CAREONE MEDICATED DANDRUFF WITH MENTHOL- selenium sulfide shampoo
American Sales Company

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 preve 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

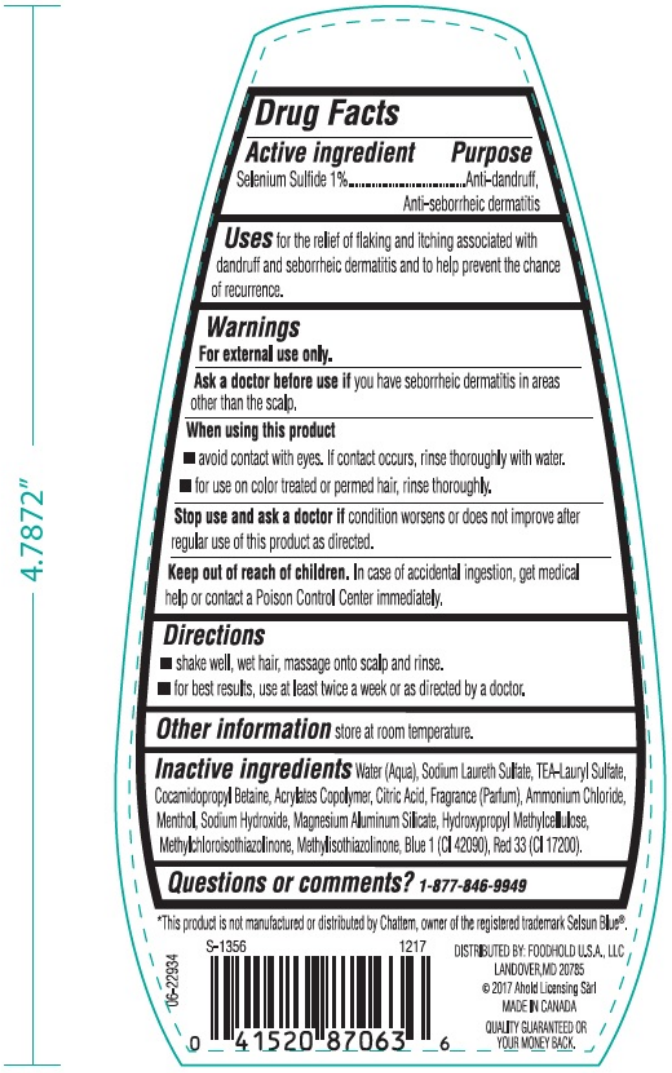
Water (Aqua), Sodium Laureth Sulfate, TEA-Lauryl Sulfate, Cocamidopropyl Betaine, Acrylates Copolymer, Citric Acid, Fragrance (Parfum), Ammonium Chloride, Menthol, Sodium Hydroxide,

Magnesium Aluminum Silicate, Hydroxypropyl Methylcelllulose, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Red 33 (CI 17200).

Questions or comments?

1-877-846-9949

Label Copy



CAREONE MEDICATED DANDRUFF WITH MENTHOL

selenium sulfide shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-718
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM SULFIDE - UNII:Z69D9E381Q)	SELENIUM SULFIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
AMMONIUM CHLORIDE (UNII: 01Q9PC255D)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
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:41520-718-11	325 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	03/27/2018	

Labeler - American Sales Company (809183973)

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

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(41520-718)

Revised: 3/2018 American Sales Company