TOPCARE GENTLE DANDRUFF DRY SCALP- pyrithione zinc 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

PYRITHIONE ZINC 1%

PURPOSE

ANTI-DANDRUFF

USES

TO HELP PREVENT RECURRENCE OF FLAKING AND ITCHING ASSOCIATED WITH DANDRUFF

WARNINGS

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE EYES THOROUGHLY WITH WATER

STOP USE 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

FOR MAXIMUM DANDRUFF CONTROL, USE EVERY TIME YOU SHAMPOO. WET HAIR, MASSAGE ONTO SCALP AND RINSE. REPEAT IF DESIRED

INACTIVE INGREDIENTS

WATER (AQUA), SODIUM LAURETH SULFATE, SODIUM LAURYL SULFATE, DIMETHICONE, COCAMIDE MEA, ZINC CARBONATE, GLYCOL DISTEARATE, SODIUM XYLENESULFONATE, FRAGRANCE (PARFUM), CETYL ALCOHOL, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, MAGNESIUM SULFATE, SODIUM CHLORIDE, SODIUM BENZOATE, MAGNESIUM CARBONATE HYDROXIDE, BENZYL ALCOHOL, PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL, CITRIC ACID, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE

LABEL COPY

TOPCARE GENTLE DANDRUFF DRY SCALP

pyrithione zinc liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-429
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ALMOND OIL (UNII: 66YXD4DKO9)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-429-14	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	07/27/2014	

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(36800-429)

Revised: 7/2014

TOPCO ASSOCIATES LLC