DYNAREX ZINC OXIDE- zinc oxide ointment 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.

1190 Zinc Oxide Ointment NDC 67777-119-00 1191 Zinc Oxide Ointment NDC 67777-119-10 1192 Zinc Oxide Ointment NDC 67777-119-20

Active Ingredient

Zinc Oxide 25%

Purpose

Skin Protectant

Uses

- Helps treat chafed skin associated with diaper rash
- Dries the oozing and weeping of poison: ivy oak sumac

Warnings

For External Use Only

When using this product

• Avoid contact with 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 Control Center (1-800-222-1222) right away.

Directions

- For diaper rash: Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry. Apply ointment liberally as often as necessary with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.
- For poison ivy, oak, and sumac: Apply as needed.

Other Information

- Store at room temperature between 15°-30°C (59°-86°F)
- Avoid excessive heat
- Tamper evident. Do not use if seal is damaged.

Inactive Ingredients

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

1190 Label



1190 Label

1191 Label



1191 Label

1192 Label



1192 Label

DYNAREX ZINC OXIDE zinc oxide ointment ointment **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:67777-119 **Route of Administration TOPICAL Active Ingredient/Active Moiety Basis of Strength** Strength **Ingredient Name** ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE 250 mg in 1 g

| Inactive Ingredients | | | | | |
|--|----------|--|--|--|--|
| Ingredient Name | Strength | | | | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | | | | | |
| CETETH-20 (UNII: I835H2IHHX) | | | | | |
| WHITE PETROLATUM (UNII: B6E5W8RQJ4) | | | | | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | | | | | |

| Packaging | | | | | | |
|-----------|----------------------|---|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:67777-119- 02 | 72 in 1 CASE | 03/27/2018 | | | |
| 1 | NDC:67777-119- 01 | 1 in 1 BOX | | | | |
| 1 | NDC:67777-119- 00 | 28.4 g in 1 TUBE; Type 0: Not a Combination Product | | | | |
| 2 | NDC:67777-119- 12 | 72 in 1 CASE | 03/27/2018 | | | |
| 2 | NDC:67777-119- 11 | 1 in 1 BOX | | | | |
| 2 | NDC:67777-119- 10 | 56.7 g in 1 TUBE; Type 0: Not a Combination Product | | | | |
| 3 | NDC:67777-119- 21 | 12 in 1 CASE | 03/27/2018 | | | |
| 3 | NDC:67777-119- 20 | 425 g in 1 JAR; 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 | 03/27/2018 | | | | |
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Labeler - Dynarex Corporation (008124539)

Revised: 11/2022 Dynarex Corporation