

HYDRATING MINERAL ZINC OXIDE SPF 40- zinc oxide cream
Spalina LLC.

DRUG FACTS

ACTIVE INGREDIENT:
 Zinc Oxide 16%

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
- Use a water resistant product if swimming or sweating.
- 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:

Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Hydrogen Dimethicone Silsesquioxane Crosspolymer

OTHER INFORMATION:

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

Made for: Spalina Inc., Irvine CA 92620
 spelaskincareandwaxing.com | customer service: 949-500-7785



SPALINA
 SKINCARE BY SPELA HERNANDEZ

Mineral Tinted SPF 40

with ceramides & antioxidants c + e

non-comedogenic • safe for sensitive skin
 chemical sunscreen free
 cruelty free • reef friendly



SPF 40 broad spectrum

net wt. 1.75 oz | 50 g

HYDRATING MINERAL ZINC OXIDE SPF 40

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85360-205(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)
GLYCERIN (UNII: PDC6A3C0OX)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V15VM0)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
TRIETHANOLAMINE (UNII: 9O3K93S3TK)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
WATER (UNII: 059QF0KO0R)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
DIMETHICONE (UNII: 92RU3N3Y1O)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85360-205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/08/2019	

Labeler - Spalina LLC. (105212651)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85360-205)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85360-205)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85360-205)

Revised: 12/2025

Spalina LLC.