

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 exposure 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

<p>Drug Facts</p> <hr/> <table border="0"> <tr> <td data-bbox="126 772 370 806">Active Ingredient</td> <td data-bbox="906 772 1019 806">Purpose</td> </tr> <tr> <td data-bbox="126 806 860 835">Zinc Oxide 10%</td> <td data-bbox="868 806 1019 835">Skin Protectant</td> </tr> </table> <hr/> <p>Uses</p> <ul style="list-style-type: none"> • Helps treat and prevent diaper rash • Protects chafed skin due to diaper rash and helps seal out wetness <hr/> <p>Warnings</p> <ul style="list-style-type: none"> • 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. <hr/> <p>Directions</p> <ul style="list-style-type: none"> • 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 exposure to wet diapers may be prolonged <hr/> <p>Other Information</p> <ul style="list-style-type: none"> • Store at 15° to 25°C (59° to 77°F) <hr/> <p>Inactive Ingredients</p> <p>* Aqua, *Arachis Hypogaea Oil *C14-22 Alcohol, *C12-20 Alkyl,*Coco-Caprylate/Caprate, *Cocoglycerides,*Glucoside, *Glycerin, Phenoxyethanol Ethylhexylglycerin, * Oleic Acid and *Silica *Natural Ingredients</p> <hr/> <table border="1"> <tr> <td data-bbox="126 1709 289 1743">Questions?</td> <td data-bbox="492 1709 930 1776">Distributed by: Wake Innovation, LLC P.O. Box 98355 Raleigh, NC 27624-8355 USA</td> </tr> <tr> <td data-bbox="126 1743 418 1776">Call toll free 1-800-831-0507</td> <td></td> </tr> </table>	Active Ingredient	Purpose	Zinc Oxide 10%	Skin Protectant	Questions?	Distributed by: Wake Innovation, LLC P.O. Box 98355 Raleigh, NC 27624-8355 USA	Call toll free 1-800-831-0507		
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Wake Innovation, LLC
www.mybumease.com
www.wakein.com



NOLAN'S DIAPER RASH SPRAY



Bum EaseTM

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.)

EXP:
LOT:

Bum EaseTM



Wake Innovation, LLC
www.mybumease.com
www.wakein.com



8 115333 100300 410

Bum Ease, now in a spray, contains the doctor recommended, active ingredient found in leading diaper rash treatments. Parents, grandparents, nurses and daycare personnel love this fast and easy spray-on formula, which eliminates the painful rubbing of baby's bottom. The NEW, EASY and HYGENIC application reduces spreading of germs. No messy clean up of fingers!
GRANDMA'S WAY, NOW IN A SPRAY!
This product is: Allergen Free, Perfume Free, Developed Without Animal Testing.

NOLAN'S DIAPER RASH SPRAY



Bum EaseTM

ZINC OXIDE SKIN PROTECTANT DIAPER RASH SPRAY

NOLAN'S DIAPER RASH SPRAY

NEW ZINC OXIDE SPRAY!!



Bum EaseTM



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3.38 fl. oz. (100 ml.)

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3.38 fl. oz. (100 ml.)

BUM EASE

zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76330-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
PEANUT OIL (UNII: 5TL50QU0W4)	
COCONUT ACID (UNII: 40U37V505D)	
Glycerin (UNII: PDC6A3C0OX)	
C14-22 ALCOHOLS (UNII: B1K89384RJ)	
C12-20 Alkyl Glucoside (UNII: K67N5Z1RUA)	
COCO-GLYCERIDES (UNII: ISE9I7DNUG)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Oleic Acid (UNII: 2UM9U37CP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	

Contains**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