RITE AID 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.

DRUG FACTS

ACTIVE INGREDIENT

SELENIUM SULFIDE 1%

PURPOSE

ANTI-DANDRUFF, ANTI-SEBORREIC DERMATITIS

USES

FOR RELIEF OF FLAKING AND ITCHING DUE TO DANDRUFF, AND SEBORRHEIC DERMATITIS, AND TO HELP PREVENT THE CHANCE OF RECURRENCE.

WARNINGS

FOR EXTERNAL USE ONLY.

ASK A DOCTOR BEFORE USING IF YOU HAVE

SEBORRHEIC DERMATITIS IN AREAS OTHER THAN THE SCALP.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH THE 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

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?

1-866-695-3030

INACTIVE INGREDIENTS:

WATER (AQUA), SODIUM LAURETH SULFATE, ACRYLATES COPOLYMER, TEA-LAURETH SULFATE, COCAMIDOPROPYL BETAINE, CITRIC ACID, AMMONIUM CHLORIDE, FRAGRANCE (PARFUM), DMDM HYDANTOIN, SODIUM HYDROXIDE, MENTHOL, MAGNESIUM ALUMINUM SILICATE, HYDROXYPROPYL METHYLCELLULOSE, BLUE 1 (CI 42090), RED 33 (CI 17200).

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RITE AID RENEWAL MEDICATED selenium sulfide liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-6201

Active Ingredient/Active Moiety	Active	Ingre	dient/A	ctive	Moiety
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ı	Active ingredient/Active whitety		
	Ingredient Name	Basis of Strength	Strength
	SELENIUM SULFIDE (UNII: Z69 D9 E38 1Q) (SELENIUM SULFIDE - UNII: Z69 D9 E38 1Q)	SELENIUM SULFIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390 UAPO)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3O11KX)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
AMMO NIUM CHLO RIDE (UNII: 01Q9 PC255D)	
DMDM HYDANTO IN (UNII: BYR0546TOW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MENTHOL (UNII: L7T10 EIP3A)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO.33 (UNII: 9DBA0SBB0L)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-6201-1	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	07/15/2013		

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(11822-6201)		

Revised: 7/2013 RITE AID CORPORATION