RASH RELIEF - zinc oxide dimethicone spray Touchless Care Concepts 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.

RASH RELIEF

Active Ingredients

Dimethicone 20% Zinc Oxide 25%

Purpose

Skin Protectant

Uses: Treats and prevents minor skin irritation - itching - diaper rash - feeding tubes sites, or lacerations.

Warnings

- Do not use over deep or puncture wounds, infections, or lacerations. For external use only.
- When using this product do not get into eyes. If contact occurs, rinse eyes throughout with water.
- Stop use and ask a doctor if condition worsens or does not improve with 7 days.

Directions

- Cleanse skin area, and allow to dry.
- Shake bottle well before use.
- Spray 4-6 inches from skin. No rub-in is required.
- Apply liberally as often as necessary- each diaper change with incontinence care- to soothe and protect irritated skin.

Inactive Ingredients

Cyclomethicone, Hexamethyldisiloxane, Lanolin, Light Mineral Oil, Microcrystalline Wax, Vitamin A Palmitate, Vitamin D3, Water, White Petrolatum

Uses: Treats and prevents minor skin irritation - itching - diaper rash - feeding tubes sites, or lacerations.

- Keep out of reach of children. If swallowed, get medical help or contact a local poison control center immediately.

Drug Facts

Active Ingredients Purpose
Dimethicone 20% Skin Protectant
Zinc Oxide 25% Skin Protectant

Uses Treats and prevents minor skin irritation: ■ Itching ■ Diaper Rash ■ Feeding tube sites ■ Cuts ■ Minor burns

Warnings Do not use over deep or puncture wounds, infections, or lacerations. For external use only.

When using this product do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if condition worsens or does not improve within 7 days.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately.

Directions ■ Cleanse skin area, and allow to dry. ■ Shake bottle well before use. ■ Spray 4-6 inches from skin. No rub-in is required. ■ Apply liberally as often as necessary- each diaper change for incontinence care- to soothe and protect irritated skin.

Inactive Ingredients Cyclomethicone, Hexamethyldisiloxane, Lanolin, Light Mineral Oil, Microcrystalline Wax, Vitamin A Palmitate Vitamin D3, Water, White Petrolatum.

Distributed by
Touchless Care
Concepts LLC
Louisville, KY 40204
(800) 779-4856





Treats & prevents irritation Soothes/Protects sensitive skin

NET WT. 2.0 OZ (56g)

Touchless-Care.com

US PATENT 6,627,178

RASH RELIEF

zinc oxide dimethicone spray

Product Information

Lanolin (UNII: 7EV65EAW6H)

Product Type HUMAN OTC DRUG Item Code (Source) NDC:15071-604

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	25 g in 100 g
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	20 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
Mineral Oil (UNII: T5L8T28FGP)		
Cyclomethicone (UNII: NMQ347994Z)		

Microcrystalline Wax (UNII: XOF597Q3KY)	
Hexamethyldisiloxane (UNII: D7M4659BPU)	
Water (UNII: 059QF0KO0R)	
Cholecalciferol (UNII: 1C6V77QF41)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
Petrolatum (UNII: 4T6H12BN9U)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:15071-604-11	56 g in 1 BOTTLE, SPRAY			
2	NDC:15071-604-22	128 g in 1 BOTTLE, SPRAY			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part347	06/21/2005			

Labeler - Touchless Care Concepts LLC (083459334)

Registrant - Touchless Care Concepts LLC (083459334)

Revised: 10/2011 Touchless Care Concepts LLC