WESTERN FAMILY 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
- helps prevent and temporarily protect chafed, chapped, cracked or windburned skin and lips

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 20º to 25ºC (68º to 77ºF)
- Lot No. and Exp. Date: see box or see crimp of tube

Inactive ingredients

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

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WESTERN FAMILY DIAPER RASH

zinc oxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68169-0375
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: BBL281NWFG)	
LANOLIN (UNII: 7EV65EAW6H)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68169-0375-4	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	10/05/2010	

Labeler - TAI GUK PHARM. CO., LTD. (631101656)

Registrant - UNITED EXCHANGE CORP. (840130579)

Establishment

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

Revised: 10/2010 TAI GUK PHARM. CO., LTD.