GOODSENSE DIAPER RASH- zinc oxide paste Geiss, Destin & Dunn, 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.

Active ingredient Purpose

Zinc oxide 40%...... Skin protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps seal out wetness

Warnings

For external use only

When using this product

• do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few 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
- allow to dry
- apply paste 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. & Exp. Date: see box or see crimp of tube

Inactive ingredients butylhydroxyanisole, lavender oil, liquid paraffin, methylparaben, petrolatum, polysorbate 60, purified lanolin, sorbitan monostearate, squalane, talc, tocopherol, acetate, water

Distributed by:

Geiss, Destin & Dunn, Inc.

Peachtree City, GA 30269

www.valuelabels.com

Made in Korea



GOODSENSE DIAPER RASH

zinc oxide paste

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-779	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	400 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)		
LAVENDER O IL (UNII: ZBP1YXW0H8)		
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)		
METHYLPARABEN (UNII: A218 C7HI9 T)		
PETROLATUM (UNII: 4T6H12BN9U)		

POLYSORBATE 60 (UNII: CAL22UVI4M)	
LANOLIN (UNII: 7EV65EAW6H)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
SQUALANE (UNII: GW89575KF9)	
TALC (UNII: 7SEV7J4R1U)	
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50804-779-04	1 in 1 BOX		
1	113 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	0 1/0 5/20 16	

Labeler - Geiss, Destin & Dunn, Inc. (076059836)

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