

ZINC OXIDE - zinc oxide ointment
Gerimedix Incorporated

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.

Zinc Oxide Ointment

Active Ingredient	Purpose
Zinc Oxide (1.8% w/w)	Skin Protectant

Purpose:

- Helps treat and prevent diaper rash
- Temporarily protects
- minor cuts
- scrapes and
- 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 in 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

Dosage & Administration

For skin protectant:

Apply liberally as needed

For diaper Rash:

change wet and soiled diapers promptly

allow to dry

apply ointment liberally with each diaper change

Keep out of reach of children.

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

Other information:

- Store at room temperature
- avoid excessive heat

- contains color additives including FDC yellow # 5

Indications & Usage

Indications: For use as a general skin protectant and diaper rash.

Inactive Ingredients

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

Principle Display Panel

Geriguard Skin Protectant

Zinc Oxide Ointment

zinc_oxide.jpg



VITAMIN ENRICHED
**geri
 gard™**
 SKIN PROTECTANT



SPECIALLY FORMULATED
 FOR GENTLE SKIN



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

4 FL OZ (113 gm)

Drug Facts

Active Ingredient	Purpose
Zinc Oxide (1.8% w/w) ...	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, 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

Reorder # 16535

Manufactured For:
 GeriGentle Corporation
 Brooklyn, NY 11231
 Made in India



6 48289 16535 7

ZINC OXIDE

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58029-223
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1.8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
CETETH-20 (UNII: I835H2IHHX)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARETH-20 (UNII: L0Q8IK9E08)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
VITAMIN A (UNII: 81G40H8B0T)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PETROLATUM (UNII: 4T6H12BN9U)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58029-223-02	24 in 1 CASE		
1		114 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/01/2011	

Labeler - Gerimedix Incorporated (153496690)

Establishment

Name	Address	ID/FEI	Business Operations
Blossom Pharmaceuticals		677381470	manufacture(58029-223)

Revised: 9/2014

Gerimedix Incorporated