

DIAPER RASH- zinc oxide cream

Kareway Product, Inc.

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.

Pure-Aid Diaper Rash Cream

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

Talc, Vacillin, Bees wax, Demethicone, Liquid paraffin, Tocopherol acetate, Sesquioleate sorbitan,

Aloe vera gel, Methylparaben, Propylparaben, Purified water

Package label

Diaper Rash Cream



DIAPER RASH
zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0502
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.1 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
AMPICILLIN TRIHYDRATE (UNII: HXQ6A1N7R6)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
MINERAL OIL (UNII: T5L8T28FGP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0502-2	1 in 1 BOX	08/25/2011	
1		57 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:67510-0502-4	1 in 1 BOX	08/25/2011	
2		114 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/25/2011	

Labeler - Kareway Product, Inc. (121840057)