

BALMEX DIAPER 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® Diaper Rash

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Zinc Oxide 11.3%	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 immediately.

Directions

- change wet or soiled diapers promptly, cleanse the diaper area, and allow to dry
- apply cream liberally as often as necessary, with each diaper change, especially at bedtime or any time when exposure to wet diapers may be prolonged

Other information

- do not use if quality seal is broken
- see bottom of carton and or top of tube for lot number and expiration date

Inactive ingredients Beeswax, benzoic acid, dimethicone, fragrance, glycine soja (soybean) oil, magnesium aspartate, methylparaben, microcrystalline wax, mineral oil, oenothera biennis (evening primrose) seed extract, olea europea (olive) leaf extract, panthenol, potassium aspartate, potassium hydroxide, propylparaben, sarcosine, sodium cocoyl amino acids, sorbitan sesquioleate, synthetic beeswax, tocopherol, water (245-230)

Questions?

1-833-389-9450

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

PRINCIPAL DISPLAY PANEL - 113 g Tube Carton

NEW LOOK-SAME PRODUCT

Balmex®
COMPLETE
PROTECTION™

Zinc Oxide

DIAPER RASH CREAM

Prevents & Heals

- Protects against
all 3 leading causes
of diaper rash
- Reduces rash in
just 1 diaper change

Pediatrician Recommended

Advanced
Formula

NET WT 4 OZ (113 g)



DIAPER RASH CREAM
Crema Para Dermatitis del Pañal

NEW LOOK-SAME PRODUCT



Zinc Oxide
DIAPER RASH CREAM
Crema Para Dermatitis del Pañal

Prevents & Heals

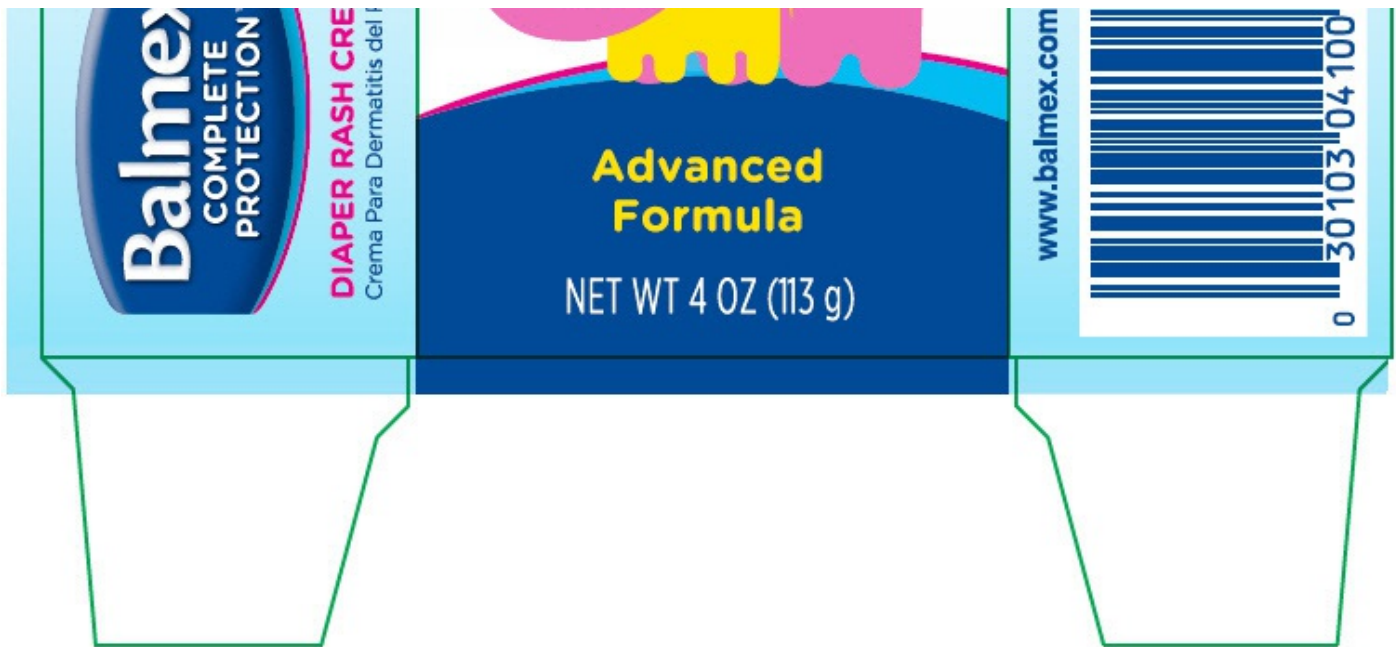
- ✓ Protects against all 3 leading causes of diaper rash
- ✓ Reduces rash in just 1 diaper change

