## BOUDREAUXS- zinc oxide cream C.B. Fleet Company, Inc.

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.

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#### **Drug Facts**

#### **Active Ingredient**

Zinc Oxide, 16%, Skin Protectant

#### Uses

- Helps treat and prevent diaper rash
- Protests chafed skin due to diapter rash and helps seal out wetness

#### **Warnings**

- For external use only
- When using this product lavoid contact with the eyes
- **Stop use and ask a doctor if** condition worsens or does not improve after 7 days
- **Keep out of reach of children** to prevent accidental ingestion
- If swallowed, seek medical help or call Poison Control Center immediately

#### **Directions for Use**

- Change wet and soiled diapers immediately
- Cleanse the diaper area and allow to dry
- Apply ointment liberally and as often as necessary with each diaper change and especially when exposed to wet diapers for a prolonged period of time, such as bedtime

#### Other Information

- Store at room temperature, 15C to 30C (59F to 86F)
- Remove foil seal from the tube's tip or from jar
- Use with infants, children and adults
- Will stain clothing and fabric

#### **Inactive Ingredients**

Castor Oil, Mineral Oil, Paraffin, Peruvian Balsam, White Petrolatum

#### **Questions or Comments**

Phone 1-855-785-2888 website www.buttpaste.com



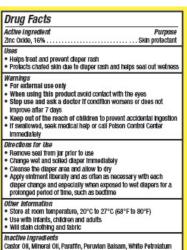


- ✓ Treats and Prevents Diaper Rash
- ✓ FREE FROM: Dyes Preservatives Parabens Talc



NET WT. 4 OZ (113 g)







I'm proud to put my name on the package you're holding - a highly effective ointment that keeps your baby's butt happy and healthy - without the unwanted ingredients!

In. Parmacist, Father of 4, Creator of Boudreaux's Butt Paste

Let's kick some rash.

Distributed by C.B. Fleet Company, Inc. Lynchburg, VA 24502

American owned and operated since 1978

www.buttpaste.com 017-500052-09

#### **BOUDREAUXS**

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zinc oxide cream

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0132-0333 Route of Administration TOPICAL

| Active Ingredient/Active Moiety                              |                   |               |  |  |
|--|-------------------|---------------|--|--|
| Ingredient Name  | Basis of Strength | Strength      |  |  |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE        | 16 g in 113 g |  |  |

| Inactive Ingredients                 |          |  |  |  |
|--------------------------------------|----------|--|--|--|
| Ingredient Name                      | Strength |  |  |  |
| CASTOR OIL (UNII: D5340 Y2I9 G)      |          |  |  |  |
| MINERAL OIL (UNII: T5L8T28FGP)       |          |  |  |  |
| PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E ) |          |  |  |  |
| BALSAM PERU (UNII: 8P5F881OCY)       |          |  |  |  |
| PETROLATUM (UNII: 4T6H12BN9U)        |          |  |  |  |

| P | Packaging        |  |                             |                           |  |
|---|------------------|--|-----------------------------|---------------------------|--|
| # | Item Code        | Package Description                                | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |  |
| 1 | NDC:0132-0333-44 | 113 g in 1 TUBE; Type 0: Not a Combination Product | 0 2/0 1/20 12               |                           |  |
| 2 | NDC:0132-0333-22 | 57 g in 1 TUBE; Type 0: Not a Combination Product  | 0 2/0 1/20 12               |                           |  |
| 3 | NDC:0132-0333-16 | 454 g in 1 JAR; Type 0: Not a Combination Product  | 0 2/0 1/20 12               |                           |  |

| Marketing Information |  |                      |                    |  |  |
|-----------------------|--|----------------------|--------------------|--|--|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |  |
| OTC monograph final   | part347                                  | 0 2/0 1/20 12        |                    |  |  |
|                       |  |                      |                    |  |  |

### Labeler - C.B. Fleet Company, Inc. (003119054)

Revised: 10/2017 C.B. Fleet Company, Inc.