# TOUCHLESS CARE ZINC OXIDE PROTECTANT- touchless care zinc oxide protectant spray Crawford Healthcare, Inc.

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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#### Touchless Care ZINC OXIDE PROTECTANT SPRAY

## **Active Ingredients**

Zinc Oxide 25%

Dimethicone 20%

## Purpose

Skin Protectant

Skin Protectant

#### Uses

- Helps treat and prevent diaper rash associated with incontinence associated dermatitis.
- Protects minor skin irritation due to excess moisture, urine or stool.
- Helps seal out wetness.

#### Warnings

Do not use on deep puncture wounds, serious burns, animal bites, or broken skin. 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 symptoms last more than 7 days or clear up and occur again within a few 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.

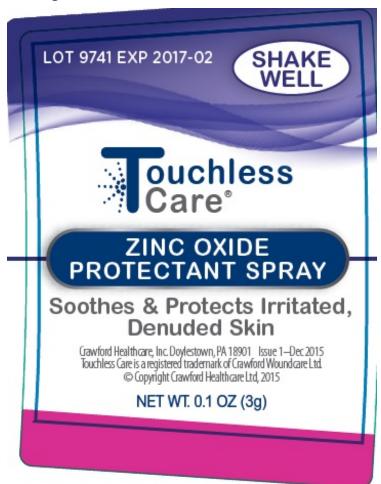
#### Other Information

Store at 59° F - 87° F (15° C - 30° C)

#### **Inactive Ingredients**

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

# Package Label



Sample card

#### **Zinc Oxide Protectant Spray**

DRUG FACTS	
Active Ingredient Zinc Oxide 25% Dimethicone 20%	<i>Purpose</i> Skin Protectant Skin Protectant
Uses   Helps treat and prevent diaper rash associated with inco  Protects minor skin irritation due to excess moisture, urine or	
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Debburdby Cowind Healthare, Inc. Doylestwn, PA 18901 Tourlies Gae is a regidered trademart Lot Cowind Healthare, Inc. © Copyright Cowind Healthare but, 2015 www.cowindochealfrace.com = 1-855-522-2211 Made in the USA Issue 3-Aug 2015 US Patient 6,627,178

Touchless Care' Spray	Individual Size	Quantity in Pk/Box	Product Code
Zinc Oxide	2.0 oz	24	62402
Protectant	4.5 oz	24	62404
Clear Protectant	2.0 oz	24	72402
Antifungal	2.0 oz	24	82402
First Aid Antibiotic	1.5 oz	24	62471

To purchase product please contact your medical supply distributor or call 855-522-2211



Crawford Healthcare Inc. 2005 South Easton Rd. I Suite 203 I Doylestown, PA 1890 Tel 855-522-2211 I Email us.info@crawfordhealthcare.com

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Reference: 1. Srellhatim A, et. all. Review on Zinc Oxide Nanoparticles: Antibacterial Activity & Toxicity Mechanism.

Vano-Micro Lett. 2015. 7(3):219-242. 2. Nolan, K. and Murmur, E. Moisturizers: Reality and the Skin benefits.

Dematologic Therapy: 2012;2(5):229-233.

CH15064-US



# TOUCHLESS CARE ZINC OXIDE PROTECTANT

touchless care zinc oxide protectant spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69502-504
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		
<b>DIMETHICO NE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
LANOLIN (UNII: 7EV65EAW6H)			
MINERAL OIL (UNII: T5L8T28FGP)			
CHOLECALCIFEROL (UNII: 1C6 V77QF41)			
PETROLATUM (UNII: 4T6H12BN9U)			
.ALPHATO CO PHERO L, DL- (UNII: 7Q WA1RIO 01)			

CORN OIL (UNII: 8470G57WFM)	
MICRO CRYSTALLINE WAX (UNII: XOF597Q3KY)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	
HEXAMETHYLDISILO XANE (UNII: D7M4659BPU)	
CYCLOMETHICONE (UNII: NMQ347994Z)	

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:69502-504- 03	3 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/14/2016		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	04/14/2016		

# Labeler - Crawford Healthcare, Inc. (042813710)

Establishment			
Name	Address	ID/FEI	Business Operations
Cosmetic Creations, Inc.		079375497	manufacture(69502-504), pack(69502-504), label(69502-504)

Revised: 4/2016 Crawford Healthcare, Inc.