

DERMASEPTIN- otc skin protectant drug products 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.

DRUG LISTING: DERMASEPTIN

Active Ingredients

- Zinc Oxide 19%
- Calamine 2%

Purpose:

- Zinc Oxide: Skin protectant
- Calamine : Skin protectant

Uses:

Dries the oozing and weeping of poison:

- Ivy
- Oak
- Sumac
- Or othe skin irritations

Warnings

- **For external use only.**
- **Avoid contact with eyes.** In case of contact, flush thoroughly with water.
- **Stop use 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 accidental ingestion contact a physician or Poison Control Center right away.

Directions

Applied as needed.

Other Information:

Store at room temperature (59°-86°F).

You may report a serious adverse event to DermaRite Industires, PO Box 7209, North Bergen, NJ 07047.

Inactive Ingredients:

Petrolatum, Lanolin, Glycerin, Menthol, Sodium Bicarbonate, methylparaben, Propylparaben

Questions

Call 1-800-337-6296 Mon-Fri 9AM-5PM EST.

DermaSeptin Package Label Principal Display Panel

124mm x 140mm

NDC 61924-210-04




DermaSeptin™

OINTMENT

SKIN PROTECTANT

with COOLING MENTHOL

Soothes
Promotes Healing



Drug Facts

Active ingredient	Purpose
Calamine 2%	Skin protectant
Zinc Oxide 19%	Skin protectant

Uses
Dries the oozing and weeping of poison:

- Ivy
- Oak
- Sumac
- Or other skin irritations

Warnings
For external use only.
Avoid contact with eyes. In case of contact, flush thoroughly with water.
Stop use and ask a doctor if ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days.
Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away.

Directions
■ Apply as needed.

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

Inactive ingredients Petrolatum, Lanolin, Glycerin, Menthol, Sodium Bicarbonate, Methylparaben, Propylparaben

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DermaRite Industries LLC • 7777 West Side Avenue
North Bergen, NJ 07047 • www.dermarite.com

MADE
IN THE
USA

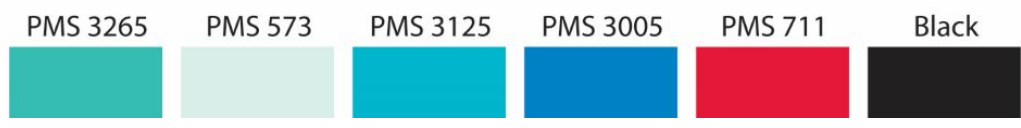
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REORDER #00212

Net Wt. 113 g (4 oz.)

Patient Name

Room #



DERMASEPTIN

otc skin protectant drug products ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61924-210
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	2.3 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	21.47 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7H9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
PETROLATUM (UNII: 4T6H12BN9U)	
MENTHOL (UNII: L7T10EIP3A)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-210-05	5 g in 1 PACKET; Type 0: Not a Combination Product	10/25/2010	
2	NDC:61924-210-04	113 g in 1 TUBE; Type 0: Not a Combination Product	10/25/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/25/2010	

Labeler - DermaRite Industries, LLC (883925562)

Registrant - DermaRite Industries, LLC (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
DermaRite Industries, LLC		883925562	manufacture(61924-210)

Revised: 9/2018

DermaRite Industries, LLC