DERMACEN SKIN 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.

Active ingredient

Zinc Oxide 5.0%

Purpose

Anorectal

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 immediately

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 Skin Protectant Cream externally to affected area

Inactive ingredients

Beeswax, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Cholecalciferol (Vitamin D3), Cyclopentasiloxane, Cyclotetrasiloxane, Dimethicone, DMDM Hydantoin, Ethylhexyl Palmitate, Glycerin, Hexyl Laurate, Hydrogenated Castor Oil, Iodopropynyl Butylcarbamate, Isopropyl palmitate, Polyglyceryl-4 Isostearate, Putified Water, Retinyl Palmitate (Vitamin A), Sodium Chloride, Tocopherol (Vitamin E), Zea Mays Oil

Questions?

Call 800-255-0262

Keep out of reach of children.

DermaCen

Skin

Protectant

Cream

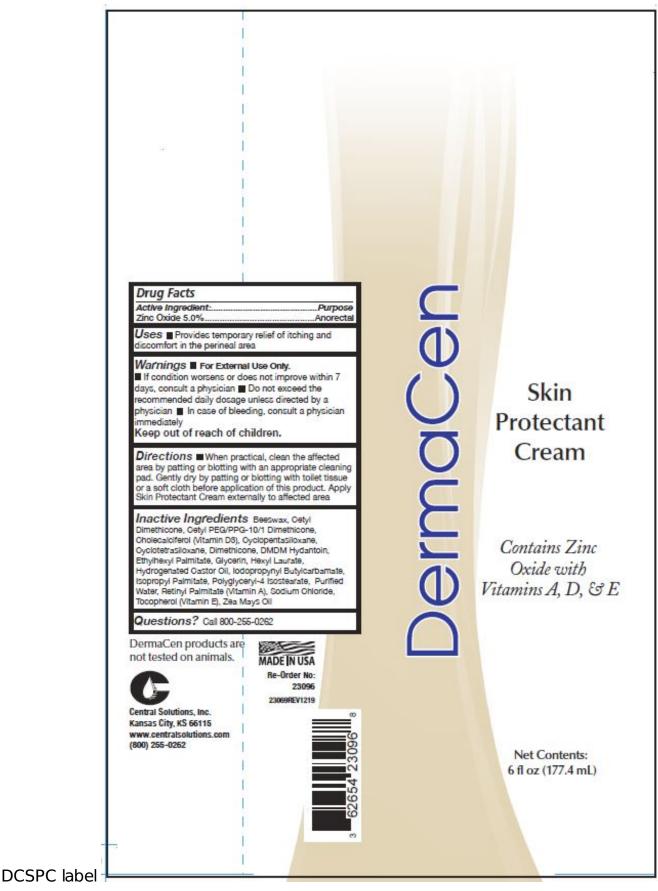
Conains Zinc

Oxide with

Vitamins A,D, and E

Net Contents:

6 fl oz (177.4 mL)



DERMACEN SKIN PROTECTANT

zinc oxide cream

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62654-148

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	50 ma in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
CYCLOMETHICONE 5 (UNII: 0THT5PCIOR)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CORN OIL (UNII: 8470G57WFM)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:62654-148- 06	177.4 mL in 1 TUBE; Type 0: Not a Combination Product	12/06/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	12/06/2019	

Establishment				
Name	Address	ID/FEI	Business Operations	
Central Solutions Inc		007118524	manufacture(62654-148)	

Revised: 1/2023 Central Solutions Inc