

JUNGSAEMMOOL ESSENTIAL SKIN NUDER LONGWEAR CUSHION FAIR LIGHT-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.

71261-011 JUNGSAEMMOOL Essential Skin Nuder Longwear Cushion Fair Light

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, Silica, Caprylyl Methicone, Butylene Glycol Dicaprylate/Dicaprate, PEG/PPG-17/6 Copolymer, Lauryl PEG-10 Tris(trimethylsiloxy)silylethyl Dimethicone, Magnesium Sulfate, Phenoxyethanol, Sorbitan Isostearate, Aluminum Hydroxide, Iron Oxides (CI 77492), Dimethicone/Vinyl Dimethicone Crosspolymer, Disteardimonium Hectorite, Stearic Acid, Triethoxycaprylylsilane, Iron Oxides (CI 77491), Fragrance(Parfum), Iron Oxides (CI 77499), 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:71261-011
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
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CAMELLIA SINENSIS SEED OIL (UNII: O5R6DK2M9K)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CERAMIDE NP (UNII: 4370DF050B)	
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: 25X5118RD4)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PEG/PPG-17/6 COPOLYMER (UNII: P5QZM4T259)	
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)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ADENOSINE (UNII: K72T3FS567)	
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: L879RBF1VN)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
PANTHENOL (UNII: WW9CM0067Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71261-011-02	2 in 1 CARTON	07/16/2020	
1	NDC:71261-011-01	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	07/16/2020	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc		689049693	manufacture(71261-011)

Revised: 7/2023

Jungsaemmool Beauty Co., Ltd.