DANDRUFF- pyrithione zinc shampoo
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 a Poison Control Center 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, Glycol Distearate, Zinc Carbonate, Sodium Xylenesulfonate, Cocamidopropyl Betaine, Dimethicone, Fragrance (Parfum), Sodium Benzoate, Guar Hydroxypropyltrimonium Chloride, Magnesium Carbonate Hydroxide, Magnesium Sulfate, Benzyl Alcohol, Citric Acid, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Red 33 (CI 17200).

Label Copy

DANDRUFF

pyrithione zinc shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-309
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36800-309-13	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/19/2017	

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(36800-309)

Revised: 6/2017 TOPCO ASSOCIATES LLC