

QUALITY CHOICE MAXIMUM STRENGTH DIAPER RASH- zinc oxide cream

Chain Drug Marketing Association

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.

Maximum Strength Diaper Rash Paste

Active ingredient

Zinc Oxide, 40.0%

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.

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 cream 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 20° to 25°C (68° to 77°F)

Inactive ingredients

cod liver oil, talc, petrolatum, lanolin, water, methylparaben, fragrance, BHA

Package/Label Principal Display Panel

Maximum Strength Diaper Rash Paste
With 40% Zinc Oxide

Helps To Heal, Soothe & Prevent Diaper Rash

NET WT 4 OZ. (113 g)

*Compare to DESITIN[®] MAXIMUM STRENGTH

Maximum Strength Original Diaper Rash Paste provides overnight relief for your baby's delicate skin. This rich, dermatologist-tested and hypoallergenic formula contains the maximum level of zinc oxide to instantly form a protective barrier to help heal and soothe discomfort caused by diaper rash.

*This product is not manufactured or distributed by Johnson & Johnson[®]
Consumer Products Company, owner of the registered trademark Desitin[®]

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Novi, MI 48376-0995

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Manufactured in Israel
0D927 CD C1

SATISFACTION GUARANTEED

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Drug Facts (continued)

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Carton Label

QUALITY CHOICE MAXIMUM STRENGTH DIAPER RASH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-165
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	40 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
COD LIVER OIL (UNII: BBL281NWFQ)	
TALC (UNII: 7SEV7J4R1U)	
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN (UNII: 7EV65EAW6H)	
WATER (UNII: 059QF0KO0R)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-165-05	1 in 1 CARTON		
1		113 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/01/2014	

Labeler - Chain Drug Marketing Association (011920774)