

JUNGSAEMMOOL ESSENTIAL SKIN NUDER LONGWEAR CUSHION MEDIUM DEEP-titanium dioxide, octinoxate, zinc oxide, 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.

71261-014 JUNGSAEMMOOL Essential Skin Nuder Longwear Cushion Medium Deep

Titanium Dioxide 9.6%

Octinoxate 7.0%

Zinc Oxide 4.9%

Octisalate 4.5%

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, Methyl Methacrylate Crosspolymer, Butylene Glycol, Methyl Trimethicone, Dimethicone, Glycerin, Niacinamide, Pentylene Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Iron Oxides (CI 77492), Caprylyl Methicone, Butylene Glycol Dicaprylate/Dicaprate, PEG/PPG-17/6 Copolymer, Silica, Lauryl PEG-10 Tris(trimethylsiloxy)silylethyl Dimethicone, Magnesium Sulfate, Phenoxyethanol, Sorbitan Isostearate, Aluminum Hydroxide, Iron Oxides (CI 77491), Dimethicone/Vinyl Dimethicone Crosspolymer, Distearidimonium Hectorite, Stearic Acid, Iron Oxides (CI 77499), Triethoxycaprylylsilane, Fragrance(Parfum), Ethylhexylglycerin, Adenosine, Trisodium Ethylenediamine Disuccinate, Camellia Sinensis Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil, Ceramide NP, Helianthus Annuus (Sunflower) Seed Oil, Panthenol, Jasminum Officinale (Jasmine) Flower/Leaf Extract, Nelumbo Nucifera Flower Extract, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Tocopherol, Freesia Refracta Extract, Iris Ensata Extract, Iris Versicolor Extract, Leontopodium Alpinum Flower/Leaf Extract, Lilium Candidum Bulb Extract, Narcissus Pseudonarcissus (Daffodil) Flower

Extract, Rose Extract

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



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Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71261-014 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 96 mg in 1 g |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 70 mg in 1 g |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 49 mg in 1 g |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 45 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

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|--|
| WATER (UNII: 059QF0KO0R) |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) |
| METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q) |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) |
| METHYL TRIMETHICONE (UNII: S73ZQI0GXM) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| NIACINAMIDE (UNII: 25X51I8RD4) |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) |
| CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL) |
| BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: 75D21FL1PI) |
| PEG/PPG-17/6 COPOLYMER (UNII: P5QZM4T259) |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) |
| MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNO) |
| SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4) |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) |
| FERRIC OXIDE RED (UNII: 1K09F3G675) |
| STEARIC ACID (UNII: 4ELV7Z65AP) |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) |
| ADENOSINE (UNII: K72T3FS567) |
| EDETATE DISODIUM (UNII: 7FLD91C86K) |
| CAMELLIA SINENSIS SEED OIL (UNII: O5R6DK2M9K) |
| SAFFLOWER OIL (UNII: 65UEH262IS) |
| CERAMIDE NP (UNII: 4370DF050B) |
| SUNFLOWER OIL (UNII: 3W1JG795YI) |
| PANTHENOL (UNII: WW9CM0O67Z) |
| JASMINUM OFFICINALE FLOWER (UNII: 0Q8K841432) |
| NELUMBO NUCIFERA FLOWER (UNII: 61W322NLDV) |
| IRIS VERSICOLOR ROOT (UNII: X43D4L3DQC) |
| LEONTOPODIUM NIVALE SUBSP. ALPINUM FLOWERING TOP (UNII: QQC1AK06RK) |
| LILIUM CANDIDUM BULB (UNII: AHG15J8AM0) |
| NARCISSUS PSEUDONARCISSUS FLOWER (UNII: L879RBF1WN) |
| TOCOPHEROL (UNII: ROZB2556P8) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71261-014-02 | 2 in 1 CARTON | 07/20/2020 | |
| 1 | NDC:71261-014-01 | 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 | 07/20/2020 | |

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

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Cosmax, Inc | | 689049693 | manufacture(71261-014) |

Revised: 7/2023

Jungsaemmool Beauty Co., Ltd.