

ZINC OXIDE- zinc oxide cream
Westminster Pharmaceuticals, LLC

Zinc Oxide

Drug Facts

Active ingredient

Zinc Oxide 22%

Purpose

Skin Protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps protect skin from wetness.

Warnings

For external use only

When using this product do not get into eyes

Stop use and ask a doctor if

- conditions worsen
- 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 right away.

Directions

- change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry.
- apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Other information

- store at 20-30°C (68-86 °F)

Inactive ingredients

aloe barbadensis leaf juice, cetyl alcohol, glycerin, glyceryl stearate SE, isopropyl palmitate, mineral oil, PEG-100 stearate, phenoxyethanol, purified water, tocopheryl acetate (vitamin E), stearyl alcohol, white petrolatum

Questions?

Call 1-844-221-7294.

PRINCIPAL DISPLAY PANEL - 113 gram Tube Label

Soothing Aloe &
Vitamin E

NDC 69367-188-04

Zinc Oxide 22%

Daily Moisturizing
Diaper Rash Cream

Premium Skin Protectant

- Helps Heal, Soothe & Prevent Diaper Rash
- Protects Chafed Skin
- Gentle on Sensitive Skin

NET WT: 4 oz (113 grams)

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Pharmaceuticals

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Manufactured for:

Westminster Pharmaceuticals, LLC
Nashville, TN 37217 Rev. 04/23



ZINC OXIDE

zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69367-188 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 22 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| |
|--|
| CETYL ALCOHOL (UNII: 936JST6JCN) |
| MINERAL OIL (UNII: T5L8T28FGP) |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| WATER (UNII: 059QF0KO0R) |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| PETROLATUM (UNII: 4T6H12BN9U) |
| GLYCERYL STEARATE SE (UNII: FCZ5MH785I) |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) |
| PEG-100 STEARATE (UNII: YD01N1999R) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:69367-188-04 | 113 g in 1 TUBE; Type 0: Not a Combination Product | 07/29/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC MONOGRAPH DRUG | M016 | 07/29/2021 | |

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 7/2021

Westminster Pharmaceuticals, LLC