

**ULTIMATE PHYSICAL SUNSCREEN TINTED- zinc oxide cream**  
**HALEM DERMATOLOGY PLLC**

**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:**

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

Manufactured for: Monica Halem MD  
 New York, NY 10075 | 212-988-2400



MONICA  
 HALEM  
 M.D.  
 NEW YORK

**ULTIMATE  
 PHYSICAL  
 SUNSCREEN**

**TINTED**

**BROAD SPECTRUM SPF 40  
 WATER RESISTANT (40 MINS)**

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 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

**ULTIMATE PHYSICAL SUNSCREEN TINTED**

zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85413-204(NDC:58892-204)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85413-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/12/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/12/2022	

**Labeler** - HALEM DERMATOLOGY PLLC (096071438)

**Establishment**

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85413-204)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85413-204)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85413-204)

Revised: 12/2025

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