

BALMEX MULTI-PURPOSE- petrolatum ointment
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® MULTI-PURPOSE

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Petrolatum 51.1%	Skin protectant

Uses

- temporarily protects minor
 - cuts
 - scrapes
 - burns
- temporarily protects and helps relieve chapped or cracked skin
- 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.

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- apply as needed
- change wet or soiled diapers promptly, cleanse the diaper area, and allow to dry
- apply ointment 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 tube for lot number and expiration date

Inactive ingredients

acacia farnesiana flower extract, allantoin, aloe barbadensis leaf extract, chamomilla recutita (matricaria) flower extract, cholecalciferol, cyclomethicone, dimethicone, fragrance, isopropyl myristate, isopropyl palmitate, lavandula angustifolia (lavender) extract, mineral oil, polyethylene, retinyl palmitate, rosmarinus officinalis (rosemary) extract, silica, tocopheryl acetate, zea mays (corn) oil (245-276)

Questions?

1-833-389-9450

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

PRINCIPAL DISPLAY PANEL - 99 g Tube Label

NEW LOOK-SAME PRODUCT

Balmex®

MULTI-PURPOSE

HEALING OINTMENT

Skin Protectant-Petrolatum 51.1%

From diaper rash to
chapped, chafed skin

- Heals, protects & soothes
- 7 healing moisturizers
plus Vitamin A & Vitamin D
- Clear and easy to apply

Pediatrician Recommended

NET WT

3.5 OZ

(99 g)



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431A

BALMEX MULTI-PURPOSE			
petrolatum ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52412-450
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	511 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Vachellia Farnesiana Flower (UNII: 8487B3MG6D)	
Allantoin (UNII: 344S277G0Z)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Chamomile (UNII: FGL3685T2X)	
Cholecalciferol (UNII: 1C6V77QF41)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Cyclomethicone 6 (UNII: XHK3U310BA)	
Dimethicone 200 (UNII: RGS4T2AS00)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Lavandula Angustifolia Subsp. Angustifolia Flowering Top (UNII: 9YT4B71U8P)	
Mineral Oil (UNII: T5L8T28FGP)	
High Density Polyethylene (UNII: UG00KM4WR7)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
Rosemary (UNII: IJ67X351P9)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
.alpha.-tocopherol Acetate, DI- (UNII: WR1WPI7EW8)	
Corn Oil (UNII: 8470G57WFM)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52412-450-35	99 g in 1 TUBE; 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(52412-450)

