RENEWAL MEDICATED- selenium sulfide liquid
RITE AID CORPORATION

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/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, FRAGRANCE (PARFUM), AMMONIUM CHLORIDE, DMDM HYDANTOIN, MENTHOL, SODIUM HYDROXIDE, MAGNESIUM ALUMINUM SILICATE, HYDROXYPROPYL METHYLCELLULOSE, BLUE 1 (CI 42090), RED 33 (CI 17200)

LABEL COPY

RENEWAL MEDICATED

selenium sulfide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11822-6191
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)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
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:11822-6191-1	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	01/13/2014	

Labeler - RITE AID CORPORATION (014578892)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(11822-6191)

Revised: 1/2015 RITE AID CORPORATION