

**LEADER DIAPER RASH CREAM- diaper rash cream cream**  
**Cardinal Health**

*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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**CR-1189**

***Active Ingredient***

Zinc Oxide 40%

***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, and allow to dry
- apply paste 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 between 20° to 25°C (68° to 77°F)
- may stain clothing

***Inactive Ingredients***

white soft paraffine, COD liver oil, lanoline, talcum, glycerine, sorbitan soiquioleate, beeswax, tocopheryl acetate, fragrance.

***Questions?***

Label

N XXXXX-XXX-XX



Maximum Strength

# Zinc Oxide 40%

LDR Diaper Rash OI 40%, 113 gm

Compare to  
**DESITIN®**  
active ingredients\*

100% Money  
Back Guarantee

## Diaper Rash Cream

Helps treat and prevent diaper rash.  
Protects chafed skin due to diaper rash  
and helps seal out wetness.

**NET WT 4 OZ (113 g)**

<p><b>Drug Facts</b></p> <p><b>Active Ingredients</b> ..... <b>Purpose</b></p> <p>Zinc Oxide 40% ..... Skin Protectant</p>	<p><b>Warnings</b> (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>
<p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ helps treat and prevent diaper rash</li> <li>■ protects chafed skin due to diaper rash and helps seal out wetness</li> </ul>	<p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ change wet and soiled diapers promptly</li> <li>■ cleanse the diaper area, and allow to dry</li> <li>■ apply paste liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged</li> </ul>
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Return to place of purchase if not satisfied.  
CIN XXXXXXXX REV. 6/18 R180512

## LEADER DIAPER RASH CREAM

diaper rash cream cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-981
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4 g in 10 g
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### Inactive Ingredients

Ingredient Name	Strength
COD LIVER OIL (UNII: BBL281NWFG)	
LANOLIN (UNII: 7EV65EAW6H)	
TALC (UNII: 7SEV7J4R1U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LIQUID PETROLEUM (UNII: 6ZAE7X688J)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-981-13	1 in 1 BOX	08/03/2018	
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	08/03/2018	

### Labeler - Cardinal Health (097537435)