#### DIAPER RASH- zinc oxide cream 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.

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#### **Drug Facts**

### 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 cream

**Product Information** 

Product Type		HUMAN OTC DRUG	Item Code (S	n Code (Source)		NDC:63941-318	
Route of Administrat	ion	TOPICAL					
Active Ingredient/	Active Moie	ty					
Ingredient Name				<b>Basis of Strength</b>		Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)				ZINC OXIDE		400 mg in 1 g	
Inactive Ingredier	nts						
		Ingredient Name				Strength	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)							
COD LIVER OIL (UNII: BBL281NWFG)							
LANOLIN (UNII: 7EV65	EAW6H)						
METHYLPARABEN (UN	NII: A2I8C7HI9T						
PETROLATUM (UNII: 4	T6H12BN9U)						
TALC (UNII: 7SEV7J4R1U)							
WATER (UNII: 059QF0KO0R)							
PARAFFIN (UNII: 1900)	E3H2ZE)						
Packaging							
# Item Code	Ι	Package Description	Marke	ting Start Date	Mark	eting End Date	
<b>1</b> NDC:63941-318-04	1 in 1 BOX		01/30/20	) 12			
1	113 g in 1 TUBE	Type 0: Not a Combination Pro	duct				
Marketing Info	rmation						
Marketing Category	Applicatio	n Number or Monograph Ci	ation Mark	teting Start Date	Mar	keting End Date	
OTC monograph final	part347		0 1/30 /2	2012			

Labeler -	Valu Merchandisers,	Co.	(86870)	3513)
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Revised: 3/2019

Valu Merchandisers, Co.