MAXIMUM STRENGTH ORIGINAL DIAPER RASH- zinc oxide cream American Sales Company

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.

Cottontails Maximum Strength Original 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

Cottontails baby care

maximum strength original diaper rash paste

Take care of your little one, from the top of their head to their tiny little toes, with Cottontails[®].

40% zinc oxide

Helps to heal, soothe & prevent diaper rash

Compare to Desitin[®] Maximum Strength Original Paste ingredients

NET WT. 4 OZ. (113 g)

Designed to be gentle on your little one, our skin care products will keep their skin smooth, soft and ready for the next exciting day.

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 irritation 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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Quality guaranteed or your money back.
0D927 D4 C1



original diaper rash paste

Take care of your little one, from the top of their head to their tiny little toes, with Cottontails*.

40% zinc oxide Designed to be gentle on your little one, our skin care products will keep their skin smooth, soft and ready for the next exciting day.

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 irritation caused by diaper rash.

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Quality guaranteed or your money back.

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	Drug Facts	Drug Facts (continued)	Other information
	Active ingredient Purpose Zinc Oxide, 40.0%Skin protectant	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	• store at 20" to 25°C (68" to 77°F)
	Uses • helps treat and prevent diaper rash • protects chafed skin due to diaper rash and helps seal out wetness	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	Inactive ingredients cod liver oil, talc, petrolatum, lanolin, water, methylparaben, fragrance, BHA
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	Warnings For external use only. When using this product • do not get into eyes	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	S
			%

Carton Label

MAXIMUM STRENGTH ORIGINAL DIAPER RASH

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-927
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	Strength

COD LIVER OIL (UNII: BBL281NWFG)	
TALC (UNII: 7SEV7J4R1U)	
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN (UNII: 7EV65EAW6H)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)	

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-927-11	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	11/15/2013	

Labeler - American Sales Company (809183973)

Revised: 9/2013 American Sales Company