TOPCO ASSOCIATES- selenium sulfide shampoo Topco Associates

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.

Topcare Medicated Shampoo-76162-171-11

Selenium Sulfide 1%

anti dandruff

For external use only.

Ask a doctor before use if you have seborrheic dermatitis in areas other than the scalp.

- 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.

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

store at room temperature.

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,

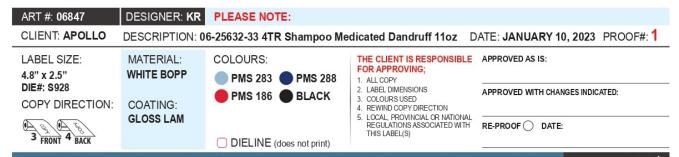
Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Red 33 (CI 17200).

1-888-423-0139

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







THIS IS NOT A COLOUR ACCURATE PROOF. Please refer to process and pantone colour charts for accurate colour representation.

Every effort has been made to ensure the accuracy of this proof. However, the client is responsible for ensuring that label size, copy, graphics and colour separations are accurate, and to notify Perflex

Label Inc. of any discrepancies prior to film, plate or label production. The client indemnifiers Perflex Label Inc. days any discrepancies six incurred due to errors on a customer signed proof.



PLEASE NOTE: A SIGNED PROOF IS REQUIRED FOR PRODUCTION. EMAIL APPROVAL TO YOUR CONTACT OR FAX TO 416 321-2267.

selenium sulfide shampoo

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76162-171

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM SULFIDE - UNII: Z69D9E381Q) SELENIUM SULFIDE 10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
AMMONIUM CHLORIDE (UNII: 01Q9PC255D)	
WATER (UNII: 059QF0KO0R)	
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FRAGRANCE CLEAN ORCO600327 (UNII: 329LCV5BTF)	
MAGNESIUM ALUMINUM SILICATE TYPE IA (UNII: SUS08ZOA9S)	
HYDROXYPROPYL METHACRYLATE (UNII: UKW89XAX2X)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ACRYLIC ACID/SODIUM ACRYLATE COPOLYMER (1:1; 600 MPA.S AT 0.2%) (UNII: M4PPW69Y4H)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

l	Packaging						
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
		NDC:76162- 171-11	325 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2023			

Marketing In	larketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	M032	05/04/2023				

Labeler - Topco Associates (006935977)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment							
Name	Address	ID/FEI	Business Operations				
Apollo Health and Beauty Care		201901209	manufacture(76162-171)				

Revised: 5/2023 Topco Associates