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

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

STOP USE AND ASK A DOCTOR IF

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), AMMONIUM LAURYL SULFATE, AMMONIUM LAURETH SULFATE, DIHYDROGENATED TALLOW PHTALIC ACID AMIDE, COCAMIDE DEA, FRAGRANCE (PARFUM), TITANIUM DIOXIDE, DIMETHICONE, HYDROXYPROPYL METHYLCELLULOSE, CITRIC ACID, SODIUM ISOSTEAROYL LACTYLATE, DMDM HYDANTOIN, ALOE

BARBADENSIS LEAF JUICE, SODIUM CITRATE, SODIUM CHLORIDE, BLUE 1 (CI 42090).

REXALL ALOE

selenium sulfide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-616
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM SULFIDE - UNII:Z69D9E381Q)	SELENIUM SULFIDE	1 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
AMMONIUM LAURETH-3 SULFATE (UNII: 896SJ235FN)	
DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE (UNII: 1R81RPY10G)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM ISOSTEAROYL LACTYLATE (UNII: 8730J0D3EV)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-616-11	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	09/25/2012	

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(55910-616)

Revised: 9/2012 DOLGENCORP INC.