DANDRUFF- pyrithione zinc shampoo
Primal Elements

Active ingredient

Pyrithione zinc 0.3%

Purpose

Anti-dandruff

Use

helps prevent recurrence of flaking and itching associated with dandruff.

Warnings

For external use only.

When using this product do not get into 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 Posion Control Center right away.

Directions

• shake well • for maximum dandruff control, use every time you shampoo • wet hair, massage onto scalp, rinse, repeat if desired • for best results, use at least twice a week or as directed by a doctor

Other information

Store at room temperature.

Inactive ingredients

Water (Aqua), Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Lauryl Sulfate, Cocamide MEA, Styrene/Acrylates Copolymer, Guar Hydroxypropyltrimonium Chloride, Sodium Citrate, Fragrance, Sodium Chloride, Dimethicone, Methylisothiazolinone,

Iodopropynyl Butylcarbamate

DANDRUFF SHAMPOO

WITH PYRITHIONE ZINC

- CONTROLS ITCHING AND FLAKING ASSOCIATED WITH DANDRUFF

- FOR ALL HAIR TYPES

- LEAVES HAIR FEELING SOFT

Compare to Head & Shoulders® Active Ingredient

12 FL OZ (355 ML)

ANTI-DANDRUFF SHAMPOO

WITH PYRITHIONE ZINC

Drug Facts

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Primal Elements Inc.
Huntington Beach, CA 92648
www.primalelements.com
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DANDRUFF
pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80801-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80801-103-01	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	05/01/2023	

Labeler - Primal Elements (968334144)

Revised: 10/2023   Primal Elements