

DERMAHARMONY PYRITHIONE ZINC WITH SHEA BUTTER- pyrithione zinc soap 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.

2% Pyrithione Zinc Bar with Shea Butter

Drug Facts

Active ingredient

Pyrithione 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

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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 final	part358H	04/25/2022	

Labeler - D3 Development, Inc. (043195877)

Revised: 4/2022

D3 Development, Inc.