DIAPER RASH- zinc oxide paste GOODSENSE

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.

Diaper Rash Paste

Drug Facts

Active ingredient

Zinc oxide 40%

Purpose

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.

Avoid contact with 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: 800-222-1222.

Directions

- change wet and soiled diapers promptly
- cleanse the diaper area
- allow to dry
- apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or any time when exposure to wet diapers may be prolonged

Other information

- store at 15 to 30°C (59 to 86°F)
- Tamper Evident: DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

Inactive ingredients

aloe barbadensis leaf juice, BHA, cetyl alcohol, coconut butter, corn starch, fragrance, hydroxyethylcellulose, lanolin, methylparaben, mineral oil, petrolatum, polysorbate 20, purified water, shea butter

Questions or comments?

866-323-0107 or www.natureplex.com

Distributed by: Perrigo Direct, Inc. Peachtree City, GA 30269

PRINCIPAL DISPLAY PANEL - 56.7 g Tube Carton

GOODSENSE® NDC 50804-079-01

Maximum Strength

Diaper Rash Paste

40% Zinc Oxide

Soothes Burning Prevents Diaper Rash Protects Skin

NET WT 2 oz (56.7 g)

Compare to active ingredients of Desitin[®] Maximum Strength*



DIAPER RASH

zinc oxide paste

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-079
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	400 mg in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
Aloe Vera Leaf (UNII: ZY81Z83H0X)			
Butylated Hydroxyanisole (UNII: REK4960K2U)			
Cetyl Alcohol (UNII: 936JST6JCN)			
Cocoa Butter (UNII: 512OYT1CRR)			
Starch, Corn (UNII: 08232NY3SJ)			
Hydroxyethyl Cellulose, Unspecified (UNII: T4V6TWG28D)			
Lanolin (UNII: 7EV65EAW6H)			
Methylparaben (UNII: A2I8C7HI9T)			
Mineral Oil (UNII: T5L8T28FGP)			
Petrolatum (UNII: 4T6H12BN9U)			
Polysorbate 20 (UNII: 7T1F30V5YH)			
Water (UNII: 059QF0KO0R)			
Shea Butter (UNII: K49155WL9Y)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50804-079- 01	1 in 1 CARTON	05/29/2020	
1		56.7 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	05/29/2020	

Labeler - GOODSENSE (076059836)

Establishment				
Name	Address	ID/FEI	Business Operations	
Natureplex LLC		062808196	MANUFACTURE(50804-079)	

Revised: 3/2022 GOODSENSE