BUM EASE - zinc oxide liquid Wake Innovation, LLC

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.

Drug Facts

Active Ingredient

Zinc Oxide 10%

Purpose

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 avoid contact with eyes.

Stop use and contact a doctor if:

- Condition worsens
- Symptoms last more than seven days or clear up and occur again within a few days.
- Keep this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Shake Well Before Use
- Hold bottle 2-3 inches from baby's bottom while spraying
- Press down on the pump to spray
- Change wet and solid diapers promptly
- Cleanse the diaper area, and allow to dry
- Apply spray liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposeure to wet diapers may be prolonged

Other Information

• Store at 15° to 25°C (59° to 77°F)

Inactive Ingredients

*Aqua, *Arachis Hypogaea Oil *C14-22 Alcohol, *C12-20 Alkyl, *Coco-Caprylate/Caprate,

- *Cocoglycerides,
- *Glucoside, *Glycerin, Phenoxyethanol Ethylhexylglycerin, *Oleic Acid and *Silica
- *Natural Ingredients

Questions?

Call toll free 1-800-831-0507

Distributed by: Wake Innovation, LLC P.O. Box 98355 Raleigh, NC 27624-8355 USA

Package Label

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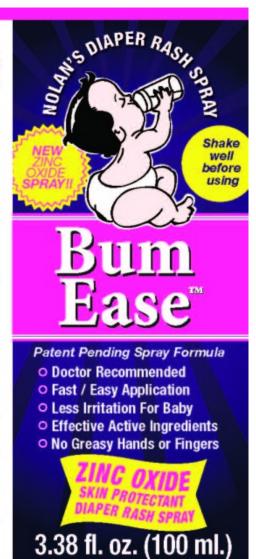
- * Aqua, *Arachis Hypogaea Oil *C14-22 Alcohol, *C12-20 Alkyl, *Coco-Caprylate/Caprate,
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ZINC OXIDE SKIN PROTECTANT DIAPER RASH SPRAY

NEW ZINC OXIDE SPRAY!!

Shake well before using

Patent Pending Spray Formula

- Doctor Recommended
- Fast / Easy Application
- Less Irritation For Baby
- Effective Active Ingredients
- No Greasy Hands or Fingers

3.38 fl. oz. (100 ml.)

BUM EASE

zinc oxide liquid

Product Informatio	n
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:76330-100

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthZinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)Zinc Oxide10 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
PEANUT O IL (UNII: 5TL50 QU0 W4)		
CO CO NUT ACID (UNII: 40 U37V505D)		
Glycerin (UNII: PDC6A3C0OX)		
C14-22 ALCOHOLS (UNII: B1K89384RJ)		
C12-20 Alkyl Glucoside (UNII: K67N5Z1RUA)		
COCO-GLYCERIDES (UNII: ISE917DNUG)		
Phenoxyethanol (UNII: HIE492ZZ3T)		
Ethylhexylglycerin (UNII: 147D247K3P)		
Oleic Acid (UNII: 2UMI9 U37CP)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	

Contains

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:76330-100-10	1 in 1 BOX				
1		100 mL in 1 BOTTLE, PUMP				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part347	07/01/2011				

Labeler - Wake Innovation, LLC (967723029)

Revised: 12/2011 Wake Innovation, LLC