

BALMEX ADULT CARE RASH- zinc oxide cream
Randob Labs, Ltd.

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.

BALMEX® ADULT CARE™ RASH

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Zinc Oxide 11.3%	Skin protectant

Uses

- helps relieve and prevent rashes and irritation due to wetness from incontinence
- protects chafed skin due to irritation and helps seal out wetness

Warnings

For external use only

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- condition worsens
- symptoms persist 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 immediately.

Directions

- gently cleanse affected skin
- pat dry with a clean, soft cloth or allow to air dry
- apply generously to affected area as needed, especially after incontinence episodes
- using a dry tissue to remove excess product from skin is most effective

Inactive ingredients mineral oil, water, beeswax, microcrystalline wax, synthetic beeswax, fragrance, sorbitan sesquioleate, oenothera biennis (evening primrose) seed extract, olea europaea (olive) leaf extract, dimethicone, tocopherol, methylparaben, glycine soja (soybean) oil, propylparaben, panthenol, sarcosine, benzoic acid, potassium aspartate, potassium hydroxide, magnesium aspartate, sodium cocoyl amino acids (309-021)

For more information please visit
www.BalmexAdult.com

Distributed by **RANDOB LABS LTD.**
Box 440, Cornwall, NY 12518

PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

Activ
Guard™

NEUTRALIZES
IRRITANTS

Balmex®
ADULTCARE™

RASH CREAM
ZINC OXIDE 11.3%

Soothes &
Protects Skin
From Irritation, Chafing & Rash

Dermatologist Tested
Works in One Use*
Odor-Free

NET WT 3 OZ (85 g)

Drug Facts

Active ingredient

Zinc oxide 11.3%

- Uses**
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 - protects chafed skin due to irritation and helps seal out wetness

Warnings

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Drug Facts (continued)

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Balmex[®] ADULTCARE[™]



NEUTRALIZES IRRITANTS

Balmex[®] ADULTCARE[™] RASH CREAM

ZINC OXIDE 11.3%

Soothes & Protects Skin
From Irritation, Chafing & Rash

- Dermatologist Tested
- Works in One Use*
- Odor-Free

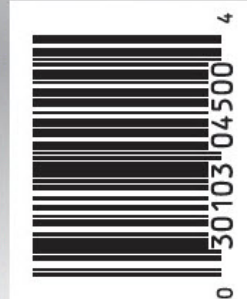
NET WT 3 OZ (85 g)

Balmex[®] Adult Care[™] Rash Cream is designed specifically to soothe and protect skin from the irritation, chafing, and rash caused by bladder leakage and proven to work in just one use.*

Powered by three proven ingredients:

- **Exclusive ActivGuard[™]** technology neutralizes irritants
- **Vitamin E** soothes and improves the healthy look of your skin
- **Zinc oxide** helps seal out wetness and prevent future rashes

Distributed by **RANDOL[®] LABS**
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*Proven to work to reduce redness with first use.

Soothes & Protects Skin
From Irritation, Chafing & Rash

- Dermatologist Tested
- Works in One Use*
- Odor-Free

Balmex[®] ADULTCARE[™] RASH CREAM

ZINC OXIDE 11.3%

NET WT 3 OZ (85 g)



BALMEX ADULT CARE RASH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52412-500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.113 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Mineral Oil (UNII: T5L8T28FGP)	
Water (UNII: 059QF0K00R)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Microcrystalline Wax (UNII: XOF597Q3KY)	
Sorbitan Sesquioleate (UNII: 0W8RRI5W5A)	
Oenothera Biennis (UNII: 76UI55V071)	
Olea Europaea Leaf (UNII: MJ95C3OH47)	
Dimethicone 100 (UNII: RO266O364U)	
Tocopherol (UNII: R0ZB2556P8)	
Methylparaben (UNII: A2I8C7HI9T)	
Soybean Oil (UNII: 241ATL177A)	
Propylparaben (UNII: Z8IX2SC1OH)	
Dexpanthenol (UNII: 1O6C93RI7Z)	
Sarcosine (UNII: Z711V88R5F)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
Potassium Aspartate (UNII: OC4598NZEQ)	
Potassium Hydroxide (UNII: WZH3C48M4T)	
Magnesium Aspartate Anhydrous (UNII: 082H981FMA)	
Sodium Cocoyl Glycinate (UNII: XLU9KH03XM)	
Propylene Glycol (UNII: 6DC9Q167V3)	
White Wax (UNII: 7GIJ5DA97F)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52412-500-03	1 in 1 CARTON	11/01/2018	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:52412-500-12	340 g in 1 JAR; Type 0: Not a Combination Product	11/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/27/2015	

Labeler - Randob Labs,Ltd. (061995007)

Establishment

Name	Address	ID/FEI	Business Operations
KIK HOLDCO COMPANY INC.		243547333	MANUFACTURE(52412-500)

Revised: 11/2018

Randob Labs,Ltd.