

ZINC THERAPY- 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.

Zinc Therapy Soap Bar

Drug Facts

Active ingredient

Pyrithione zinc 2%

Purpose

Dandruff, Seborrheic dermatitis

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, sodium cocoate*, sodium palm kernelate*, water, glycerin, titanium dioxide, Avena Sativa (oat) kernel flour, olive oil, vitamin E, table salt, pentasodium pentetate

Questions?

1-800-827-3730

www.dermaharmony.com

Distributed by:

D3 Development, Inc., Portland, ME 04101

Made in the USA

dermaharmony

Zinc Therapy SOAP

2% Pyrithione Zinc for Seborrheic Dermatitis & Dandruff

NET WT 4.0 OZ (113 G)

Drug Facts (continued)	
Other information ■ Store at room temperature ■ Lot number and expiration date are printed on back panel.	
Inactive ingredients: Sodium palmate, sodium cocoate*, sodium palm kernelate*, water, glycerin, titanium dioxide, <i>Avena Sativa</i> (oat) kernel flour, olive oil, vitamin E, table salt, pentasodium pentetate	
* 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
Zinc Therapy
SOAP

2% Pyrithione Zinc for Seborrheic Dermatitis & Dandruff

NET WT 4.0 OZ (113 G)

Drug Facts	
Active ingredient	Purpose
Pyrithione zinc 2%	Dandruff, Seborrheic dermatitis
Uses: Controls and reduces the symptoms of dandruff and seborrheic dermatitis.	
Warnings: For external use only	
Drug Facts (continued)	
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.	

ZINC THERAPY

pyrithione zinc soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:718 19-00 1
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
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)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SODIUM PALMATE (UNII: S0A6004K3Z)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71819-001-01	28 g in 1 CELLO PACK; Type 0: Not a Combination Product	05/01/2018	
2	NDC:71819-001-04	113 g in 1 CELLO PACK; Type 0: Not a Combination Product	05/01/2018	
3	NDC:71819-001-44	226 g in 1 CELLO PACK; Type 0: Not a Combination Product	03/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	05/01/2018	

Labeler - D3 Development, Inc. (043195877)