

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 MD,
NEW YORK

KIDS

ULTIMATE
PHYSICAL
SUNSCREEN

BROAD SPECTRUM SPF 40
WATER RESISTANT (40 MINS)

Net Wt. 4 oz. (115 g)



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
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85413-205-13	113 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(85413-205)

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