

NON-TINTED FACE MINERAL SUNSCREEN SPF40- titanium dioxide, zinc oxide cream
Lisa Nadler Skin Care and Waxing

DRUG FACTS

ACTIVE INGREDIENTS:

Titanium Dioxide 8%

Zinc Oxide 3.8%

PURPOSE:

Sunscreen

Sunscreen

USES:

Helps prevent sunburn. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early skin 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 the 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:

• After 80 minutes of swimming or sweating

• Immediately after towel drying

• 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-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG-18/18-Hydrogen Dimethicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahydroxyldecyl Ascorbate, Tocopheryl Acetate

OTHER INFORMATION:

• Protect this product from excessive heat and direct sun

• May stain some fabrics

• PA +++

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NON-TINTED FACE MINERAL SUNSCREEN SPF 40

net wt. 1.8

NON-TINTED FACE MINERAL SUNSCREEN SPF40			
titanium dioxide, zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85370-202(NDC:58892-202)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	80 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	38 mg in 1 g

Inactive Ingredients				
Ingredient Name				Strength
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)				
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)				
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)				
ALUMINA (UNII: LMI26O6933)				
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)				
CYCLOHEXASILOXANE (UNII: XHK3U310BA)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85370-202-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/04/2019	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M020	06/04/2019	

Labeler - Lisa Nadler Skin Care and Waxing (102003495)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85370-202)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85370-202)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85370-202)