

**JUNGSAEMMOOL ESSENTIAL SKIN NUDER 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.*

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**71261-002 JUNGSAEMMOOL Essential Skin Nuder Cushion Medium**

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

Ask a doctor to use for children under 6 months

For external use only

Do not use on damaged or broken skin

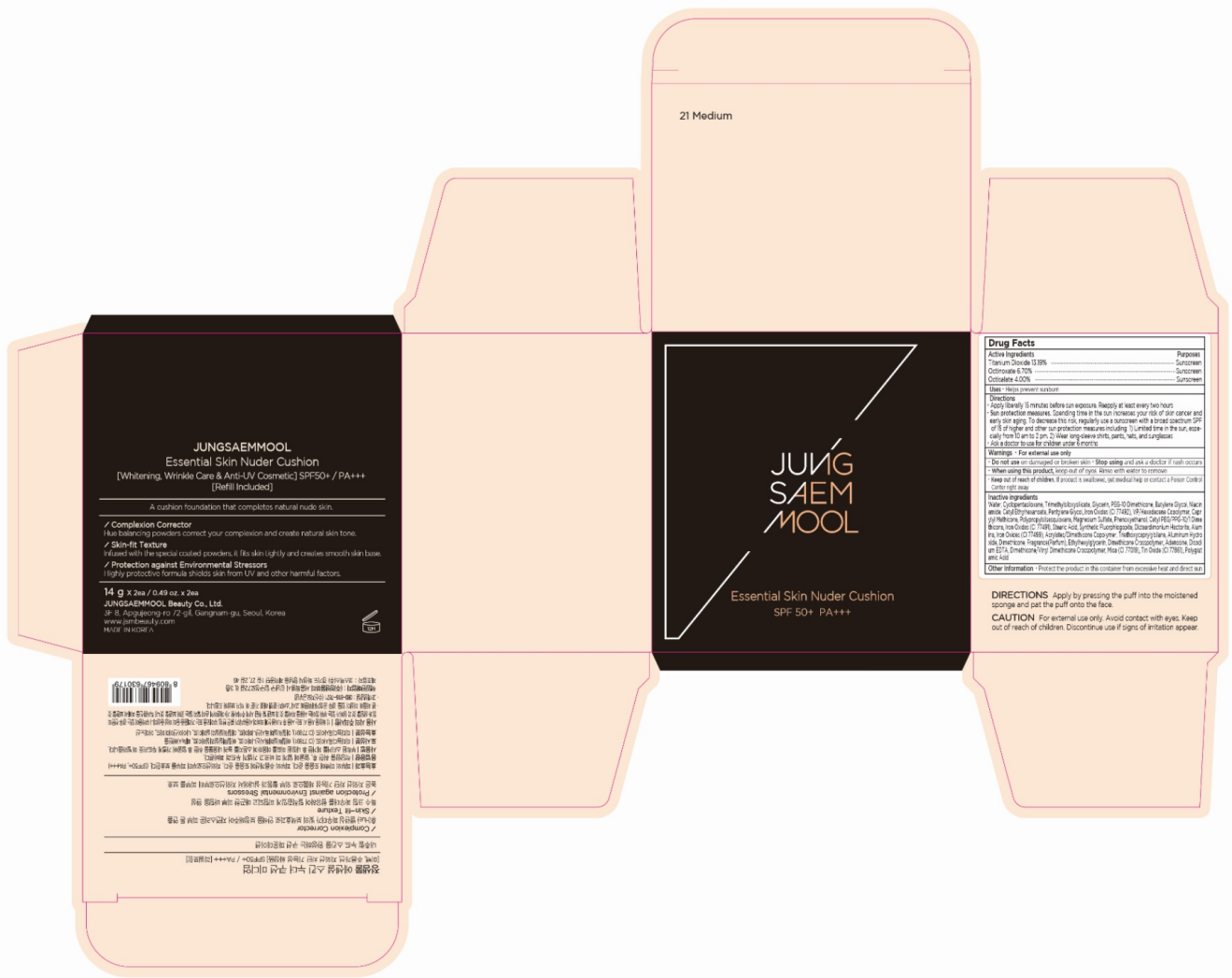
When using this product, keep out of eyes. Rinse with water to remove.

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, Trimethylsiloxysilicate, Glycerin, PEG-10 Dimethicone, Butylene Glycol, Niacinamide, Cetyl Ethylhexanoate, Pentylene Glycol, Iron Oxides (CI 77492), VP/Hexadecene Copolymer, Caprylyl Methicone, Polypropylsilsesquioxane, Magnesium Sulfate, Phenoxyethanol, Cetyl PEG/PPG-10/1 Dimethicone, Iron Oxides (CI 77491), Stearic Acid, Synthetic Fluorophlogopite, Distearidimonium Hectorite, Alumina, Iron Oxides (CI 77499), Acrylates/Dimethicone Copolymer, Triethoxycaprylylsilane, Aluminum Hydroxide, Dimethicone, 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



# JUNGSAEMMOOL ESSENTIAL SKIN NUDER CUSHION MEDIUM

titanium dioxide, octinoxate, octisalate cream

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:71261-002 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE  | 131.9 mg in 1 g |
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)             | OCTINOXATE        | 67 mg in 1 g    |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)             | OCTISALATE        | 40 mg in 1 g    |

## Inactive Ingredients

| Ingredient Name                 | Strength |
|---------------------------------|----------|
| <b>WATER</b> (UNII: 059QF0KO0R) |          |

|  |
|--|
| <b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)   |
| <b>TRIMETHYLSILOXSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)                                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |
| <b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V15VM0)   |
| <b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)  |
| <b>NIACINAMIDE</b> (UNII: 25X51I8RD4)  |
| <b>CETYL ETHYLHEXANOATE</b> (UNII: 134647WMX4)   |
| <b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)   |
| <b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)  |
| <b>VINYLPYRROLIDONE/HEXADECENE COPOLYMER</b> (UNII: KFR5QEN0N9)                                |
| <b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)   |
| <b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)                                  |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)   |
| <b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)</b> (UNII: V2W71V8T0X)                               |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)   |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)   |
| <b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)  |
| <b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)   |
| <b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)   |
| <b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)  |
| <b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)   |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y10)  |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)   |
| <b>DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6) |
| <b>ADENOSINE</b> (UNII: K72T3FS567)  |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)   |
| <b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE)</b> (UNII: H895X08VNQ)           |
| <b>MICA</b> (UNII: V8A1AW0880)   |
| <b>STANNIC OXIDE</b> (UNII: KM7N50LOS6)  |

### Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71261-002-02 | 1 in 1 CARTON  | 10/16/2020           |                    |
| 1 | NDC:71261-002-01 | 14 g in 1 CONTAINER; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:71261-002-04 | 2 in 1 CARTON  | 10/16/2020           |                    |
| 2 | NDC:71261-002-03 | 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** - Jungsaemmool Beauty Co., Ltd. (694214725)

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

**Establishment**

| Name        | Address | ID/FEI    | Business Operations    |
|-------------|---------|-----------|------------------------|
| Cosmax, Inc |         | 689049693 | manufacture(71261-002) |

Revised: 7/2021

Jungsaemmool Beauty Co., Ltd.