

BARE SKIN SMOOTH MINERAL TINT- zinc oxide cream
Skin & Bare It LLC

DRUG FACTS (cont)

• **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-sleeved shirts, pants, 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

Manufactured for: Skin & Bare It
 19108 E Elk Creek Dr., Parker, CO 80134

BARE
SKIN



SMOOTH MINERAL TINT
 SPF 40 BROAD SPECTRUM
 ceramides / zinc oxide / antioxidants c+e



Net Wt. 1.75 oz / 50 g

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BARE SKIN SMOOTH MINERAL TINT

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85425-208(NDC:58892-208)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
CI 77491 (UNII: 1K09F3G675)
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)
DIMETHICONE (UNII: 92RU3N3Y1O)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
CI 77492 (UNII: EX438O2MRT)
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
CERAMIDE 3 (UNII: 4370DF050B)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
CI 77499 (UNII: XM0M87F357)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85425-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/29/2020	

Labeler - Skin & Bare It LLC (115072286)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85425-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85425-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85425-208)