# MCKESSON SKIN PROTECTANT- zinc oxide cream McKesson Medical-Surgical 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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#### Skin Protectant Cream

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

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 Skin Protectant Cream externally to affected area.

Inactive ingredients

Purified Water, Cyclotetrasiloxane, Isopropyl Palmitate, Ethylhexyl Palmitate, Glycerin, Cyclopentasiloxane, Polyglyceryl-4 Isostearate,

Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Cetyl Dimethicone, Dimethicone, Tocopherol (Vitamin E), Zea Mays Oil, Retinyl Palmitate (Vitamin A), Cholecalciferol (Vitamin D3), Beeswax, Hydrogenated Castor Oil, Sodium Chloride, DMDM Hydantoin, Iodopropynyl Butylcarbamate

Questions? Call 1-800-777-4908

NDC 68599-5312-6

McKesson

Skin

**Protectant** 

Cream

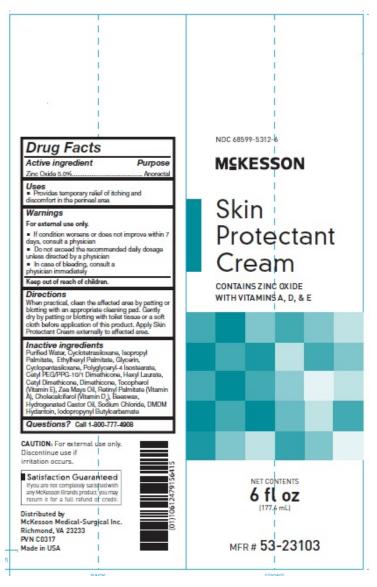
Contains Zinc Oxide

with Vitamins A, D, and E

**NET CONTENTS** 

6 oz

#### MFR # 53-23103



### MCKESSON SKIN PROTECTANT

zinc oxide cream

| Product Information   |                |                    |            |          |                |  |
|---|----------------|--------------------|------------|----------|----------------|--|
| Product Type  | HUMAN OTC DRUG | Item Code (Source) |            | NDC:68   | NDC:68599-5312 |  |
| Route of Administration   | TOPICAL        |                    |            |          |                |  |
|   |                |                    |            |          |                |  |
| A sainer Transport dis mat/A sainer Biff singer                     |                |                    |            |          |                |  |
| Active Ingredient/Active Moiety                                     |                |                    |            |          |                |  |
| Ingre   |                | Basis of Strei     | ngth       | Strength |                |  |
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) |                |                    | ZINC OXIDE |          | 50 mg in 1 mL  |  |
|   |                |                    |            |          |                |  |
|   |                |                    |            |          |                |  |
| Inactive Ingredients  |                |                    |            |          |                |  |

Strength

**Ingredient Name** 

| CETYL DIMETHICO NE 25 (UNII: U4AS1BW4ZB)                   |  |
|--|--|
| <b>DIMETHICO NE</b> (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)                         |  |
| DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)                      |  |
| METHYLPARABEN (UNII: A2I8C7HI9T)                           |  |
| WATER (UNII: 059QF0KO0R)                                   |  |
| CYCLOMETHICONE 4 (UNII: CZ227117JE)                        |  |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)                        |  |
| MINERAL OIL (UNII: T5L8T28FGP)                             |  |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)                     |  |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820 DPX33S7)             |  |
| CETYL PEG/PPG-10/1 DIMETHICO NE (HLB 2) (UNII: V2W71V8T0X) |  |
| HEXYL LAURATE (UNII: 4CG9F9W01Q)                           |  |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                    |  |
| GLYCERIN (UNII: PDC6 A3C0 OX)                              |  |

| Packaging |                      |  |                         |                       |
|-----------|----------------------|--|-------------------------|-----------------------|
| #         | Item Code            | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
| 1         | NDC:68599-5312-<br>1 | 24 in 1 CASE   | 10/25/2018              | 0 1/16/20 19          |
| 1         |                      | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |
| 2         | NDC:68599-5312-<br>2 | 24 in 1 CASE   | 10/25/2018              | 0 1/16/20 19          |
| 2         |                      | 207 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |
| 3         | NDC:68599-5312-      | 24 in 1 CASE   | 10/25/2018              |                       |
| 3         |                      | 117 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |

| Marketing Information |  |                      |                    |  |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph final   | part347                                  | 04/24/2014           |                    |  |
|                       |  |                      |                    |  |

## **Labeler** - McKesson Medical-Surgical Inc. (023904428)

| Establishment     |         |           |                         |  |
|-------------------|---------|-----------|-------------------------|--|
| Name              | Address | ID/FEI    | Business Operations     |  |
| Central Solutions |         | 007118524 | manufacture(68599-5312) |  |