

DERMAHARMONY PYRITHIONE ZINC WITH SHEA BUTTER- pyrrithione zinc soap
D3 Development, Inc.

2% Pyrrithione Zinc Bar with Shea Butter

Drug Facts

Active ingredient

Pyrrithione zinc 2%

Purpose

Dandruff, Seborrheic dermatitis soap

Uses

Controls and reduces the symptoms of dandruff and seborrheic dermatitis.

Warnings

For external use only

Ask a doctor before use if you have a condition that 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 as directed.

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

Directions

- Use on affected areas in place of your regular soap
- For best results use at least twice a week or as directed by a doctor
- Work up a lather using warm water and massage into affected areas
- Rinse well

Other information

- Store at room temperature
- Lot number and expiration date are printed on back panel.

Inactive ingredients

Sodium palmate, shea butter, sodium cocoate*, sodium palm kernelate*, glycerin, water, cocoa butter, titanium dioxide, Avena Sativa (oat) kernel flour, tetrasodium glutamate diacetate, tocopheryl acetate (vitamin E), Rosmarinus officinalis (rosemary) leaf extract.

*May contain this ingredient

Questions?

1-800-827-3730

www.dermaharmony.com

Distributed by:

D3 Development, Inc., Portland, ME 04101

Made in the USA

dermaharmony

2% Pyrithione Zinc SOAP with Shea Butter

For Seborrheic Dermatitis & Dandruff

NET WT 3.7 OZ (105 G)

Drug Facts (continued)

Other information

- Store at room temperature
- Lot number and expiration date are printed on back panel.

Inactive ingredients Sodium palmate, shea butter, sodium cocoate*, sodium palm kernelate*, glycerin, water, cocoa butter, titanium dioxide, table salt, Avena Sativa (oat) kernel flour, tetrasodium glutamate diacetate, tocopheryl acetate (vitamin E), Rosmarinus officinalis (rosemary) leaf extract. * May contain this ingredient

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DERMAHARMONY PYRITHIONE ZINC WITH SHEA BUTTER

pyrithione zinc soap

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71819-017 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5) | PYRITHIONE ZINC | 2 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| SHEA BUTTER (UNII: K49155WL9Y) | |

| |
|---|
| COCOA BUTTER (UNII: 512OYT1CRR) |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) |
| WATER (UNII: 059QF0KO0R) |
| SODIUM COCOATE (UNII: R1TQH25F4I) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| OATMEAL (UNII: 8PI54V663Y) |
| SODIUM PALM KERNELATE (UNII: 6H91L1NXTW) |
| TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY) |
| SODIUM PALMATE (UNII: S0A6004K3Z) |
| .ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) |
| ROSEMARY (UNII: IJ67X351P9) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71819-017-37 | 105 g in 1 PACKAGE; Type 0: Not a Combination Product | 04/25/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M032 | 04/25/2022 | |

Labeler - D3 Development, Inc. (043195877)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| Vanguard Soap, LLC. | | 831404954 | manufacture(71819-017) |

Revised: 12/2024

D3 Development, Inc.