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

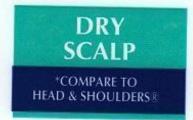
Top Care.

dandruff shampoo

WITH PYRITHIONE ZINC

hair is cleaned and conditioned while moisturizers help soothe the scalp

with almond oil



14.2 FL OZ (420 mL)

06-19674

Drug Facts

Active ingredient

Purpose Anti-dandruff

Pyrithione Zinc 1%...

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 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 Hydroxypropytrimonium Chloride, Magnesium Sulfate, Sodium Chloride, Sodium Benzoate, Magnesium Carbonate Hydroxide, Benzyl Alcohol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Citric Acid, Methylchiloroisothia-zolinone, Methylisothiazolinone.

*This product is not manufactured or distributed by Procter & Gamble, distributor of Head & Shoulders® Dry Scalp Care.

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
© TOPCO AHB514
QUESTIONS? 1-888-423-0139
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MADE IN CANADA



This TOP CARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



36-19675

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)	
SO DIUM LAURETH SULFATE (UNII: BPV390 UAP0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
ZINC CARBO NATE (UNII: EQR32Y7H0 M)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MAGNESIUM CARBO NATE HYDRO XIDE (UNII: YQO029 V1L4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ALMOND OIL (UNII: 66 YXD4DKO9)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	

F	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