

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.

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)

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| Reorder No. DERM23103 | |
|  | Central Solutions, Inc. Kansas City, KS 66115 (800) 255-0262 www.centraisolutions.com |
| 23103REV0610 | |

zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item 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: 0THT5PC10R) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) | |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) | |
| HEXYL LAURATE (UNII: 4CG9F9W01Q) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| CORN OIL (UNII: 8470G57WFM) | |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | 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 | 01/01/2001 | |

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