BOUDREAUXS- zinc oxide paste 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.

Active Ingredient

Zinc Oxide, 40%....Skin Protectant

Uses

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

Warning

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 after 7 days.

Keep out of the reaach of children

to prevent accidental ingestion.

If swallowed, seek medical help or call Poison Control Center immediately.

Directions for Use

- Change wet and soiled diaper 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 tempature, 20C to 27C (68F to 80F).
- Remove seal from jar before use.
- 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



BOUDREAUXS

zinc oxide paste

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Product	Intorr	nation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:0132-0194

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthZINC OXIDE (UNII: SOIZLOH54Z) (ZINC CATION - UNII:13S1S8SF37)ZINC CATION40 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340 Y2I9 G)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: 19 O0 E3H2ZE)	
BALSAM PERU (UNII: 8P5F881OCY)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:0132-0194-14	397 g in 1 JAR; Type 0: Not a Combination Product	10 / 0 1 / 20 16			
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part347	10/01/2016			

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

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