

ZINC OXIDE- zinc oxide ointment
BRANDS INTERNATIONAL

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.

GenMed ZINC OXIDE Ointment USP with Blue Dye

Active ingredient

Zinc Oxide (20% w/w)

Purpose

Skin Protectant

Purpose

- 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 areas of the body

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 diapers promptly
- cleanse the diaper area and allow to dry
- apply ointment liberally with each diaper change, especially at bedtime or any time when exposure to wet diapers may be prolonged
- for poison ivy, oak, sumac
- apply ointment liberally as often as needed

Other information

- store at 59°-86° F (15°-30°C)

- avoid excessive heat

Inactive ingredients

mineral oil, petrolatum

PACKAGE LABEL

Drug Facts

Active ingredient
Zinc oxide 20%

Purpose
Skin Protectant

Uses
Helps treat and prevent diaper rash. Protects chafed skin due to diaper rash and helps seal out wetness. Dries the oozing and weeping of poison ivy, poison oak and poison sumac.

Warnings
For external use only
When using this product, avoid contact with the eyes.
Stop use and ask a doctor if: condition worsens, symptoms last more than 7 days or clear up and occur again within a few days.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Center right away.

Directions
apply liberally as often as necessary
For diaper rash:
change wet or soiled diapers promptly
cleanse the diaper area and allow to dry
apply ointment liberally, as often as necessary, with each diaper change and especially at bedtime or any time when exposure to wet diapers may be prolonged
Other information
Store at room temperature 15° - 30° C (59° - 86°F)

Inactive Ingredients
mineral oil, petrolatum

DISTRIBUTED BY
101 CHASE AVE
SUITE 205
LAKEWOOD NJ 08701
SALES@OMNIGRPCOM

LOT
EXP

Questions or concerns?
Just give us a call at
1-800-XXX-XXXX.

MADE IN CANADA
MANUFACTURED BY
BRANDS INTERNATIONAL

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GM2ZO16



Zinc Oxide Ointment USP

With Blue Dye

20%

- Provides soothing relief from poison ivy, oak and sumac
- Treats and prevents diaper rash

NET WT. 16 OZ (1 LB) (454 G)

ZINC OXIDE

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50157-333
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
PETROLATUM (UNII: 4T6H12BN9U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-333-45	454 g in 1 TUBE; Type 0: Not a Combination Product	03/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/15/2023	

Labeler - BRANDS INTERNATIONAL (243748238)

Revised: 3/2023

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