ZINC OXIDE- zinc oxide ointment Topco Associates 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.

Drug Facts

Active Ingredient

Zinc Oxide 20%

Purpose

Skin Protectant

Uses

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

For external use only.

When using this product

• do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur 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 or soiled diapers promptly
- clean the diaper area
- allow to dry
- apply cream liberally as often as necessary, with each diaper change, especially at bedtime or any time prolonged exposure to wet diapers may be prolonged.

Other Information

• store at 20-25°C (68-77°F)

Inactive Ingredients

bees wax, BHT, cod liver oil, fragrance, lanolin, methylparaben, petrolatum, purified water



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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		



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This TOP CARE® product is laboratory, testood to guarantee its highest quality. Your total satisfaction is guaranteed.







NET WT 2 OZ (56.7g)

- · Helps treat & prevent diaper rash
- · Protects chated skin due to disper rash & helps protect from wetness
- . Dries the oozing & weeping of poison ivy, poison oak, & poison sumac

Zinc Oxide Ointment

SKIN PROTECTANT

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- Zinc Oxide Ointment

SKIN PROTECTANT

NDC Nº 38800-100-05





ZINC OXIDE

zinc oxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
COD LIVER OIL (UNII: BBL281NWFG)			
LANOLIN (UNII: 7EV65EAW6H)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
PETROLATUM (UNII: 4T6H12BN9U)			
WATER (UNII: 059QF0KO0R)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-100-02	1 in 1 BOX		
1		56.7 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/01/2013	

Labeler - Topco Associates LLC (006935977)

Revised: 7/2013 Topco Associates LLC