

COOLBOTTOMS DIAPER RASH- dimethicone cream
pH R&D 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.

**Cool
bottoms®
DIAPER RASH CREAM**

Drug Facts

Active Ingredient

Dimethicone 1%

Purpose

Skin protectant

Uses

- helps treat diaper rash
- temporarily protects and helps relieve chapped or cracked skin
- protects chafed skin as associated with diaper rash and helps seal out wetness

Warnings

For external use only

When Using This Product

- Keep out of eyes.
Rinse eyes thoroughly with water to remove.

Stop use and ask a doctor if:

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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- change wet and soiled diapers promptly
- cleanse the diaper area
- allow to dry
- apply cream liberally as often as necessary, especially at bedtime when exposure to wet diapers may be prolonged.

Inactive Ingredients

Water, Mineral Oil, White Petrolatum, Sorbitol, Ceresine, Sorbitan Sesquioleate, Lanolin Alcohol,

Phenoxyethanol, Magnesium Hydroxide, Ethylhexylglycerin, BHT

Questions?

M-F CST Call: 1-877-725-RASH

Distributed by
GinJen
Hammond, LA 70401

PRINCIPAL DISPLAY PANEL - 57g jar carton

***developed by a
pediatrician***

PATENTED

***Cool
bottoms®***

DIAPER RASH CREAM

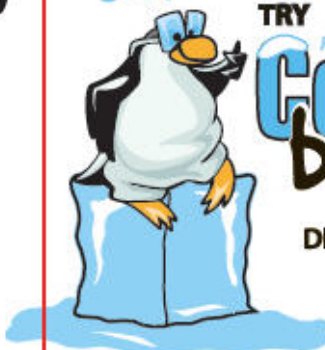
***skin protectant
cools and soothes***

NET WT 2 OZ (57g)



Mom!
Dad!

diaper rash just
won't go away?



TRY

PATENTED

Cool
botfoms[®]

DIAPER RASH CREAM
skin protectant
cools and soothes

Drug Facts (continued)

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botfoms[®]

DIAPER RASH CREAM
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cools and soothes

NET WT 2 OZ (57g)

biodegradable



recyclable

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Hammond, LA 70401

Patent 6805875, Patents Pending



7 93573 75558 2



order online at
www.coolbottoms.com



Patents Pending, U.S. Patent 6805875

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ARCTIC WHITE FORMULA cools and soothes! Diaper rashes that persist are hard for babies AND parents. **COOL BOTTOMS®** is **THE FIRST** diaper cream of its kind! **COOL BOTTOMS®** is specially formulated to soothe that irritating rash, while its fresh, unscented white formula maintains the neutrality of baby's skin for a cool, smooth bottom.

Drug Facts (continued)

Inactive Ingredients

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KO on Outside

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COOLBOTTOMS DIAPER RASH

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50952-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	0.57 g in 57 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Mineral Oil (UNII: T5L8T28FGP)	
Petrolatum (UNII: 4T6H12BN9U)	
Sorbitol (UNII: 506T60A25R)	
Sorbitan Sesquileate (UNII: 0W8RRI5W5A)	
Lanolin Alcohols (UNII: 884C3FA9HE)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Magnesium Hydroxide (UNII: NBZ3QY004S)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50952-001-04	4 in 1 BOX		
1		28 g in 1 JAR		
2	NDC:50952-001-05	8 in 1 BOX		
2		28 g in 1 JAR		
3	NDC:50952-001-06	12 in 1 BOX		

3		28 g in 1 JAR		
4	NDC:50952-001-07	24 in 1 BOX		
4		28 g in 1 JAR		
5	NDC:50952-001-01	1 in 1 BOX		
5		57 g in 1 JAR		
6	NDC:50952-001-02	12 in 1 BOX		
6		57 g in 1 JAR		
7	NDC:50952-001-03	24 in 1 BOX		
7		57 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/25/2010	

Labeler - pHR&D LLC (833115764)

Revised: 11/2010

pHR&D LLC