

**DIAPER CREAM- diaper cream ointment**  
**Private Label Select Ltd CO**

*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.*

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**MikesRXment Diaper Rash Ointment**

**MIKESRX Dosage n Admin**

**Directions**

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 anytime exposure to wet diapers may be prolonged. Apply with each fistula management and dressing changes. Pay special attention to changes at bedtime to provide protection through the evening hours.

**MIKESRX Inactive Ingredients**

**Inactive Ingredients** Beeswax\*, Castor Seed Oil\*, Coconut Oil\*, Jojoba Oil\*, Lanolin, Olive Fruit Oil\*, Shea Butter\*, Sunflower Seed Oil\*, Tocopherol \*Certified Organic Ingredient(s)

**MIKESRX Indications Usage**

**Uses** Skin protectant that helps to seal out wetness, helps to protect, helps to heal skin irritations associated with diaper dermatitis caused by urine, diarrhea/ and or stools, perspiration, minor burns, cuts, scrapes, itching, fistula site drainage & or leakage.

**MIKESRX OTC-Active Ingredients**

**Drug Facts**

**Active Ingredients**

**Purpose**

Menthol 0.44% ..... External analgesic | Anti-itch  
Zinc Oxide 20.6% ..... Skin protectant | Anorectal astringent

**MIKESRX Keep out of reach of Children**

**Warnings**

**For external use only** • Avoid contact with eyes • Keep out of the reach of children • Do not use on deep puncture wounds, infections or lacerations • If swallowed get medical help or contact a poison control center immediately.

**Stop use and ask doctor if**

condition worsens • symptoms last more than 7 days or clear up and occur again within a few days

**MIKESRX Purpose**

**Drug Facts**

**Active Ingredients**

**Purpose**

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## MIKESRX Warnings

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## MikesRX Diaper Rash Ointment



# MIKESRX.COM™

NATURAL INGREDIENTS

## DIAPER RASH OINTMENT & SKIN PROTECTANT

Sold exclusively at [mikesrx.com](http://mikesrx.com) & [americanrx.com](http://americanrx.com)
Net Wt. 4oz (113g)

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Menthol 0.11% .....	External analgesic / Anti-itch
Zinc Oxide 20.6% .....	Skin protectant / Anorectal astringent
<b>Uses</b> Skin protectant that helps to seal out wetness, helps to protect, helps to heal skin irritations associated with diaper dermatitis caused by urine, diarrhea/ and or stools, perspiration, minor burns, cuts, scrapes, itching, fistula site drainage & or leakage.	
<b>Warnings</b> For external use only • Avoid contact with eyes • Keep out of the reach of children • Do not use on deep puncture wounds, infections or lacerations • If swallowed get medical help or contact a poison control center immediately.	
<b>Stop use and ask doctor if</b> condition worsens • symptoms last more than 7 days or clear up and occur again within a few days	
<b>Directions</b> 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 anytime exposure to wet diapers may be prolonged. Apply with each fistula management and dressing changes. Pay special attention to changes at bedtime to provide protection through the evening hours.	
<b>Inactive Ingredients</b> Beeswax*, Castor Seed Oil*, Coconut Oil*, Jojoba Oil*, Lanolin, Olive Fruit Oil*, Shea Butter*, Sunflower Seed Oil*, Tocopherol *Certified Organic Ingredient(s)	
Manufactured in the U.S.A. for Pavan & Michael LLC. • 19-35 Hazen St. East Elmhurst, NY 11370	



Store  
 in  
 cool  
 dry  
 place  
 (59-86°F)  
 (15-30°C)

## DIAPER CREAM

diaper cream ointment

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-157
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>MENTHOL</b> (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	0.5 g in 100 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	22 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-157-21	113 g in 1 TUBE; Type 0: Not a Combination Product	02/27/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/27/2019	

**Labeler** - Private Label Select Ltd CO (005415463)

Revised: 5/2019

Private Label Select Ltd CO