

NON TINTED REPLENISHING DAILY PROTECTION- zinc oxide cream
LUNDQUIST INSTITUTE FOR BIOMEDICAL INNOVATION AT HARBOR-UCLA
MEDICAL CENTER

DRUG FACTS

Table with 2 columns: ACTIVE INGREDIENT, PURPOSE. Row 1: Zinc Oxide 16%, 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-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, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer

OTHER INFORMATION:
• Protect this product from excessive heat and direct sun

MANUFACTURED FOR:
The Lundquist Institute
Torrance, CA 90502



Non-tinted Replenishing
Daily Protection



Broad Spectrum SPF 40
with Ceramides, Zinc Oxide
& Antioxidants C & E

Net Wt. 1.75 oz / 50 g

Table with 3 main sections: Product Information, Active Ingredient/Active Moiety, Inactive Ingredients. Product Information includes Product Type, Route of Administration, Item Code. Active Ingredient/Active Moiety includes Ingredient Name, Basis of Strength, Strength. Inactive Ingredients section is empty.

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85625-226-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/12/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/12/2025	

**Labeler** - LUNDQUIST INSTITUTE FOR BIOMEDICAL INNOVATION AT HARBOR-UCLA MEDICAL CENTER (069926962)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85625-226)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85625-226)

### Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85625-226)