SOOTHE AND COOL PROTECT- zinc oxide and white petrolatum paste Medline Industries, Inc.

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 Facts

Active ingredients

White Petrolatum 50% Zinc Oxide 10%

Purpose

Skin Protectant

Uses

- Temporarily relieves skin irritation including itching, burning, and discomfort
- Temporarily forms a protective coating over inflamed tissues to help prevent drying
- Protects minor skin irritation associated with diaper rash and helps seal out wetness

Warnings

For external use only

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

When using this product

• Do not get into the eyes

Stop use and ask a doctor if

• Condition worsens or does not improve within 7 days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- gently cleanse and dry affected area
- apply liberally to affected area as needed

Other information

Protect from freezing, avoid excessive heat.

Inactive ingredients

Allantoin, Benzethonium Chloride, Eugenia Caryophyllus (Clove) Flower Oil, Zea Mays (Corn) Starch, Retinyl Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E), Xanthan Gum

www.medline.com

Manufactured in USA for Medline Industries, Inc.,

Mundelein, IL 60060 USA. **1-800-MEDLINE**

NDC: 53329-004-10

SOOTHE & COOL®

PROTECT

ZINC OXIDE

SKIN PASTE

- Provides a thick, protective barrier
- Enhanced with vitamins A & E

Net Wt. 2.5 oz (71 g)

REF MSC095450



SOOTHE AND COOL PROTECT

zinc oxide and white petrolatum paste

Zille Oxide and white perioditum paste							
Product Information							
HUMAN OTC DRUG	Item Code (Source)		NDC:53329-004				
TOPICAL							
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Active Ingredient/Active Moiety							
redient Name		Basis of Stre	ngth	Strength			
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE		100 mg in 1 g			
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)		PETROLATUM		500 mg in 1 g			
	HUMAN OTC DRUG TOPICAL	HUMAN OTC DRUG TOPICAL topical tety redient Name K OXIDE - UNII:SOI2LOH54Z)	HUMAN OTC DRUG Item Code (Source) TOPICAL Item Code (Source) TOPICAL Basis of Street Tedient Name Basis of Street IC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE	HUMAN OTC DRUG Item Code (Source) NDC:53 TOPICAL Item Code (Source) NDC:53 State Code (Source) State Code (Source)			

Inactive Ingredients						
	Strength					
ALLANTOIN (UNII: 344						
BENZETHO NIUM CHL	ORIDE (UNII: PH41D05744)					
CHOLECALCIFEROL	(UNII: 1C6V77QF41)					
CLOVE OIL (UNII: 5783						
VITAMIN A PALMITAT						
ALPHA-TOCOPHEROI						
STARCH, CORN (UNII:						
XANTHAN GUM (UNII: '						
Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:53329-004-02	71 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 1/20 0 7				
Marketing Information						
Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part346	0 1/0 1/20 0 7				

Labeler - Medline Industries, Inc. (025460908)

Registrant - Dhaliwal Labs Illinois, Llc (079679410)

Revised: 1/2019

Medline Industries, Inc.