

SHOPKO DIAPER RASH MAXIMUM STRENGTH- zinc oxide cream

Shopko Stores Operating Co., LLC

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.

SHOPKO® Diaper Rash Paste Maximum Strength

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

SHOPKO®

Diaper Rash Paste Maximum Strength

40% Zinc Oxide

Helps Heal, Soothe & Prevent Diaper Rash

Compare to Desitin® Maximum Strength Original Paste 40% Zinc Oxide Diaper Rash Paste Ingredients

NET WT 4 OZ (113 g)

SHOPKO® Diaper Rash Paste Maximum Strength 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®

Distributed by Emilia Personal Care Inc.

5890 Sawmill Road, Suite 230, Dublin, OH 43017

Questions? Call 1-866-543-5125

Made in Israel

SHOPKO® Satisfaction Guaranteed

By Refund or Exchange

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0D927 8C C1



Carton Label

SHOPKO DIAPER RASH MAXIMUM STRENGTH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:370 12-927
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: BBL281NWFG)	

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:370 12-927-11	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	12/10/2013	

Labeler - Shopko Stores Operating Co., LLC (023252638)