

**COTTONTAILS DIAPER RASH - zinc oxide ointment**  
**AMERICAN SALES**

*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	Purpose
Zinc oxide, 40% .....	Skin protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps protect skin from wetness

Warnings

For external use only

Do not use

over deep or puncture wounds, infections or lacerations

When using this product avoid contact with the eyes

Stop use and ask a doctor if condition worsens or does not improve within 7 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, and allow to dry
- apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other information

- store at 20° to 25°C (68° to 77°F)
- Lot No. and Exp. Date: see box or see crimp of tube

Inactive ingredients

BHA, cod liver oil (high in vitamin A and D), fragrance, lanolin, methylparaben, petrolatum, talc and purified water, light mineral oil, tartrazine yellow #4 (FD and C yellow #4)

DISTRIBUTED BY: AMERICAN SALES COMPANY

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[www.Care1.info](http://www.Care1.info)

Made in Korea



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## COTTONTAILS DIAPER RASH

zinc oxide ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-343
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.4 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
COD LIVER OIL (UNII: BBL281NWFQ)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYL PARABEN (UNII: A2I8C7HI9T)	

<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-343-40	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	05/01/2012	

**Labeler** - AMERICAN SALES (809183973)

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