

TINTED REPLENISHING DAILY PROTECTION- zinc oxide cream

HELTON SKIN & LASER INSTITUTE

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-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/Methicone Silsesquioxane Crosspolymer

OTHER INFORMATION:

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

MANUFACTURED FOR:
Helton Skin & Laser Institute
Newport Beach, CA 92660



HELTON
SKIN &
INSTITUTE

Tinted Replenishing
Daily Protection

SPF
Broad Spectrum
with Ceramide
& Antioxidants

Net Wt. 1.7 oz

TINTED REPLENISHING DAILY PROTECTION

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85679-208(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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CERAMIDE 3 (UNII: 4370DF050B)
CI 77492 (UNII: EX438O2MRT)
CI 77499 (UNII: XM0M87F357)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)
DIMETHICONE (UNII: 92RU3N3Y1O)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
CI 77491 (UNII: 1K09F3G675)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85679-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/22/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/22/2024	

Labeler - HELTON SKIN & LASER INSTITUTE (043023268)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85679-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85679-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85679-208)