

DIAPER RASH- zinc oxide ointment
Valu Merchandisers, Co.

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.

Best Choice Diaper Rash Ointment

Active ingredient

Zinc Oxide 40%

Purpose

Skin Protectant

Uses

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

Warnings

For external and/or intrarectal 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 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
- clean the diaper area
- allow to dry
- apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime exposure to wet diapers may be prolonged

Other information

store at 20 to 25C (68 to 77F)

Inactive ingredients

butylated hydroxytoluene, cod liver oil, fd&c yellow #4, lanolin, methyl paraben, paraffin wax, purified water, talc powder, white petrolatum

Questions or comments?

Call toll free: 1-800-883-0085

Package label

Diaper Rash Cream



DIAPER RASH

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-418
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
LANOLIN (UNII: 7EV65EAW6H)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
TALC (UNII: 7SEV7J4R1U)	
WATER (UNII: 059QF0K00R)	
PARAFFIN (UNII: I9O0E3H2ZE)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
COD LIVER OIL (UNII: BBL281NWFQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-418-04	1 in 1 BOX	01/30/2012	
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	01/30/2012	

Labeler - Valu Merchandisers, Co. (868703513)

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Valu Merchandisers, Co.