EQUALINE MOISTURIZING DANDRUFF - selenum sulfide shampoo
SUPERVALU 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

ANTIDANDRUFF

USES

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

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 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 WEEK OR AS DIRECTED BY A DOCTOR.

QUESTIONS? COMMENTS?

1-877-932-7948

INACTIVE INGREDIENTS

WATER (AQUA), AMMONIUM LAURYL SULFATE, AMMONIUM LAURETH SULFATE,

DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE, COCAMIDE MEA, 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).

LABEL COPY

EQUALINE MOISTURIZING DANDRUFF

selenum sulfide shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41163-616
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM - UNII:H6241UJ22B)	SELENIUM SULFIDE	1 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
AMMONIUM LAURETH-5 SULFATE (UNII: 43ZIH89I48)	
DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE (UNII: 1R81RPY10G)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
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:41163-616-11	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	03/23/2012	

Labeler - SUPERVALU INC. (006961411)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture

Revised: 3/2012 SUPERVALU INC.