# DERMACEN PROTECTANT- zinc oxide cream Central Solutions 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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#### **Drug Facts**

Active Ingredient

Zinc oxide 5.0%

Purpose

Anorectal Cream

Uses

Provides temporary relief of itching and discomfort in the perineal area

Warnings

For External Use Only

If condition worsens or does not improve within 7 days, consult a physician

Do not exceed the recommended daily dosage unless directed by a physician

In case of bleeding, consult a physician promptly

Keep out of reach of children

Directions

When practical, clean the affected area by patting or blotting with an appropriate cleaning pad. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product. Apply DermaCen Protectant Cream externally to the affected area.

**Inactive Ingredients** 

Purified Water, Cyclotetrasiloxane, Cyclopentasiloxane, Mineral Oil, Isopropyl Palmitate, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Ethylhexyl Palmitate, Glycerin, Cetyl Dimethicone, Dimethicone, Tocopherol, Zea Mays Oil, Retinyl Palmitate, Cholecalciferol, Beeswax, Hydrogenated Castor Oil, Sodium Chloride, Diazolidinyl Urea, Methyl Paraben

DermaCen

**Protectant Cream** 

A medicated

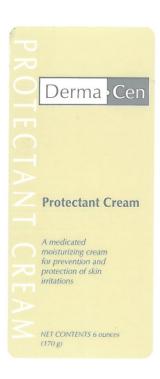
moisturizing cream

for prevention and

protection of skin

irritations

Net Contents 6 ounces (170g)





the affected area.

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Reorder No. DERM23103



Central Solutions, Inc. Kansas City, KS 66115 (800) 255-0262 www.centralsolutions.com

23103REV0610

zinc oxide cream

#### **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:62654-313

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.0 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
QUADRO SILAN (UNII: C5KT601WPM)		
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)		
MINERAL OIL (UNII: T5L8T28FGP)		
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH6 3 M)		
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)		
HEXYL LAURATE (UNII: 4CG9F9W01Q)		
ETHYLHEXYL PALMITATE (UNII: 2865993309)		
GLYCERIN (UNII: PDC6A3C0OX)		
<b>DIMETHICO NE</b> (UNII: 92RU3N3Y1O)		
TOCOPHEROL (UNII: R0ZB2556P8)		
CORN OIL (UNII: 8470G57WFM)		
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)		
CHOLECALCIFEROL (UNII: 1C6 V77QF41)		
YELLOW WAX (UNII: 2ZA36H0S2V)		
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
WATER (UNII: 059QF0KO0R)		

ı	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:62654-313- 06	170 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/06/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	0 1/0 1/20 0 1	

## Labeler - Central Solutions Inc (007118524)

Establishment			
Name	Address	ID/FEI	Business Operations
Central Solutions Inc		007118524	manufacture(62654-313)

Revised: 12/2018 Central Solutions Inc