

BALMEX DIAPER RASH- zinc oxide 11.3% cream

Randob Labs, LTD

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.

Drug Facts Active ingredient Zinc oxide 11.3% 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 jar for lot number and expiration date Inactive ingredients 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	Datos del Medicamento Ingredientes Activos Óxido de Zinc 11.3% Propósito Protege la Piel Usos • ayuda a tratar y prevenir las roscaduras de pañal • protege la piel irritada por las roscaduras 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. Instrucciones de uso • 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 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 benzoico, dimeticona, aceite de soya (glycine soja), aspartato de magnesio, cera microcristalina, aceite mineral, extracto de orango (oenothera biennis), extracto de hoja de olivo (olea europae), panthenol, bálsamo del Perú, fenoxietanol, hidróxido de potasio, sarcosina, amoníaco de coccol ácido, sesquióleato de sorbitol, cera sintética de abeja, tocoferol, agua	COMPLETE PROTECTION Balmex COMPLETE PEACE OF MIND ZINC OXIDE DIAPER RASH CREAM Crema Para Dermatitis del Pañal PARABEN FREE PROTECTS Against wetness & chafing NEUTRALIZES Rash causing irritants with soothing botanicals EASY ON, EASY OFF CLINICALLY PROVEN to reduce redness in 3 HOURS 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. Questions? / Preguntas? 1-833-389-9450 Distributed by RANDOB LABS Box 440, Cornwall, NY 12518 © 2020 All Rights Reserved. 421E www.balmex.com	0 30103 04200 3
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BALMEX DIAPER RASH

zinc oxide 11.3% cream

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
SOYBEAN OIL (UNII: 241ATL177A)	
MAGNESIUM ASPARTATE (UNII: R17X820ROL)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
MINERAL OIL (UNII: T5L8T28FGP)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
PANTHENOL (UNII: WW9CM0O67Z)	
BALSAM PERU (UNII: 8P5F881OCY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM ASPARTATE (UNII: OC4598NZEQ)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SARCOSINE (UNII: Z711V88R5F)	
COCO ACID CHLORIDES (UNII: R7N8Y0XMX7)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
TOCOPHEROL (UNII: ROZB2556P8)	
WATER (UNII: 059QF0KO0R)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	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: 12/2024

Randob Labs, LTD