

ZINC OXIDE- 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.

Zinc Oxide

Drug Facts

Active ingredient

Zinc Oxide (20%w/w)

Purpose

Skin Protectant

Uses

- helps treat and prevent diaper rash
- 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
- do not use over large area of the body

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
- if you are allergic to any of these ingredients

Do not use on

- deep puncture wounds
- animal bites
- serious burns

Keep out of reach of children.

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

Directions for Diaper Rash

- change wet and soiled diaper promptly
- cleanse the diaper area and allow to dry
- apply as needed

Other information

- store at 59°-86°F (15°-30°C)
- avoid excessive heat

Inactive Ingredients

Cetostearyl Alcohol, Cetomacrogol 1000, Lanolin, Light Liquid Paraffin, White Soft Paraffin

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Box



ZINC OXIDE

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69771-109
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 (UNII: I835H2IHHX)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69771-109-38	1 in 1 BOX	01/15/2017	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69771-109-39	1 in 1 BOX	01/15/2017	
2		56.8 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	01/15/2017	

Labeler - Geri-Gentle Corporation (080367686)

Revised: 8/2021

Geri-Gentle Corporation