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



diapers promptly ■cleanse the diaper area

poison control center right away. swallowed, get medical help or contact a

Irections ■apply liberally as often as necessar

Zinc Oxide 20%

Protectant FOR EXTERNAL USE ONLY

NET WT. 1oz (28g)

.Skin Protectan Purpose

Active Ingredient Drug Facts www.geritrex.com

Geritrex, LLC 40 Commercial Ave Middletown NY 10941 1-800-736-3437

Warnings Stop use and ask a doctor if condition rash. Protects chafed skin due to diaper worsens or does not improve within 7 days product, avoid contact with the eyes ■ For external use only When using this vy, poison oak and poison sumac mash and helps seal out wetness. Uses ■ helps treat and prevent diaper dries the cozing and weeping of poison Keep out of reach of children. If

oom temperature 20°-25°C (68°-77°F)

Inactive ingredients mineral oil and

white petrolatum

Other information Store at controlled be prolonged anytime when exposure to wet diapers may change and especially at bedtime or as often as necessary, with each diaper and allow to dry ■apply o intraent liberally, For diaper rash: Change wet or soiled

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
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 and white petrolatum



54162 04056
Distributed by Gentrex, ILC

40 Commercial Ave, Middletown NY 1094 1-800-736-3437 • www.geritrex.com

START 5 mm



NDC 54162-040-16

Zinc Oxide 20% Ointment

Skin Protectant

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

| Drug Facts | |
|--|--|
| Active Ingredient Purpose Zinc Oxide 20% Skin Protectant | |
| Uses the helps teat and prevent diaper rash. Protects challed skin due to diaper rash and helps seal out, warhess. ■ these the occing and weeping of poison ivy, poison cake and poison surnee. | |
| 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 linearity as other as necessary or dispertain: change with consoled dispers promptly searces the disper area and allow hodry searces the dispers area and allow hodry apply and the search dispers and and search area and allow and apply and allow and allow and search area and allow and apply and allow and apply and allow and apply and ap | |
| Other information Store at controlled room temperature 20°-25°C (68°-777F) | |
| 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

| 3 | | |
|---|-------------------|-------------|
| 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 O IL (UNII: T5L8T28FGP) | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| P | 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