## P.O.V. CLASSIC DANDRUFF- 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.

-----

#### **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**

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, Acrylates Copolymer, Glycol Disterate, Cocamidopropyl Betaine, Cocamide MEA, Laureth-4, Fragrance (Parfum), Sodium Hydroxide, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Red 33 (CI 17200).

#### Questions or comments?

1-866-695-3030

#### **Label Copy**





- DUAL ACTION, PH BALANCED FORMULA
- CONTAINS PYRITHIONE ZINC
- HELPS RELIEVE ITCHING AND FLAKING.

**14.2** FL OZ (420 mL)

06-22807

# POV. CLASSIC DANDRUFF SHAMPOO

Go fresh and free with our Classic Dandruff Shampoo. This gentle formula cleanses to fight dandruff and flakes for softer, healthier hair. It's that everyday clean you crave, and a rousing afterfeel you'll love!

### 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 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** 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, Acrylates Copolymer, Glycol Distearate, Cocamidopropyl Betaine, Cocamide MEA, Laureth-4, Fragrance (Parfum), Sodium Hydroxide, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (Cl 42090), Red 33 (Cl 17200).

Questions or comments?1-866-695-3030

#### MADE IN CANADA

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

6-22808



#### P.O.V. CLASSIC DANDRUFF

pyrithione zinc shampoo

Dra	duct	Info	rmation
Prn			

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63148-411

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)			
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)			
GLYCOL DISTEARATE (UNII: 13W7MDN21W)			
COCAMIDO PRO PYL BETAINE (UNII: 50CF3011KX)			
COCO MONOETHANOLAMIDE (UNII: C80684146D)			
LAURETH-4 (UNII: 6HQ855798J)			
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)			
EDETATE SO DIUM (UNII: MP1J8420 LU)			
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)			
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)			
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:63148-411-	420 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(63148-411)	

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