DOCTOR OS DIAPER BALM- zinc oxide ointment Dr. O's Dermabalm, 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.

Doctor O's Diaper Balm

Drug Facts

Active ingredients

Zinc Oxide 30%

Purpose

Skin protectant

Uses

- Helps treat and prevent diaper rash
- Protects minor skin irritation associated with diaper rash and helps seal out wetness

Warnings

For external use only.

When using this product • Keep out of 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 the reach of children. If swallowed seek medical attention or contact a Poison Control Center right away.

Directions

- 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

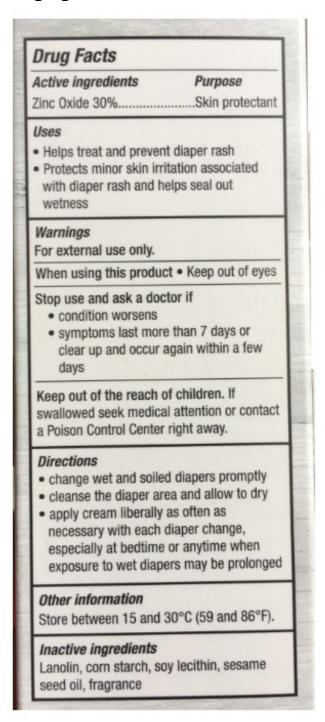
Other information

Store between 15 and 30°C (59 and 86°F).

Inactive ingredients

Lanolin, corn starch, soy lecithin, sesame seed oil, fragrance

Packaging



DOCTOR OS DIAPER BALM

zinc oxide ointment

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73570-001 |
|-------------------------|----------------|--------------------|---------------|
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|---|-------------------|---------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 30 g in 100 g | |

| Inactive Ingredients | | | |
|--------------------------------------|----------|--|--|
| Ingredient Name | Strength | | |
| LANOLIN (UNII: 7EV65EAW6H) | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | | | |
| SESAME OIL (UNII: QX10HYY4QV) | | | |

| P | Packaging | | | |
|---|----------------------|--|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:73570-001- 02 | 1 in 1 CARTON | 02/14/2020 | |
| 1 | | 100 g in 1 TUBE; 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 | 02/14/2020 | |
| | | | |

Labeler - Dr. O's Dermabalm, Llc (016334106)

| Establishment | | | | |
|-------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| NATURAL TECHNOLOGY, LLC | | 618561906 | manufacture(73570-001) | |

Revised: 7/2021 Dr. O's Dermabalm, Llc