

PROTECTION E AND C LIGHTLY TINTED- zinc oxide cream

CLEAR SKIN SOLUTIONS, LLC

DRUG FACTS

ACTIVE INGREDIENTS:

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 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 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, 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

Clear Skin Solutions
Ardmore, OK
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clearskinsolutions.com



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CLEAR SKIN
SOLUTIONS



Protection E & C
Lightly Tinted

SPF 40 BROAD SPECTRUM
with Ceramides

1.75 oz | 50 g

PROTECTION E AND C LIGHTLY TINTED

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85563-208
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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CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CI 77491 (UNII: 1K09F3G675)	
CI 77499 (UNII: XM0M87F357)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CI 77492 (UNII: EX438O2MRT)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CERAMIDE 3 (UNII: 4370DF050B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85563-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/30/2021	

Labeler - CLEAR SKIN SOLUTIONS, LLC (076140083)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85563-208)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85563-208)