

# BALMEX DIAPER RASH- zinc oxide 11.3% 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 Cream

Zinc Oxide 11.3%

Skin Protectant

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

**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.

If swallowed, seek medical help or contact a Poison Control Center immediately.

Change wet and 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 anytime when exposure to wet diapers may be prolonged.

Beeswax, benzoic acid, dimethicone, glycine soja (soybean) oil, magnesium aspartate, microcrystalline wax, mineral oil, oenothera biennis (evening primrose) seed extract, olea europae (olive) leaf extract, panthenol, Peruvian balsam, Phenoxyethanol, potassium aspartate, potassium hydroxide, sarcosine, sodium cocoyl amino acids, sorbitan sesquioleate, synthetic beeswax, tocopherol, water.

<b>Drug Facts</b> <b>Active ingredient</b> Zinc oxide 11.3% <b>Purpose</b> Skin protectant <b>Uses</b> • Helps treat and prevent diaper rash • protects chafed skin due to diaper rash and helps seal out wetness <b>Warnings</b> <b>For external use only</b> When using this product • do not get into eyes. <b>Stop use and ask a doctor if</b> • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days. <b>Keep out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center immediately. <b>Directions</b> • 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 <b>Other information</b> • do not use if quality seal is broken • see bottom of jar for lot number and expiration date <b>Inactive ingredients</b> beeswax, benzoic acid, dimethicone, glycine soja (soybean) oil, magnesium aspartate, microcrystalline wax, mineral oil, oenothera biennis (evening primrose) seed extract, olea europaea (olive) leaf extract, panthenol, peruvian balsam, phenoxyethanol, potassium aspartate, potassium hydroxide, sarcosine, sodium cocoyl amino acids, sorbitan sesquioleate, synthetic beeswax, tocopherol, water	<b>Datos del Medicamento</b> <b>Ingredientes Activos</b> Óxido de Zinc 11.3% <b>Propósito</b> Protege la Piel <b>Usos</b> • 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 <b>Precauciones</b> <b>Para uso externo solamente</b> Cuando use este producto evite el contacto con los ojos. <b>Deje de usarlo y consulte a su médico</b> si la condición empeora o dura más de 7 días. <b>Mantenga fuera del alcance de los niños.</b> En caso de consumo accidental, busque ayuda médica o contacte al Centro de Control de Envenenamiento inmediatamente <b>Instrucciones de uso</b> • cambie los pañales mojados rápidamente • limpie el área del pañal y deje secar • aplique la crema tan frecuentemente como sea necesario, o con cada cambio de pañal, especialmente a la hora de dormir o en cualquier momento que se tenga contacto con pañales mojados durante un tiempo prolongado <b>Otra información</b> • 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 <b>Ingredientes no activos</b> cera de abeja, ácido benzoico, dimeticona, aceite de soja (glycine soja), aspartato de magnesio, cera microcristalina, aceite mineral, extracto de saúco (oenothera biennis), extracto de hoja de olivo (olea europaea), pantenol, bálsamo del Perú, fenoxietanol, hidróxido de potasio, sarcosina, aminoácidos de coccol sodico, sesquioxido de sorbitan, cera sintética de abeja, tocoferol, agua	<p><b>PROTECTS</b> Against wetness &amp; chafing</p> <p><b>NEUTRALIZES</b> Rash causing irritants with soothing botanicals</p> <p><b>EASY ON, EASY OFF</b></p> <p><b>CLINICALLY PROVEN</b> to reduce redness in 3 HOURS</p>	<p>COMPLETE PROTECTION</p> <p><b>Balmex</b></p> <p>COMPLETE PEACE OF MIND</p> <p>ZINC OXIDE <b>DIAPER RASH CREAM</b> Crema Para Dermatitis del Pañal</p>  <p>PEDIATRICIAN RECOMMENDED</p> <p>NET WT 16 OZ (453 g)</p>	<p>PARABEN FREE</p> <p>Only Balmex gives you the complete package for your baby's comfort and your peace of mind. Balmex prevents rash before it starts by forming a protective barrier and neutralizing rash-causing irritants with proven botanical extracts. Balmex works quickly to soothe and heal an existing rash. Gentle on baby's delicate skin, it's easy to apply and remove. So you and your baby can completely enjoy each precious moment.</p> <p>Questions? / Preguntas? 1-833-389-9450 Distributed by <b>RANDOB LABS</b> Box 440, Cornwall, NY 12518 © 2020 All Rights Reserved 421E www.balmex.com</p>
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## BALMEX DIAPER RASH

zinc oxide 11.3% cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52412-285
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	11.3 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>DIMETHICONE 350</b> (UNII: 2Y53S6ATLU)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>MAGNESIUM ASPARTATE</b> (UNII: R17X820ROL)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>EVENING PRIMROSE OIL</b> (UNII: 3Q9L08K71N)	
<b>OLEA EUROPAEA LEAF</b> (UNII: MJ95C3OH47)	
<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
<b>BALSAM PERU</b> (UNII: 8P5F881OCY)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POTASSIUM ASPARTATE</b> (UNII: OC4598NZEQ)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>SARCOSINE</b> (UNII: Z711V88R5F)	
<b>COCO ACID CHLORIDES</b> (UNII: R7N8Y0XMX7)	
<b>SORBITAN SESQUIOLEATE</b> (UNII: 0W8RRI5W5A)	
<b>SYNTHETIC BEESWAX</b> (UNII: 08MNR5YE2R)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:52412-285-16	453 g in 1 JAR; Type 0: Not a Combination Product	04/19/2021	
2	NDC:52412-285-12	340 g in 1 JAR; Type 0: Not a Combination Product	04/19/2021	
3	NDC:52412-285-04	1 in 1 CARTON	04/19/2021	
3		113 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:52412-285-02	1 in 1 CARTON	04/19/2021	
4		56 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:52412-285-03	1 in 1 CARTON	04/04/2023	
5		85 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	M016	04/19/2021	

**Labeler** - Randob Labs, LTD (061995007)

**Registrant** - Derma Care Research Labs (116817470)

## Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(52412-285)

Revised: 4/2023

Randob Labs, LTD