

ZINC OXIDE 20% - zinc oxide ointment
GERITREX LLC

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 20% Ointment

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 or does not improve within 7 days

Keep out of reach of children.

If swallowed, get medical help or contact a poison control 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 anytime when exposure to wet diapers may be prolonged

Other information

Store at controlled room temperature 20°-25°C (68°-77°F).

Inactive ingredients

mineral oil, petrolatum

NDC 54162-040-28



Zinc Oxide 20% Ointment

Skin Protectant
FOR EXTERNAL USE ONLY

NET WT. 1oz (28g)



Geritrex
Distributed by
Geritrex, LLC
40 Commercial Ave
Middletown, NY 10941
1-800-756-3437
www.geritrex.com

Drug Facts

Active Ingredient Purpose
Zinc Oxide 20%..... 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 the product, avoid contact with the eyes ■

Stop use and ask a doctor if condition worsens or does not improve within 7 days
■ Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions ■ apply liberally as often as necessary
For diaper rash ■ change wet or soiled diaper's 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 anytime when exposure to wet diapers may be prolonged

Other information Store at controlled room temperature 20°-25°C (68°-77°F).

Inactive ingredients mineral oil and white petrolatum

UNVARNISH 7 mm

NDC 54162-040-56



Zinc Oxide 20% Ointment

Skin Protectant
FOR EXTERNAL USE ONLY

NET WT. 56g(2oz.)

Drug Facts	
Active Ingredient	Purpose
Zinc Oxide 20%	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 or does not improve within 7 days	
Keep out of reach of children. If swallowed, get medical help or contact a poison control 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 anytime when exposure to wet diapers may be prolonged	
Other information Store at controlled room temperature 20°-25°C (68°-77°F).	
Inactive ingredients mineral oil and white petrolatum	



54162-04056 6
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START 5 mm



NDC 54162-040-16

Zinc Oxide 20% Ointment

Skin Protectant
FOR EXTERNAL USE ONLY
NET WT. 1 LB. (454g)

Drug Facts	Purpose
Active Ingredient	Skin Protectant
Zinc Oxide 20%	
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 or does not improve within 7 days	
Keep out of reach of children. If swallowed, get medical help or contact a poison control 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 anytime when exposure to wet diapers may be prolonged
Other information	Store at controlled room temperature 20°-25°C (68°-77°F)
Inactive ingredients	mineral oil and white petrolatum



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ZINC OXIDE 20%

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	.2 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-040-28	28 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2018	
2	NDC:54162-040-56	56 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2018	
3	NDC:54162-040-16	454 g in 1 JAR; Type 0: Not a Combination Product	09/17/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/17/2018	

Labeler - GERITREX LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
GERITREX LLC		112796248	manufacture(54162-040)

Revised: 9/2018

GERITREX LLC