261-003-01	14 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	10/16/2020	

Labeler - Jungsaemmoool Beauty Co., Ltd. (694214725)

Registrant - Jungsaemmoool Beauty Co., Ltd. (694214725)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc		689049693	manufacture(71261-003)

