

BABY LOVE PERSONAL CARE DIAPER RASH- zinc oxide cream
Delta Brands & Products LLC

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.

Drug Facts

Active Ingredient

Zinc oxide 13%

Purpose

Skin Protectant

Uses

- helps treat and prevent diaper rash
- soothes and relieves irritated skin
- protects your baby's skin from wetness

Warnings

For external use only

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days or symptoms clear up and occur again in 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
- ointment should be applied at every 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)

Inactive Ingredients

water, mineral oil, petrolatum, yellow wax, dimethicone, sorbitan sesquioleate, microcrystalline wax, PEG-30 dipolyhydroxysterate, phenoxyethanol, potassium hydroxide, alpha-tocopherol acetate, aloe vera extract

Package Label

<div style="text-align: center;">  <h1 style="margin: 10px 0;">Diaper Rash Cream</h1> <ul style="list-style-type: none"> • with natural zinc oxide • gentle formula • hypoallergenic  <p style="text-align: center; margin: 10px 0;">maximum rash protection NET WT 4.5 OZ (127 g)</p> </div>	<p>Baby Love ...Baby Pure. Tender skin needs gentle formulations. Our diaper rash cream helps prevent, soothe, and treat diaper rash.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left; padding: 5px;">Drug Facts</th> </tr> <tr> <th style="text-align: left; padding: 5px;">Active ingredient</th> <th style="text-align: left; padding: 5px;">Purpose</th> </tr> <tr> <td style="padding: 5px;">Zinc oxide 13%</td> <td style="padding: 5px;">Skin protectant</td> </tr> <tr> <th colspan="2" style="text-align: left; padding: 5px;">Uses</th> </tr> <tr> <td colspan="2" style="padding: 5px;"> <ul style="list-style-type: none"> ■ helps treat and prevent diaper rash ■ soothes and relieves irritated skin ■ protects your baby's skin from wetness </td> </tr> <tr> <th colspan="2" style="text-align: left; padding: 5px;">Warnings</th> </tr> <tr> <td colspan="2" style="padding: 5px;">For external use only</td> </tr> <tr> <td colspan="2" style="padding: 5px;">When using this product ■ avoid contact with eyes.</td> </tr> <tr> <td colspan="2" style="padding: 5px;">Stop use and ask a doctor if ■ condition worsens or does not improve within 7 days or symptoms clear up and occur again in a few days</td> </tr> <tr> <td colspan="2" style="padding: 5px;">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <th colspan="2" style="text-align: left; padding: 5px;">Directions</th> </tr> <tr> <td colspan="2" style="padding: 5px;"> <ul style="list-style-type: none"> ■ change wet and soiled diapers promptly ■ cleanse the diaper area ■ allow to dry ■ ointment should be applied at every diaper change, specially at bedtime or anytime when exposure to wet diapers may be prolonged </td> </tr> <tr> <th colspan="2" style="text-align: left; padding: 5px;">Other information</th> </tr> <tr> <td colspan="2" style="padding: 5px;">■ store at 20° to 25°C (68° to 77°F)</td> </tr> <tr> <th colspan="2" style="text-align: left; padding: 5px;">Inactive ingredients</th> </tr> <tr> <td colspan="2" style="padding: 5px;">water, mineral oil, petrolatum, yellow wax, dimethicone, sorbitan sesquioleate, microcrystalline wax, PEG-30 dipolyhydroxysterate, phenoxyethanol, potassium hydroxide, alpha-tocopherol acetate, aloe vera extract</td> </tr> </table> <div style="margin-top: 10px;"> <p style="font-size: small;">ITEM NO: 92497 Manufactured for DELTA BRANDS & PRODUCTS LLC Larchmont, NY 10538 USA www.deltabrands.com Made in India</p>  </div>	Drug Facts		Active ingredient	Purpose	Zinc oxide 13%	Skin protectant	Uses		<ul style="list-style-type: none"> ■ helps treat and prevent diaper rash ■ soothes and relieves irritated skin ■ protects your baby's skin from wetness 		Warnings		For external use only		When using this product ■ avoid contact with eyes.		Stop use and ask a doctor if ■ condition worsens or does not improve within 7 days or symptoms clear up and occur again in a few days		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		Directions		<ul style="list-style-type: none"> ■ change wet and soiled diapers promptly ■ cleanse the diaper area ■ allow to dry ■ ointment should be applied at every diaper change, specially at bedtime or anytime when exposure to wet diapers may be prolonged 		Other information		■ store at 20° to 25°C (68° to 77°F)		Inactive ingredients		water, mineral oil, petrolatum, yellow wax, dimethicone, sorbitan sesquioleate, microcrystalline wax, PEG-30 dipolyhydroxysterate, phenoxyethanol, potassium hydroxide, alpha-tocopherol acetate, aloe vera extract	
Drug Facts																																	
Active ingredient	Purpose																																
Zinc oxide 13%	Skin protectant																																
Uses																																	
<ul style="list-style-type: none"> ■ helps treat and prevent diaper rash ■ soothes and relieves irritated skin ■ protects your baby's skin from wetness 																																	
Warnings																																	
For external use only																																	
When using this product ■ avoid contact with eyes.																																	
Stop use and ask a doctor if ■ condition worsens or does not improve within 7 days or symptoms clear up and occur again in a few days																																	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.																																	
Directions																																	
<ul style="list-style-type: none"> ■ change wet and soiled diapers promptly ■ cleanse the diaper area ■ allow to dry ■ ointment should be applied at every diaper change, specially at bedtime or anytime when exposure to wet diapers may be prolonged 																																	
Other information																																	
■ store at 20° to 25°C (68° to 77°F)																																	
Inactive ingredients																																	
water, mineral oil, petrolatum, yellow wax, dimethicone, sorbitan sesquioleate, microcrystalline wax, PEG-30 dipolyhydroxysterate, phenoxyethanol, potassium hydroxide, alpha-tocopherol acetate, aloe vera extract																																	

BABY LOVE PERSONAL CARE DIAPER RASH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72133-321
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
MINERAL OIL (UNII: T5L8T28FGP)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PETROLATUM (UNII: 4T6H12BN9U)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72133-321-45	127 g in 1 TUBE; Type 0: Not a Combination Product	04/09/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/09/2018	

Labeler - Delta Brands & Products LLC (080999173)

Revised: 4/2018

Delta Brands & Products LLC