

PREMIER VALUE DIAPER RASH - zinc oxide ointment
TAI GUK PHARM. CO., LTD.

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, 40%	Skin protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps protect skin from wetness

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

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

Inactive ingredients

BHA, cod liver oil (high in vitamin A and D), fragrance, lanolin, methylparaben, petrolatum, talc and purified water, light mineral oil, tartrazine yellow #4 (FD and C yellow #4)

Distributed By:

Chain Drug Consortium, LLC.

3301 N.W. Boca Raton Blvd., Suite 101

Boca Raton, FL 33431



Enter section text here

PREMIER VALUE DIAPER RASH

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68 169-0 128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.40 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
COD LIVER OIL (UNII: BBL281NWFQ)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	

TALC (UNII: 7SEV7J4R1U)	
WATER (UNII: 059QF0KO0R)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68169-0128-2	1 in 1 CARTON		
1		113 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/30/2010	

Labeler - TAIGUK PHARM. CO., LTD. (631101656)

Registrant - UNITED EXCHANGE CORP. (840130579)

Establishment

Name	Address	ID/FEI	Business Operations
TAIGUK PHARM. CO., LTD.		631101656	manufacture

Revised: 9/2010

TAI GUK PHARM. CO., LTD.