REXALL ALOE- selenium sulfide liquid DOLGENCORP INC.

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 RELIEF OF FLAKING AND ITCHING ASSOCIATED WITH DANDRUFF AND SEBORRHEIC DERMATITIS AND TO HELP PREVENT THE CHANCE OF RE-OCCURRENCE.

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, AND RINSE THOROUGHLY. FOR BEST RESULTS, USE AT LEAST TWICE A WEEK OR AS DIRECTED BY A DOCTOR.

INACTIVE INGREDIENTS:

WATER (AQUA), SODIUM LAURETH SULFATE, DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE, SODIUM CHLORIDE, COCAMIDOPROPYL BETAINE, TITANIUM DIOXIDE, SODIUM STEAROYL LACTYLATE, FRAGRANCE (PARFUM), DIMETHICONE, CITRIC ACID, DMDM HYDANTOIN, SODIUM CITRATE, ALOE BARBADENSIS LEAF POWDER,

QUESTIONS OR COMMENTS?

1-877-932-7948

LABEL COPY





REXALL ALOE

selenium sulfide liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-621	
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)	
SO DIUM LAURETH SULFATE (UNII: BPV390 UAPO)	
DIHYDRO GENATED TALLO W PHTHALIC ACID AMIDE (UNII: 1R8 1RPY10 G)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
SODIUM STEARO YL LACTYLATE (UNII: IN99IT31LN)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
DMDM HYDANTO IN (UNII: BYR0546 TOW)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-621-11	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	07/31/2013		

Labeler - DOLGENCORP INC. (068331990)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture (55910-621)	

Revised: 8/2013 DOLGENCORP INC.