

RUGBY ZINC OXIDE- zinc oxide ointment

Rugby Laboratories

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.

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

Inactive ingredients

mineral oil, petrolatum

Questions or comments?

Call **1-800-645-2158** 9 am - 5 pm EST, Monday – Friday

Store at room temperature 15° - 30°C (59° - 86°F).

R0507


Principal Display Panel – Jar Label

Rugby® NDC 0536-5700-98
SKIN PROTECTANT

Zinc Oxide
Ointment USP

- provides soothing relief from poison ivy, oak and sumac
- Treats and prevents diaper rash

Net Wt 1 lb (454 g)

| | |
|--|--|
|  NDC 0536-5700-98 SKIN PROTECTANT Zinc Oxide Ointment USP • Provides soothing relief from poison ivy, oak and sumac • Treats and prevents diaper rash Net Wt 16 oz (1 lb) (454 g) <small>Distributed by: Rugby Laboratories 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 www.rugbylaboratories.com</small> | |
| Drug Facts | Purpose Zinc oxide 20%.....Skin Protectant |
| Active ingredient Zinc oxide 20%..... | Uses <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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 • apply liberally as often as necessary For diaper rash: <ul style="list-style-type: none">• 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 any time when exposure to wet diapers may be prolonged |
| Other information store at room temperature 15° - 30°C (59° - 86°F). | Inactive ingredients mineral oil, petrolatum |
| Questions or comments? 1-800-645-2158 | |
|  Rev. 11/16 R-101 Re-order No. 370124 7908012 3 05365 70098 6 | |

Principal Display Panel - 30 g Tube

Rugby Zinc Oxide Ointment USP

Skin protectant Zinc Oxide 20%

Help Soothe & Protect Chafed Skin

NET WT 30G (1.05oz)



NDC 0536-5700-28

Zinc Oxide Ointment USP

Skin Protectant • Zinc Oxide 20%

NET WT. 30 g (1.05 oz)

Active ingredient Zinc oxide 20% **Purpose** Skin protectant

Uses ■ Protects skin ■ Dries the oozing and weeping of poison ivy, oak and sumac ■ Aids in the prevention of diaper rash ■ Protects and relieves chafed skin due to diaper rash and helps seal out wetness. **Warnings** **For external use only** ■ When using this product avoid contact with eyes. ■ Stop use and ask a doctor if condition worsens or does not improve within 7 days. This may be a sign of a serious condition. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Apply ointment liberally as often as necessary ■ For the treatment of diaper rash, change wet and soiled diapers promptly ■ Cleanse the diaper area and allow to dry ■ Apply with each diaper change, especially at bedtime or anytime when exposure to wet diaper may be prolonged. **Other information** Store at controlled room temperature 20°-25°C (68°-77°F).

Questions or comments? (800) 645-2158

KEEP CARTON FOR COMPLETE DRUG FACTS. Dist. By RUGBY LABORATORIES R-101
17177 N Laurel Park Drive, Suite 233 • Livonia, MI 48152 USA • Re-Order No. : 370563 Rev.01/18

Principal Display Panel - 30 g Carton

Rugby Zinc Oxide Ointment USP

Skin protectant Zinc Oxide 20%

Help Soothe & Protect Chafed Skin

NET WT 30G (1.05oz)



RUGBY ZINC OXIDE

zinc oxide ointment

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-5700 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 200 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------|----------|
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0536-5700-98 | 454 g in 1 JAR; Type 0: Not a Combination Product | 03/23/2004 | |
| 2 | NDC:0536-5700-28 | 1 in 1 CARTON | 09/24/2018 | |
| 2 | | 30 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:0536-5700-25 | 1 in 1 CARTON | 09/06/2018 | |
| 3 | | 60 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 | 03/23/2004 | |

Labeler - Rugby Laboratories (079246066)

Revised: 1/2021

Rugby Laboratories