

**DERMAHARMONY SEBORRHEIC DERMATITIS- pyrithione zinc cream**  
**D3 Development, 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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**Seborrheic Dermatitis Cream**

***Drug Facts***

***Active ingredient***

Pyrithione zinc 0.25%

***Purpose***

Seborrheic dermatitis cream

***Uses***

- Relieves skin and/or scalp itching, irritation, redness, flaking and scaling due to seborrheic dermatitis
- Helps eliminate recurrence of seborrheic dermatitis

***Warnings***

**For external use only**

**Ask a doctor before use if** condition covers a large area of the body.

**When using this product** avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water

**Stop use and ask a doctor if** condition worsens or does not improve after regular use of the product as directed.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

Apply to affected area one to four times daily

***Other information***

- Store at 59° to 77°F (15° to 25°C)
- Lot number and expiration date can be found on lid.

***Inactive ingredients***

Water, prunus amygdalus dulcis (sweet almond) oil, persea gratissima (avocado) oil, behentrimonium methosulfate, cetyl alcohol, glycerin, coco nucifera (coconut) oil, ricinus communis (castor) oil, stearyl alcohol, beeswax, shea butter, mango seed butter, phenoxyethanol, caprylyl glycol, tocopherol (vitamin E), hydroxyethylcellulose

***Questions?***

**1-800-827-3730**

[www.dermaharmony.com](http://www.dermaharmony.com)

**Distributed by:**

D3 Development, Inc.

Portland, ME 04101

dermaharmony

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Contains 0.25% Pyrithione Zinc

3 FL OZ (89 ml)



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NO ARTIFICIAL COLOR



NOT TESTED ON ANIMALS



FRAGRANCE FREE

## DERMAHARMONY SEBORRHEIC DERMATITIS

pyrithione zinc cream

### Product Information

|                         |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:718 19-002 |
| Route of Administration | TOPICAL        |                    |                |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

|   |                        |                  |
|---|------------------------|------------------|
| <b>PYRITHIONE ZINC</b> (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5) | <b>PYRITHIONE ZINC</b> | 0.25 g in 100 mL |
|---|------------------------|------------------|

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                           |          |
| <b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)                               |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                 |          |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                          |          |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                               |          |
| <b>HYDROXYETHYL CELLULOSE (1800 MPAS AT 2%)</b> (UNII: 6OX6A5C7B6) |          |
| <b>STEARYL ALCOHOL</b> (UNII: 2KR89I4HIY)                          |          |
| <b>ALMOND OIL</b> (UNII: 66YXD4DKO9)                               |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                                    |          |
| <b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)                              |          |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)                            |          |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                              |          |
| <b>CASTOR OIL</b> (UNII: D5340Y2I9G)                               |          |
| <b>BEHENTRIMONIUM METHO SULFATE</b> (UNII: 5SHP745C61)             |          |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                              |          |
| <b>MANGIFERA INDICA SEED BUTTER</b> (UNII: 4OXD9M35X2)             |          |

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71819-002-03 | 89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 07/26/2019           |                    |
| 2 | NDC:71819-002-06 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/26/2020           |                    |
| 3 | NDC:71819-002-08 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/26/2020           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part358H                                 | 07/26/2019           |                    |

**Labeler** - D3 Development, Inc. (043195877)