EQUATE CLASSIC SPICE 2 IN 1 DANDRUFF- pyrithione zinc s hampoo Wal-Mart Stores 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.

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

Label Copy





EQUATE CLASSIC SPICE 2 IN 1 DANDRUFF

pyrithione zinc shampoo

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-432
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: PDC6 A3C0 OX)		
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)		
LAURETH-4 (UNII: 6HQ855798J)		
GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)		
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:49035-432- 12	399 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2017	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	04/27/2017		

Labeler - Wal-Mart Stores Inc (051957769)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Apollo Health and Beauty Care Inc.		201901209	manufacture(49035-432)	

Revised: 4/2017 Wal-Mart Stores Inc