CAREONE MOISTURIZING DANDRUFF- 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.

Active Ingredient

Selenium Sulfide 1%

Purpose

Anti-Dandruff

Uses

Controls flaking, scaling and itching associated with dandruff.

Warnings

For external use only

Do not use

- on scalp that is broken or inflamed
- if you are allergic to ingredients in this product

When using this product

avoid contact with eyes. If product gets into eyes, rinse eyes thoroughly with water.

Stop using this product 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

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake well
- shampoo, then rinse thoroughly
- for best results, use at least twice a week or as directed by a doctor

Questions? Comments?

1 - 877 - 932 - 7948

Inactive Ingredients

Water (Aqua), Ammonium Lauryl Sulfate, Ammonium Laureth Sulfate, Dihydrogenated Tallow Phthalic Acid Amide, Cocamide DEA, Fragrance (Parfum), Titanium Dioxide, Dimethicone, Hydroxypropyl Methylcellulose, Citric Acid, Sodium Isostearoyl Lactylate, DMDM Hydantoin, Aloe Barbadensis Leaf Juice, Sodium Citrate, Sodium Chloride, Blue 1 (CI 42090)

Front and Back Labels

CAREONE MOISTURIZING DANDRUFF

selenium sulfide shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-611
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM - UNII:H6241UJ22B)	SELENIUM SULFIDE	1 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
AMMONIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM ISOSTEAROYL LACTYLATE (UNII: 8730J0D3EV)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE (UNII: 1R81RPY10G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-611-11	325 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	08/19/2011	

Labeler - American Sales Company (809183973)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care		201901209	manufacture

Revised: 8/2011 American Sales Company