DERMAHARMONY ZINC THERAPY- pyrithione zinc liquid 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 Cleanser

Drug Facts

Active ingredient

Pyrithione zinc 2%

Purposes

Dandruff, Seborrheic dermatitis

Uses

Controls, reduces, and helps stop the symptoms of dandruff and seborrheic dermatitis.

Warnings

For external use only

Ask a doctor before use if you have seborrheic dermatitis that covers a large portion 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

- Shake before each use
- 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 on bottom

Inactive ingredients

Water, Lauryl Glucoside, Cocamidopropyl Hydroxysultaine, Sodium Lauroamphoacetate, Distearyl Phthalic Acid Amide, Sodium Chloride, Lauramine Oxide, Melaleuca Alternifolia (Tea Tree) Oil, Soyethyl Morpholinium Ethosulfate, Phenoxyethanol, Aloe Barbadensis Leaf Juice

Ouestions?

1-800-827-3730

Distributed by: D3 Development, Inc., Portland, ME 04101

Made in USA from U.S. and imported ingredients

dermaharmony

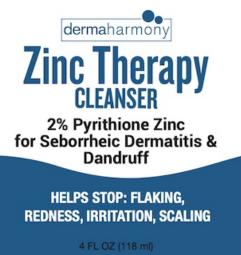
Zinc Therapy CLEANSER

2% Pyrithione Zinc for Seborrheic Dermatitis & Dandruff

HELPS STOP: FLAKING, REDNESS, IRRITATION, SCALING

4 FL OZ (118 ml)





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DERMAHARMONY ZINC THERAPY

pyrithione zinc liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:71819-016 Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength PYRITHIONE ZINC (UNII: R95302RHZ5) (PYRITHIONE ZINC - UNII:R95302RHZ5) PYRITHIONE ZINC 2 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)			
WATER (UNII: 059QF0KO0R)			
COCAMIDOPROPYL HYDROXYSULTAINE (UNII: 62V75NI93W)			
SOYETHYL MORPHOLINIUM ETHOSULFATE (UNII: J8C5W5HH18)			

DISTEARYL PHTHALAMIC ACID (UNII: 5552GSZ9LI)	
TEA TREE OIL (UNII: VIF565UC2G)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:71819- 016-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/05/2021		
2	NDC:71819- 016-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/05/2021		
3	NDC:71819- 016-64	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/05/2021		
4	NDC:71819- 016-99	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/05/2021		
5	NDC:71819- 016-10	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/05/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	09/05/2021		

Labeler - D3 Development, Inc. (043195877)

Revised: 9/2021 D3 Development, Inc.