P.O.V. DRY SCALP DANDRUFF- pyrithione zinc s hampoo 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 thoroughly with water.

Stop use and ask a doctor if

condition worsens or does not improve with 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

Wet hair and apply evenly to scalp, massaging gently. Rinse thoroughly. Repeat as needed. For best results, use at least twice a week or as directed by a doctor.

Inactive ingredients

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

Questions or comments?

1-866-695-3030

Label Copy





Our Dry Scalp Dandruff Shampoo works to alleviate symptoms associated with dry scalp and dandruff. Thorough care provides deep cleansing and hydrating comfort for a healthy scalp, irritant-free!

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MADE IN CANADA

Distributed by: Apollo Health & Beauty Care Inc. 1 Apollo Place, Toronto, ON M3J 0H2

6.22810

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P.O.V. DRY SCALP DANDRUFF

pyrithione zinc shampoo

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63148-416

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)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
LAURETH-4 (UNII: 6HQ855798J)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16 G315W7A)	
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
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:63148-416- 24	701 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/20/2017		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	11/20/2017		

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(63148-416)	

Revised: 11/2017 Apollo Health and Beauty Care Inc.