QC DIAPER RASH - zinc oxide cream Quality Home Products

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 10%

Purpose

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 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

- store at room temperature
- Lot No and Exp Date: see box or see crimp of tube

Inactive ingredients

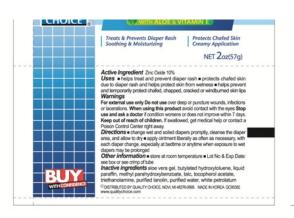
aloe vera gel, butylated hydroxytoluene, liquid paraffin, methyl parahydroxybenzoate, talc, tocopherol

Package label

QC Diaper Rash Cream



Zinc Oxide Ointment Cream



QC DIAPER RASH

zinc oxide cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64525-5382		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.10 g in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)			
MINERAL OIL (UNII: T5L8T28FGP)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
TALC (UNII: 7SEV7J4R1U)			
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
TROLAMINE (UNII: 9O3K93S3TK)			
LANOLIN (UNII: 7EV65EAW6H)			
WATER (UNII: 059QF0KO0R)			
PETROLATUM (UNII: 4T6H12BN9U)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC	64525-5382-2	1 in 1 BOX		
1		57 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/12/2011	

Labeler - Quality Home Products (205554157)

Revised: 9/2011 Quality Home Products