TOPCARE GENTLE DANDRUFF CLINICAL STRENGTH- selenium sulfide liquid
TOPCO ASSOCIATES 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 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 CONTACT OCCURS, RINSE EYES THOROUGHLY WITH WATER. FOR USE ON COLOR TREATED OR PERMED HAIR, RINSE THOROUGHLY

STOP USE AND ASK A DOCTOR IF

CONDITION WORSENS OR DOES NOT IMPROVE AFTER REGULAR USE OF THIS PRODUCT AS DIRECTED

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

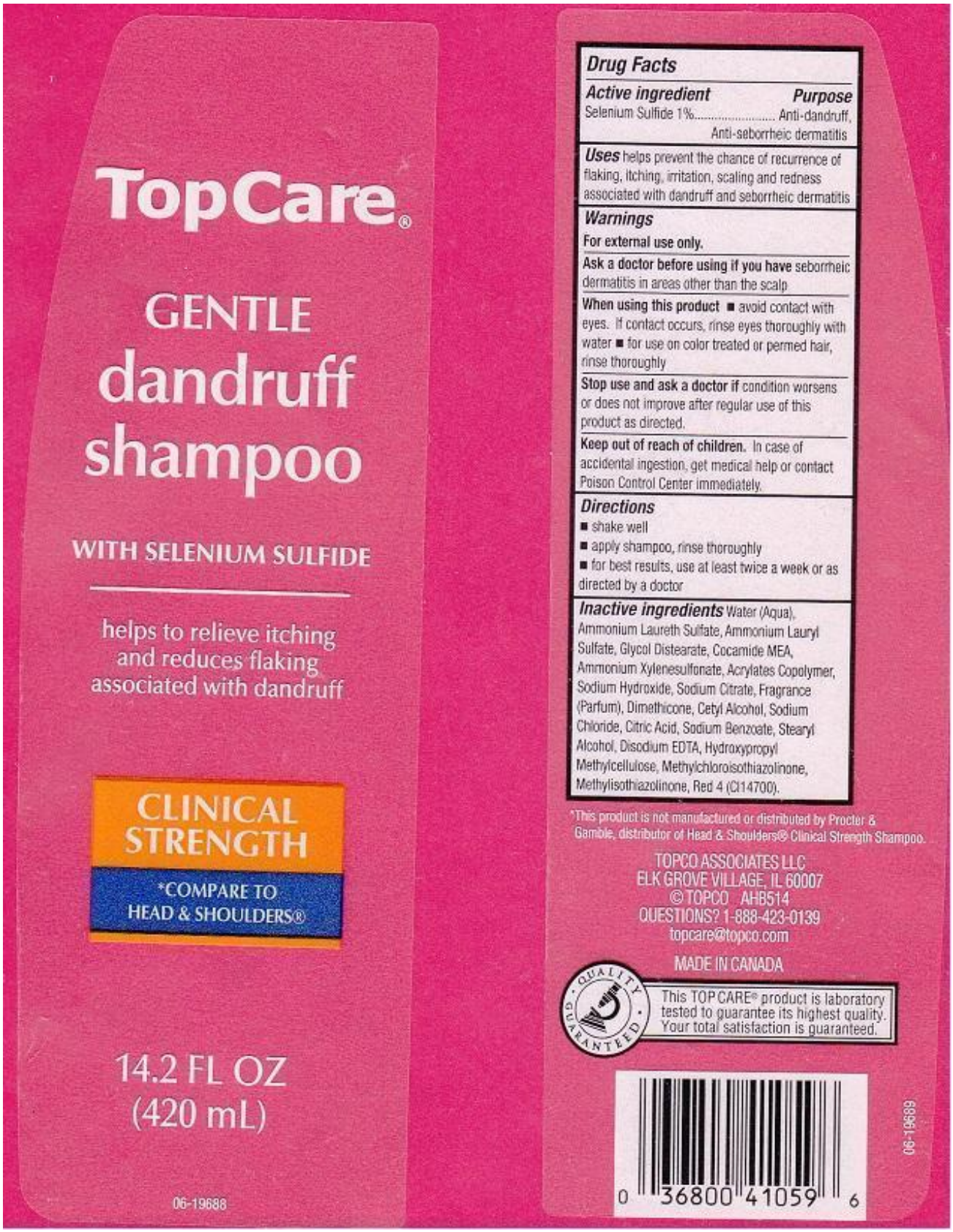
DIRECTIONS

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

INACTIVE INGREDIENTS

WATER (AQUA), AMMONIUM LAURETH SULFATE, AMMONIUM LAURYL SULFATE, GLYCOL DISTEARATE, COCAMIDE MEA, AMMONIUM XYLENESULFONATE, ACRYLATES COPOLYMER, 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



TOPCARE GENTLE DANDRUFF CLINICAL STRENGTH
selenium sulfide liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-618
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)	
AMMONIUM LAURETH-3 SULFATE (UNII: 896SJ235FN)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
AMMONIUM XYLENESULFONATE (UNII: 4FZY6L6XCM)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-618-14	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	07/28/2014	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(36800-618)

Revised: 7/2014

TOPCO ASSOCIATES LLC