ZINC OXIDE- zinc oxide ointment Dynarex 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 Ointment

Section Text

Active Ingredient Purpose

Zinc Oxide (200mg in each gram) 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 in eyes.

Stop use and ask a doctor if:

- conditions worsens
- symptoms last more than 7 days or clear up and occur again in a few days, consult a physician.
- over large areas of the body
- if you are allergic to any of these ingredients

Do not use on:

- deep or puncture wounds
- animal bites
- serious burns

Keep out of reach of children

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 anytime when exposure to wet diapers may be prolonged

For poison ivy, poison oak, poison sumac:

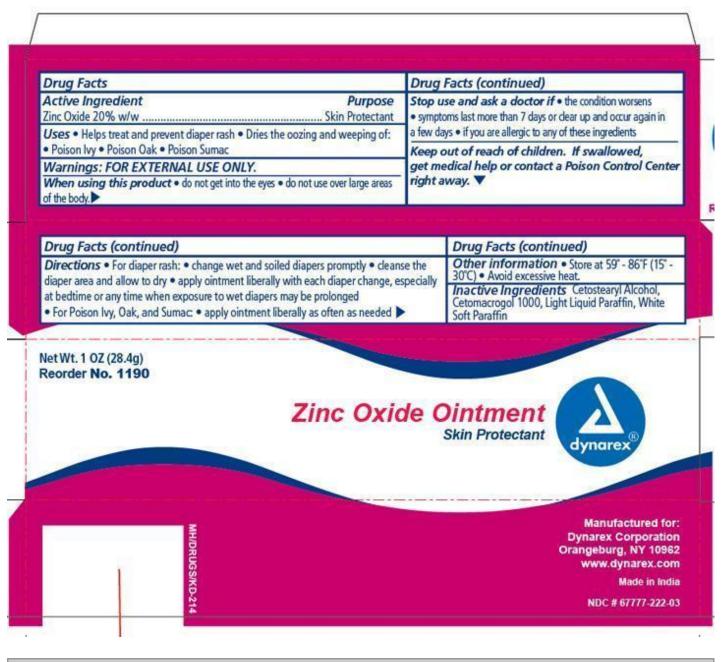
• apply liberally as often as needed

Inactive Ingredients

Cetostearyl alcohol, Cetomacrogal 1000, Light Liquid Paraffin, White Soft Paraffin

Principal Display

zinc.jpg



| I Toudet Informa | tion | | | | | |
|--------------------------------------------------------------------|---------------------------------------------------|-------------------------------------------------------------------|--------------------|------------------------|---------------|----------------|
| Product T ype | | HUMAN OTC DRUG | Item Code (Source) | | NDC:67777-222 | |
| Route of Administra | tion | TOPICAL | | | | |
| | | | | | | |
| Active Ingredien | t/Active Moi | ety | | | | |
| | Ingre | dient Name | | Basis of Stren | | Strength |
| ZINC OXIDE (UNII: SC | DI2LOH54Z) (ZIN | COXIDE - UNII:SOI2LOH54Z) | | ZINC OXIDE | | 200 mg in 1 g |
| | | | | | | |
| Inactive Ingredie | nts | | | | | |
| | | Ingredient Name | | | | Strength |
| CETOSTEARYL ALC | OHOL (UNII: 2D | <u> </u> | | | | 0 |
| CETETH-20 (UNII: 183 | 5H2IHHX) | | | | | |
| LIGHT MINERAL OIL | . (UNII: N6K5787 | 'QVP) | | | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | | | | | |
| | | | | | | |
| | | | | | | |
| Packaging | | | | | | |
| # Item Code | | Package Description | N | Marketing Start Date | Mar | keting End Dat |
| | 28.34 g in 1 TUE | E; Type 0: Not a Combination P | roduct 0 | 3/17/2010 | | |
| 1 NDC:67777-222-03 | 0 | | | uct 03/17/2010 | | |
| | _ | 3E; Type 0: Not a Combination P | product 0 | 3/17/2010 | | |
| 2 NDC:67777-222-01 | 56.68 g in 1 TUI | 3E; Type 0: Not a Combination P Type 0: Not a Combination Proc | | 3/17/2010 3/17/2010 | | |
| 2 NDC:67777-222-01 | 56.68 g in 1 TUI | | | | | |
| 2 NDC:67777-222-01 | 56.68 g in 1 TUI | | | | | |
| 2 NDC:67777-222-01 3 NDC:67777-222-02 | 56.68 g in 1 TUI 425.1 g in 1 JAR; | | | | | |
| 2 NDC:67777-222-01 | 56.68 g in 1 TUI 425.1 g in 1 JAR; ormation | | duct 0 | | Mar | keting End Dat |

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

| Establishment | | | | | | | | |
|-----------------------------------|---------|-----------|----------------------------|--|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | | |
| Galentic Pharma (India) Pvt. Ltd. | | 864201135 | manufacture(67777-222) | | | | | |

Revised: 4/2017

Dynarex Corporation