

JUNGSAEMMOOL SKIN NUDER COVER LAYER CUSHION MEDIUM- titanium dioxide, octinoxate, octisalate cream
Jungsaemmool 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.

71261-024 JUNGSAEMMOOL Skin Nuder Cover Layer Cushion Medium

Titanium Dioxide 19.34%

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

Ask a doctor to use for children under 6 months

For external use only

Do not use on damaged or broken skin

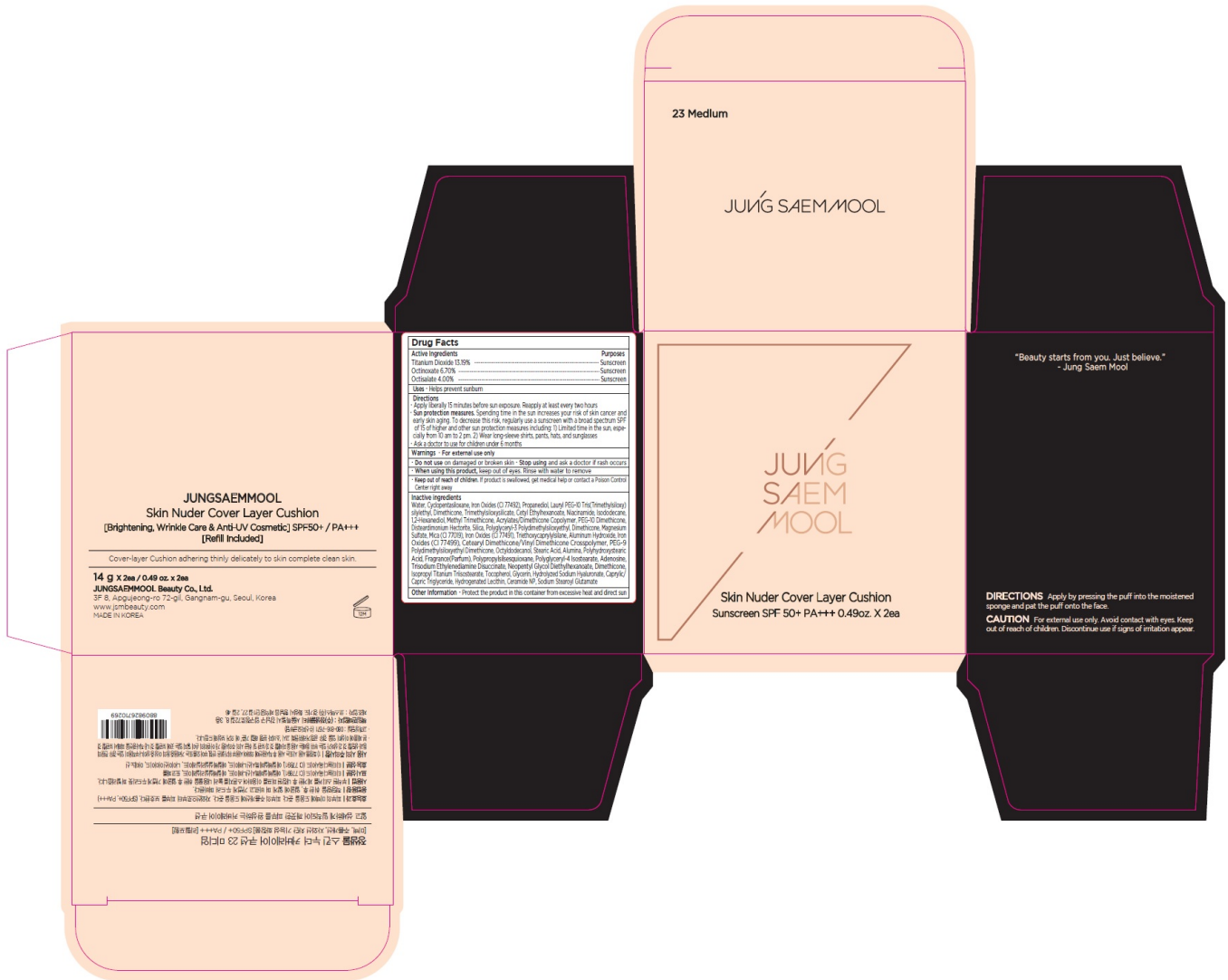
When using this product, keep out of eyes. Rinse with water to remove.

Stop using and ask a doctor if rash occurs.

Keep out of reach of the children. If product is swallowed, get medical help or contact a poison control center right away.

Water, Cyclopentasiloxane, Iron Oxides (CI 77492), Propanediol, Lauryl PEG-10 Tris(trimethylsiloxy)silylethyl, Dimethicone, Trimethylsiloxysilicate, Cetyl Ethylhexanoate, Niacinamide, Isododecane, 1,2-Hexanediol, Methyl Trimethicone, Acrylates/Dimethicone Copolymer, PEG-10 Dimethicone, Distearidimonium Hectorite, Silica, Polyglyceryl-3 Polydimethylsiloxyethyl, Dimethicone, Magnesium Sulfate, Mica (CI 77019), Iron Oxides (CI 77491), Triethoxycaprylylsilane, Aluminum Hydroxide, Iron Oxides (CI 77499), Cetearyl Dimethicone/Vinyl Dimethicone Crosspolymer, PEG-9 Polydimethylsiloxyethyl Dimethicone, Octyldodecanol, Stearic Acid, Alumina, Polyhydroxystearic Acid, Fragrance(Parfum), Polypropylsilsesquioxane, Polyglyceryl-4 Isostearate, Adenosine, Trisodium Ethylenediamine Disuccinate, Neopentyl Glycol Diethylhexanoate, Dimethicone, Isopropyl Titanium Triisostearate, Tocopherol, Glycerin, Hydrolyzed Sodium Hyaluronate, Caprylic/Capric Triglyceride, Hydrogenated Lecithin, Ceramide NP, Sodium Stearoyl Glutamate

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



JUNGSAEMMOOL SKIN NUDER COVER LAYER CUSHION MEDIUM

titanium dioxide, octinoxate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71261-024
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	193.4 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	67 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
PROPANEDIOL (UNII: 5965N8W85T)
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)
CETYL ETHYLHEXANOATE (UNII: 134647VMX4)
NIACINAMIDE (UNII: 25X5118RD4)
ISODODECANE (UNII: A8289P68Y2)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)
MICA (UNII: V8A1AW0880)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
FERRIC OXIDE RED (UNII: 1K09F3G675)
STEARIC ACID (UNII: 4ELV7Z65AP)
ALUMINUM OXIDE (UNII: LMI26O6933)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
OCTYLDODECANOL (UNII: 461N1O614Y)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)
ADENOSINE (UNII: K72T3FS567)
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)
DIMETHICONE (UNII: 92RU3N3Y1O)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KBJ1I)
TOCOPHEROL (UNII: R0ZB2556P8)
GLYCERIN (UNII: PDC6A3C0OX)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
CERAMIDE NP (UNII: 4370DF050B)
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71261-024-02	2 in 1 CARTON	03/28/2022	
1	NDC:71261-024-01	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 final	part352	03/28/2022	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc		689049693	manufacture(71261-024)

Revised: 3/2022

Jungsaemmool Beauty Co., Ltd.