

PREMIER VALUE ZINC OXIDE - zinc oxide cream

Chain Drug Consortium, 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	Purpose
Zinc Oxide 20%.....	Skin protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps protect skin from wetness
- protects and dries the oozing and weeping of poison ivy, poison oak and poison sumac
- helps prevent and temporarily protect chafed, chapped, cracked or windburned skin and lips

Warnings For external use only

Do not use over deep or puncture wounds, infections or lacerations

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

- 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

- Lot No. and Exp. Date: see box or see crimp of tube
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients aloe vera gel, liquid paraffin, tocopherol acetate, white beeswax, white petrolatum

Distributed By

Chain Drug Consortium

3301 NW Boca Raton Blvd. Suite 101

Boca Raton, FL 33431

Made in Korea



PREMIER VALUE ZINC OXIDE

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-252
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MINERAL OIL (UNII: T5L8T28FGP)	

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WHITE WAX (UNII: 7G1J5DA97F)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-252-00	1 in 1 CARTON		
1		56 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/30/2013	

Labeler - Chain Drug Consortium, LLC (101668460)