HEALTHY ACCENTS- selenium sulfide liquid DZA BRANDS LLC

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 INGREDIENTS

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-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 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 WEEK OR AS DIRECTED BY A DOCTOR.

QUESTIONS? COMMENTS?

1-866-322-2439

INACTIVE INGREDIENTS:

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

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HEALTHY ACCENTS selenium sulfide liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55316-620 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)		
SO DIUM LAURETH SULFATE (UNII: BPV390 UAP0)		
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)		
TEA-LAURYL SULFATE (UNII: E8458C1KAA)		
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)		
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)		
AMMO NIUM CHLO RIDE (UNII: 01Q9PC255D)		
DMDM HYDANTO IN (UNII: BYR0546 TOW)		
MENTHOL (UNII: L7T10EIP3A)		
SODIUM HYDRO XIDE (UNII: 55X04QC32I)		
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		

Pa	nckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-620-11	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	07/02/2013	

Labeler - DZA BRANDS LLC (090322194)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(55316-620)	

Revised: 7/2013 DZA BRANDS LLC