DERMAMED- skin protectant ointment
DermaRite Industries, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DermaMed

Active ingredient

Aluminum Hydroxide Gel 2%

Purpose

Skin protectant

Uses

Dries the oozing and weeping of poison: ivy, oak, or sumac, or other skin irritations.

Warnings

For external use only.

Avoid contact with eyes. In case of contact, flush thoroughly with water.

Warnings

Stop and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Warnings

Keep out of reach of children.

In case of accidental ingestion contact a Physician or Poison Control Center right away.

Directions

Apply liberally to the affected area as needed or as directed by a physician.

Other information

- Store at room temperature (59º- 86ºF)
- You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047.

Inactive ingredients

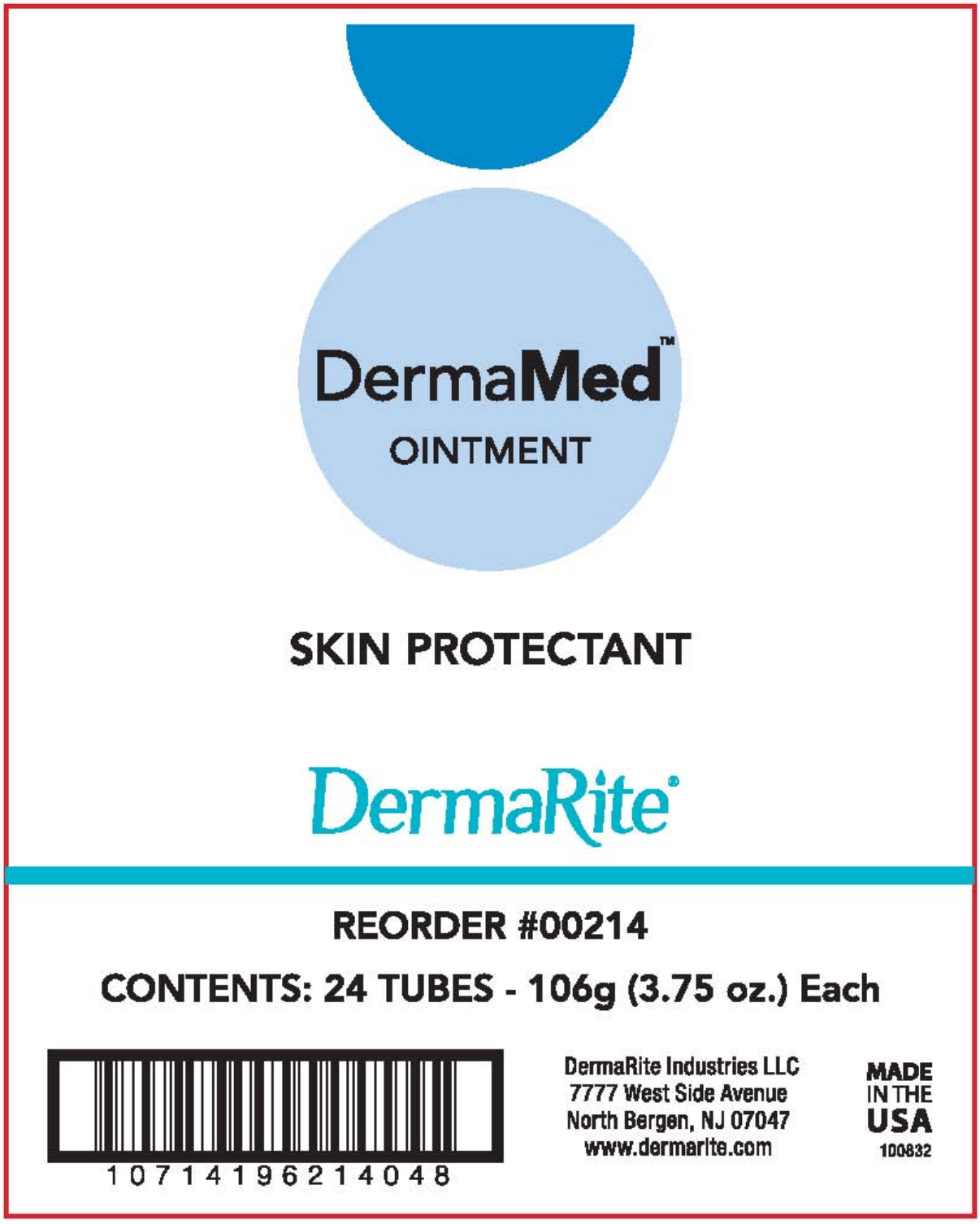
Petrolatum, Lanolin, Water, Propylene Glycol, Stearyl Alcohol, Calcium Carbonate, Magnesium Hydroxide, Zinc Chloride, DMDM Hydantoin, Methylparaben, Propylparaben, Sodium Laureth Sulfate, Lanolin Alcohol, Cholecalciferol, Zea Mays (Corn) Oil, Retinyl Palmitate, Citric Acid, Sodium

Chloride

Questions?

Call 800-337-6296 Mon - Fri 9AM - 5PM EST.

DermaMed Package Label and Principal Display Panel



DERMAMED

skin protectant ointment

Product Information			

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61924-214
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
LANOLIN (UNII: 7EV65EAW6H)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
PROPYLENE GLYCOL 1-(2-METHYLBUTYRATE) (UNII: 9Q5W5G6461)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CORN OIL (UNII: 8470G57WFM)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC CHLORIDE (UNII: 86Q357L16B)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PETROLATUM (UNII: 4T6H12BN9U)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-214-04	106 g in 1 TUBE; Type 0: Not a Combination Product	10/18/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/18/2016	

Labeler - DermaRite Industries, LLC (883925562)

Registrant - DermaRite Industries, LLC (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
DermaRite Industries, LLC		883925562	manufacture(61924-214)