CAREONE MEDICATED DANDRUFF- selenium sulfide liquid
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 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 EYES 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, APPLY SHAMPOO AND RINSE THOROUGHLY. 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, AMMONIUM CHLORIDE, SODIUM HYDROXIDE, DMDM HYDANTOIN, FRAGRANCE (PARFUM), MAGNESIUM ALUMINUM SILICATE, HYDROXYPROPYL METHYLCELLULOSE, MENTHOL, BLUE 1 (CI 42090), RED 33 (CI 17200)

LABEL COPY

CAREONE MEDICATED DANDRUFF

selenium sulfide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-719
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)	
TEA-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)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MENTHOL (UNII: L7T10EIP3A)	
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:41520-719-11	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	11/17/2014	

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(41520-719)

Revised: 11/2014 AMERICAN SALES COMPANY