

**20PERCENT ZINC OXIDE NON TINTED- zinc oxide cream**  
**JEFFREY J. ROTH, M.D., A PROFESSIONAL CORPORATION**

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 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  
 • 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 am- 2 pm  
 • Wear long sleeve shirts and 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  
 • May stain some fabrics.

Manufactured for:  
 Jeffrey J. Roth, M.D., F.A.C.S  
 6140 S. Fort Apache Rd. #100 Las Vegas NV, 89148  
 www.jjrothmd.com • (702)-450-0777



# Really Great Sunscreen

20% Zinc Oxide  
 Non-Tinted  
 SPF 40

UVA & UVB  
 Broad Spectrum  
 Water Resistant  
 (40 mins)

Face & Body  
 Great for Kids Too!

net wt. 4 oz | 113 g

RothMD  
 Medical Grade Sunscreen

## 20PERCENT ZINC OXIDE NON TINTED

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85585-205(NDC:58892-205)
<b>Route of Administration</b>	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
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	

<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z591F64N)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)
<b>PEG-30 DIPOLYHYDROXYSTEARATE</b> (UNII: 9713Q0S7FO)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>STEARYL DIMETHICONE (400 MPA.S AT 50C)</b> (UNII: R327X197HY)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85585-205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/03/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/03/2020	

**Labeler** - JEFFREY J. ROTH, M.D., A PROFESSIONAL CORPORATION (557562910)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85585-205)

### Establishment

Name	Address	ID/FEI	Business Operations
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Fragrance Manufacturing INC		793406000	manufacture(85585-205)
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## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85585-205)

Revised: 12/2025

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