

GERIGARD-SKIN PROTECTANT- zinc oxide ointment
Geri-Gentle Corporation

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.

Gerigard™-Skin Protectant

Drug Facts

Active Ingredient

Zinc Oxide (1.8% w/w)

Purpose

Skin Protectant

Uses

- Helps treat and prevent diaper rash.
- Temporarily protects:
 - minor cuts
 - scrapes
 - burns
- Dries the oozing and weeping of:
 - poison ivy
 - poison oak
 - poison sumac

Warnings

- **For External Use Only.**

When using this product

- Do not get into eyes

Stop use and ask a doctor if

- Condition worsens
- Symptoms last more than 7 days or clear up and occur again in a few days, consult a physician

Keep out of reach of children

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

Directions

- Apply liberally as needed
- For diaper rash:
 - change wet and soiled diapers promptly
 - allow to dry
- Apply ointment liberally with each diaper change

Other information

- Store at room temperature 15° - 30°C (59° - 86°F)
- Avoid excessive heat
- Contains color additives including FD&C Yellow No. 5 (Tartrazine).

Inactive ingredients

Aloe Vera Leaf, Alpha-Tocopherol, Alcohol, Cetyl Alcohol, Cholecalciferol, Glycerin, Lanolin, Lavender Mineral Oil, Paraffin, Petrolatum, Phenoxyethanol, Polyethylene Glycol 6000, Polysorbate 60, Propylparaben Sodium, Steareth-20, Ceteth-10, Cetostearyl , Methylparaben, Trolamine, Vitamin A, Water

PRINCIPAL DISPLAY PANEL - 113 gm Tube Label

gerigente™

VITAMIN ENRICHED

geri

gard™

SKIN PROTECTANT

SPECIALLY FORMULATED

FOR GENTLE SKIN

AloeSoft

VITAMIN A • VITAMIN D • VITAMIN E

ZINC OXIDE • ALOE VERA

4 FL OZ (113 gm)



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geri
gardTM
 SKIN PROTECTANT



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Inactive ingredients Aloe Vera Leaf, Alpha-Tocopherol, Ceteth-10, Cetostearyl Alcohol, Cetyl Alcohol, Cholecalciferol, Glycerin, Lanolin, Lavender, Methylparaben, Mineral Oil, Paraffin, Petrolatum, Phenoxyethanol, Polyethylene Glycol 6000, Polysorbate 60, Propylparaben Sodium, Steareth-20, Trolamine, Vitamin A, Water	

ROOM #

PATIENT NAME:

NDC # 58029-223-02
 Manufactured For:
 GeriGentle Corporation
 Brooklyn, NY 11231
 Made in India

Reorder # 16535



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GERIGARD-SKIN PROTECTANT
 zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69771-108
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.8 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
.Alpha.-Tocopherol (UNII: H4N855PNZ1)	
Ceteth-10 (UNII: LF9X1PN3XJ)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Cholecalciferol (UNII: 1C6V77QF41)	
Glycerin (UNII: PDC6A3C0OX)	
Lanolin (UNII: 7EV65EAW6H)	
Methylparaben (UNII: A2I8C7HI9T)	
Mineral Oil (UNII: T5L8T28FGP)	
Paraffin (UNII: I9O0E3H2ZE)	
Petrolatum (UNII: 4T6H12BN9U)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Polyethylene Glycol 6000 (UNII: 30IQX730WE)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Propylparaben Sodium (UNII: 625NNB0G9N)	
Stearth-20 (UNII: L0Q8IK9E08)	
Trolamine (UNII: 9O3K93S3TK)	
Vitamin A (UNII: 81G40H8B0T)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69771-108-37	113 g in 1 TUBE; Type 0: Not a Combination Product	01/15/2009	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	01/15/2009	

Labeler - Geri-Gentle Corporation (361663839)

Establishment			
Name	Address	ID/FEI	Business Operations

Revised: 1/2018

Geri-Gentle Corporation