

GERIGARD- 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

Drug Facts

Active ingredient

Zinc Oxide (1.8% w/w)

Purpose

Skin Protectant

Uses:

- Helps treat and prevent diaper rash.
- Helps seal out wetness.
- 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, 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.

Package Labeling:

125.50 mm

155.00 mm

ALOE VERA
VITAMIN A • VITAMIN D
VITAMIN E • ZINC OXIDE

4 FL. OZ. (113g)

Drug Facts

Active ingredient	Purpose
Zinc Oxide 1.8%	Skin Protectant

Uses ■ Helps treat and prevent rash associated with diaper rash, incontinence or exposure to feces and urine
 ■ Protects skin against irritation due to such rash and
 ■ Helps protect skin from exposure to wetness

Warnings
FOR EXTERNAL USE ONLY

When using this product ■ Avoid contact with eyes
 ■ If eye contact occurs, flush with water

Stop use and ask a doctor if
 ■ condition worsens or doesn't improve within seven days

Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.

Directions
 ■ Change wet or soiled diapers promptly
 ■ Clean diaper area with a mild cleanser, paying special attention to the perineum, buttocks, lower abdomen and inner thighs
 ■ Allow area to dry
 ■ Apply to affected area as often as necessary or with each diaper change, especially at bedtime or any time when exposure to soiled diapers may be prolonged

Other information
 ■ Store at room temperature 15° - 30°C (59° - 86°F)
 ■ Avoid excessive heat

Inactive Ingredients Aloe Barbadosis Gel, Alpha Tocopherol (Vitamin E), Cetostearyl Alcohol, Cholecalciferol (Vitamin D), FD&C Yellow No.5, FD&C Yellow No.6, Glycerin, Glyceryl Mono Stearate, Isopropyl Myristate, Lanolin, Lavender, Mineral Oil, Paraffin, Phenoxyethanol, Sodium Benzoate, Sodium Laureth-3 Sulfate, Stearic Acid, Vitamin A Palmitate, Water

GeriGentle

NDC# 69771-050-04
 Manufactured for:
 Geri-Gentle Corporation
 Brooklyn, NY 11224
 www.ggentle.com

Made In India
Reorder# 16535

Pantone 369

Pantone 266

GERIGARD

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69771-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	18 mg in 1 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)	
STEARETH-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:69771-050-04	24 in 1 CASE	08/07/2018	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/07/2018	

Labeler - Geri-Gentle Corporation (080367686)

Revised: 2/2020

Geri-Gentle Corporation