TOPCARE GENTLE DANDRUFF DRY SCALP- pyrithione zinc liquid TopCo Associates LLC

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.

Drug Facts

Active ingredient

Pyrithione Zinc 1%

Purpose

Anti-dandruff

Uses

to help prevent recurrence of flaking and itching associated with dandruff.

Warnings

For external use only.

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 of this product as directed.

Keep out of reach of children.

In case of accidental ingestion, get medical help or contact Poison Control Ceneter immediately.

Directions

- for maximum dandruff control, use every time you shampoo
- wet hair, massage onto scalp and rinse
- repeat if desired

Inactive ingredients

Water (Aqua), Sodium Laureth Sulfate, Sodium Chloride, Cocamide MEA, Glycol Distearate, Dimethicone, Acrylates Copolymer, Glycerin, Cocamidopropyl Betaine, Fragrance (Parfum), Laureth-4, Guar Hydroxypropyltrimonium Chloride, Sodium Hydroxide, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone.

Label Copy

TopCare.

GENTLE dandruff shampoo

WITH PYRITHIONE ZINC

hair is cleaned and conditioned while moisturizers help soothe the scalp

with almond oil



14.2 FL OZ (420 mL)

06-19674

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*This product is not manufactured or distributed by Procter & Gamble, distributor of Head & Shoulders® Dry Scalp Care.

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
© TOPCO AHB514
OUESTIONS? 1-888-423-0139
topcare@topco.com
MADE IN CANADA



This TOP CARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



5-23007

TOPCARE GENTLE DANDRUFF DRY SCALP

pyrithione zinc liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:36800-429

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pyrithione Zinc (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	Pyrithione Zinc	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
LAURETH-4 (UNII: 6HQ855798J)	
GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
SO DIUM HYDRIDE (UNII: 23J3BHR95O)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36800-429- 13	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/28/2017		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part358H	04/28/2017			

Labeler - TopCo Associates LLC (006935977)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment					
Name	Address	ID/FEI	Business Operations		
Apollo Health and Beauty Care Inc.		201901209	manufacture(36800-429)		

Revised: 5/2017 TopCo Associates LLC