

ULTIMATE PHYSICAL SUNSCREEN- zinc oxide cream
HALEM DERMATOLOGY PLLC

DRUG FACTS (cont)

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

MONICA
 HALEM
 M.D.
 NEW YORK

**ULTIMATE
 PHYSICAL
 SUNSCREEN**

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

Net Wt. 4 oz. (115 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

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85413-205(NDC:58892-205)
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
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85413-205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/02/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/02/2021	

Labeler - HALEM DERMATOLOGY PLLC (096071438)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85413-205)

Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Fragrance Manufacturing Inc.		793406000	manufacture(85413-205)
------------------------------	--	-----------	------------------------

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85413-205)

Revised: 12/2025

HALEM DERMATOLOGY PLLC