

DEW MINERAL- zinc oxide cream
ADVANCED AESTHETIC DERMATOLOGY

Active Ingredients

Zinc Oxide 20%

PURPOSE

SUNSCREEN

USES

Helps Prevent Sunburn. If used as directed with other sun protection measures (see "Directions"), decreases the risk of skin cancer and early skin aging caused by the sun.

WARNINGS

For external use only. Do not use on broken or damaged skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

WARNING

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS

Apply liberally 15 minutes before sun exposure. Use a water-resistant product if swimming or sweating. Reapply at least every 2 hours. Children under 6 months: Ask a doctor. 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 value of 15 or higher and other sun protection measures including: Limit time in the sun, especially from 10 a.m. - 2 p.m. Wear long-sleeved shirts, pants, hats and sunglasses.

INACTIVE INGREDIENTS

Bismuth Oxychloride, C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Iron Oxides, Mica, Microcrystalline

Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

OTHER INFORMATION

- Protect this product from excessive heat and direct sun • May stain some fabrics

DRUG FACTS (cont)
INACTIVE INGREDIENTS: Bismuth Oxychloride, C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Iron Oxides, Hydrogren Dimethicone, Mica, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

OTHER INFORMATION:

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Foto Facial[®]
Age Delay[™]
SKIN CARE PRODUCTS

PHYSICAL SUNSCREEN
UV A & B PROTECTION
SPF 40 DEWY TINTED

20% Zinc Oxide
Broad Spectrum
Water Resistant
(40 minutes)
Net Wt. 2.1 oz / 60 g

DRUG FACTS
ACTIVE INGREDIENTS: Zinc Oxide 20%
PURPOSE: Sunscreen
USES: Helps prevent sunburn. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early skin aging caused by the sun.
WARNINGS: For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
DIRECTIONS:
 • Apply liberally 15 minutes before sun exposure.
 • Reapply:
 • After 40 minutes of swimming or sweating
 • Immediately after towel drying
 • At least every 2 hours
 • Children under 6 months:
 Ask a doctor
• 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 value of 15 or higher and other sun protection measures including:
 • Limit time in the sun, especially from 10 am-2 pm
 • Wear long-sleeved shirts, pants, hats, and sunglasses

DEW MINERAL

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:87197-204(NDC:58892-204)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
CI 77491 (UNII: 1K09F3G675)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CI 77492 (UNII: EX438O2MRT)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
GLYCERIN (UNII: PDC6A3C0OX)	
CI 77499 (UNII: XM0M87F357)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87197-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/01/2023	

Labeler - ADVANCED AESTHETIC DERMATOLOGY (090257273)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(87197-204)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(87197-204)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(87197-204)

Revised: 12/2025

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