SHOPKO BEAUTY MAXIMUM STRENGTH MEDICATED DANDRUFF- selenium sulfide 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

Selenium Sulfide 1%

Purpose

Anti-dandruff, Anti-seborrheic dermatitis

Uses

for the relief of flaking and itching associated with dandruff and seborrheic dermatitis and to help prevent the chance of recurrence.

Warnings

For external use only.

Ask a doctor before use if

you have seborrheic dermatitis in areas other than the scalp.

When using this product

- avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- for use on color-treated or permed hair, rinse thoroughly.

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

- shake well, wet hair, massage onto scalp and rinse.
- for best results, use at least twice a week or as directed by a doctor.

Other information

store at room temperature.

Inactive ingredients

Water (Aqua), Sodium Laureth Sulfate, TEA-Lauryl Sulfate, Cocamidopropyl Betaine, Acrylates

Copolymer, Citric Acid, Fragrance (Parfum), Ammonium Chloride, Menthol, Sodium Hydroxide, Magnesium Aluminum Silicate, Hydroxypropyl Methylcellulose, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Red 33 (CI 17200).

Questions or comments?

1-866-695-3030

Label Copy



SHOPKO BEAUTY MAXIMUM STRENGTH MEDICATED DANDRUFF selenium sulfide shampoo Product Information Product Type HUMAN OTC DRUG Route of Administration HUMAN OTC DRUG TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SELENIUM SULFIDE (UNII: Z69 D9 E38 1Q) (SELENIUM SULFIDE - UNII: Z69 D9 E38 1Q)	SELENIUM SULFIDE	10 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
TRIETHANO LAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)	
AMMO NIUM CHLO RIDE (UNII: 01Q9 PC255D)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
HYPROMELLOSES (UNII: 3NXW29 V3WO)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO.33 (UNII: 9DBA0SBB0L)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63148-005- 11	325 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 2/15/20 18		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part358H	02/15/2018			

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(63148-005)	