RITE AID RENEWAL CLINICAL- 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-SEBORRHEIC DERMATITIS

USES

HELPS PREVENT THE CHANCE OF RECURRENCE OF FLAKING, ITCHING, IRRITATION, SCALING AND REDNESS ASSOCIATED WITH DANDRUFF AND SEBORRHEIC DERMATITIS.

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 EYES. IF PRODUCT GETS INTO EYES, RINSE THOROUGHLY WITH WATER. FOR USE ON COLOR TREATED OR PERMED HAIR, RINSE THOROUGHLY.

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

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

SHAKE WELL, APPLY SHAMPOO, RINSE THOROUGHLY. FOR BEST RESULTS, USE AT LEAST TWICE A WEKK OR AS DIRECTED BY A DOCTOR.

QUESTIONS OR COMMENTS?

1-866-695-3030

INACTIVE INGREDIENTS:

WATER (AQUA), AMMONIUM LAURETH SULFATE, AMMONIUM LAURYL SULFATE, GLYCOL DISTEARATE, COCAMIDE MEA, ACRYLATES COPOLYMER, AMMONIUM XYLENESULFONATE, SODIUM HYDROXIDE, SODIUM CITRATE, FRAGRANCE (PARFUM), DIMETHICONE, CETYL ALCOHOL, SODIUM CHLORIDE, CITRIC ACID, SODIUM BENZOATE, STEARYL ALCOHOL, DISODIUM EDTA, HYDROXYPROPYL METHYLCELLULOSE, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, RED 4 (CI 14700).

LABEL COPY



RITE AID RENEWAL CLINICAL

selenium sulfide liquid

ı	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-6181
ı	Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
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)		
AMMO NIUM LAURETH-3 SULFATE (UNII: 896 SJ235FN)		
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)		
GLYCOL DISTEARATE (UNII: 13W7MDN21W)		
COCO MONOETHANOLAMIDE (UNII: C80684146D)		
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)		
AMMO NIUM XYLENES ULFO NATE (UNII: 4FZY6L6 XCM)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
SO DIUM CHLO RIDE (UNII: 451W47IQ8X)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
STEARYL ALCOHOL (UNII: 2KR8914H1Y)		
EDETATE SO DIUM (UNII: MP1J8420LU)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)		
METHYLISO THIAZO LINO NE (UNII: 229 D0 E1QFA)		
FD&C RED NO. 4 (UNII: X3W0 AM1JLX)		

I	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-6181-4	420 mL in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	03/26/2013		

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 (11822-6181)	

Revised: 3/2013 RITE AID CORPORATION