

ULTRA ZINC MINERAL NON TINTED- zinc oxide cream

Skin Therapy Studio LLC

DRUG FACTS

ACTIVE INGREDIENT:	PURPOSE:
Zinc Oxide 20%	Sunscreen

USES:  
Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early 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 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:  
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, Hydrogren Dimethicone, 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

MANUFACTURED FOR:  
Skin Therapy Studio | Philadelphia, PA 19143  
Skintherapystudios@gmail.com



FOR PEOPLE WITH COLOR

EST. 2023

SPF  
40

ULTRA ZINC

MINERAL SUNSCREEN

Broad Spectrum  
Water Resistant (40 minutes)

Reef Friendly • Cruelty Free  
Non-Comedogenic

MADE BY AN ESTHETICIAN

Net Wt. 4 oz / 113 g

ULTRA ZINC MINERAL NON TINTED

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85357-205
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
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)			

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85357-205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/13/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/13/2024	

**Labeler** - Skin Therapy Studio LLC (113674755)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85357-205)

Establishment

Name	Address	ID/FEI	Business Operations
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Custom Analytics LLC		144949372	analysis(85357-205)
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Revised: 5/2025

Skin Therapy Studio LLC