

ZINC OXIDE SPF 40 TINTED- zinc oxide cream

Skin Restoration Aesthetics

Active Ingredient:

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

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

Warning:

Keep out of the reach of children

DRUG FACTS

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MANUFACTURED FOR:

The Skin Restoration

San Jose, CA 95131 www.theskinrestoration.com 3 85296 20460 9



Zinc Oxide

SPF 40

tinted

spf 40 broad spectrum
water resistant (40 minutes)
sunscreen

Net Wt. 2.1 oz / 60 g

ZINC OXIDE SPF 40 TINTED

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85296-204
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
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
IRON OXIDES (UNII: 1K09F3G675)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
GLYCERIN (UNII: PDC6A3C0OX)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
MICA (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85296-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/18/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/18/2024	

Labeler - Skin Restoration Aesthetics (134407850)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85296-204)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85296-204)

Revised: 3/2025

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