

2 IN 1 ANTIDANDRUFF- pyrithione zinc shampoo
Apollo Health and Beauty Care 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.

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.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- For best results, use at least twice a week or as directed by a doctor.
- For maximum dandruff control, use every time you shampoo.
- Wet hair, massage onto scalp and rinse. Repeat if desired.

Other information

Store at room temperature.

Inactive ingredients

Water (Aqua), Sodium Laureth Sulfate, Sodium Chloride, Acrylates Copolymer, Glycol Distearate, Cocamidopropyl Betaine, Laureth-4, Dimethicone, Fragrance (Parfum), Cocamide MEA, Guar Hydroxypropyltrimonium Chloride, Sodium Hydroxide, Tetrasodium EDTA, Methylchloroisoithiazolinone, Methylisoithiazolinone, Blue 1 (CI 42090), Red 33 (CI 17200).

Label Copy



2 IN 1 ANTIDANDRUFF

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-415
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: 059QF0K00R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	

SODIUM CHLORIDE (UNII: 451W47IQ8X)
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)
GLYCOL DISTEARATE (UNII: 13W7MDN21W)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
LAURETH-4 (UNII: 6HQ855798J)
DIMETHICONE (UNII: 92RU3N3Y1O)
CO CO MONOETHANOLAMIDE (UNII: C80684146D)
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
EDETATE SODIUM (UNII: MP1J8420LU)
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:63148-415-14	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/29/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	03/29/2017	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(63148-415)