Pediatrician Recommended



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Datos del Medicamento	Datos del Medicamento (continuación)
Propósito Óxido de Zinc 11.3% Protege la Piel	Propósito Óxido de Zinc 11.3% Protege la Piel
Ingredientes Activos Óxido de Zinc 11.3% Protege la Piel	Ingredientes Activos Óxido de Zinc 11.3% Protege la Piel
Usos • ayuda a tratar y prevenir las rozaduras de pañal • protege la piel irritada por las rozaduras de pañal y ayuda a mantener la piel seca	Usos • ayuda a tratar y prevenir las rozaduras de pañal • protege la piel irritada por las rozaduras de pañal y ayuda a mantener la piel seca
Precauciones Para uso externo solamente Cuando use este producto evite el contacto con los ojos. Deje de usarlo y consulte a su médico si la condición empeora o dura más de 7 días. Mantenga fuera del alcance de los niños. En caso de consumo accidental, busque ayuda médica o contacte al Centro de Control de Envenenamiento inmediatamente ▶	Precauciones Para uso externo solamente Cuando use este producto evite el contacto con los ojos. Deje de usarlo y consulte a su médico si la condición empeora o dura más de 7 días. Mantenga fuera del alcance de los niños. En caso de consumo accidental, busque ayuda médica o contacte al Centro de Control de Envenenamiento inmediatamente ▶
Otra información • no use si el sello de calidad está roto • vea la fecha de caducidad en la parte inferior de la caja o en el tubo	Otra información • no use si el sello de calidad está roto • vea la fecha de caducidad en la parte inferior de la caja o en el tubo
Ingredientes no activos cera de abeja, ácido benzóico, dimeticona, fragancia, aceite de soja (glycine soap), aspartato de magnesio, metilparabeno, cera microcristalina, aceite mineral, extracto de onagra (oenothera biennis), extracto de hoja de olivo (olea europaea), germen, alcohol, extracto de pasiflora, propilparabeno, sarcosina, aminocácidos de cocoil sodio, sequeudato de sorbitol, cera sintética de abeja, tocoferol, agua (245-230)	Ingredientes no activos cera de abeja, ácido benzóico, dimeticona, fragancia, aceite de soja (glycine soap), aspartato de magnesio, metilparabeno, cera microcristalina, aceite mineral, extracto de onagra (oenothera biennis), extracto de hoja de olivo (olea europaea), germen, alcohol, extracto de pasiflora, propilparabeno, sarcosina, aminocácidos de cocoil sodio, sequeudato de sorbitol, cera sintética de abeja, tocoferol, agua (245-230)



EXTRA PROTECTION for your baby's comfort

Balmex Complete Protection™ protects against all 3 leading causes of diaper rash to help keep your baby comfortable and rash-free.

IT PROTECTS AGAINST:

- ✓ **Diaper Wetness**
- ✓ **Skin Chafing**

PLUS

- ✓ **Digestive Enzymes**
found in dirty diapers
that irritate skin

Balmex's Advanced Formula is designed to help stop the rash before it starts by providing extra protection against skin irritation. If a rash develops, Balmex will work quickly to relieve discomfort and help heal the rash. In fact, a clinical study shows that **Balmex Complete Protection™** reduces diaper rash in just 1 diaper change.

Balmex contains the #1 Doctor recommended ingredient

for the treatment of diaper rash plus soothing vitamins B5 and E. It goes on smoothly allowing for gentle application and removal to keep baby's delicate skin comfortable.

**Recommended by
Pediatricians & Trusted by
Moms for over 50 years**

Questions? / Preguntas? 1-833-389-9450

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411A

BALMEX DIAPER RASH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52412-400
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
Yellow Wax (UNII: 2ZA36H0S2V)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
Dimethicone 100 (UNII: RO266O364U)	
Soybean Oil (UNII: 241ATL177A)	
Magnesium Aspartate Anhydrous (UNII: 082H981FMA)	

Methylparaben (UNII: A2I8C7HI9T)
Microcrystalline Wax (UNII: XOF597Q3KY)
Mineral Oil (UNII: T5L8T28FGP)
Oenothera Biennis (UNII: 76UI55V071)
Olea Europaea Leaf (UNII: MJ95C3OH47)
Dexpanthenol (UNII: 1O6C93RI7Z)
Potassium Aspartate (UNII: OC4598NZEQ)
Potassium Hydroxide (UNII: WZH3C48M4T)
Propylene Glycol (UNII: 6DC9Q167V3)
Propylparaben (UNII: Z8IX2SC1OH)
Sarcosine (UNII: Z711V88R5F)
Sorbitan Sesquioleate (UNII: 0W8RRI5W5A)
Tocopherol (UNII: R0ZB2556P8)
Water (UNII: 059QF0KO0R)
Sodium Cocoyl Glycinate (UNII: XLU9KH03XM)
White Wax (UNII: 7G1J5DA97F)

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52412-400-04	1 in 1 CARTON	11/01/2018	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:52412-400-16	453 g in 1 JAR; Type 0: Not a Combination Product	11/01/2018	
3	NDC:52412-400-02	1 in 1 CARTON	11/01/2018	
3		56 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:52412-400-05	5.1 g in 1 PACKAGE; 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(52412-400)