

REPLENISHING DAILY PROTECTION- zinc oxide cream
The Maui Medical Group, Inc

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/Methicone Silsesquioxane Crosspolymer

OTHER INFORMATION:
• Protect this product from excessive heat and direct sun
• May stain some fabrics

MANUFACTURED FOR:
Dr. Ellecia Cook | Kahului, HI 96732
mmgderm.com (808) 242 6460



Replenishing
Daily Protection
Mineral Sunscreen SPF 40
With Antioxidants
and Ceramides

Broad Spectrum
Chemical Free
Reef Friendly
Age Defying

Net Wt. 1.75 oz / 50 g

Table with 4 main sections: Product Information, Active Ingredient/Active Moiety, and Inactive Ingredients. Includes details like Product Type (HUMAN OTC DRUG), Item Code (NDC:85394-208), and Ingredient Name (ZINC OXIDE).

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85394-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/20/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/20/2024	

Labeler - The Maui Medical Group, Inc (077677102)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85394-208)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85394-208)