

SAFEGWAY CARE DANDRUFF- pyrrithione zinc liquid
SAFEGWAY 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

PYRITHIONE ZINC 1%

PURPOSE

ANTIDANDRUFF

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 WITH WATER

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

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

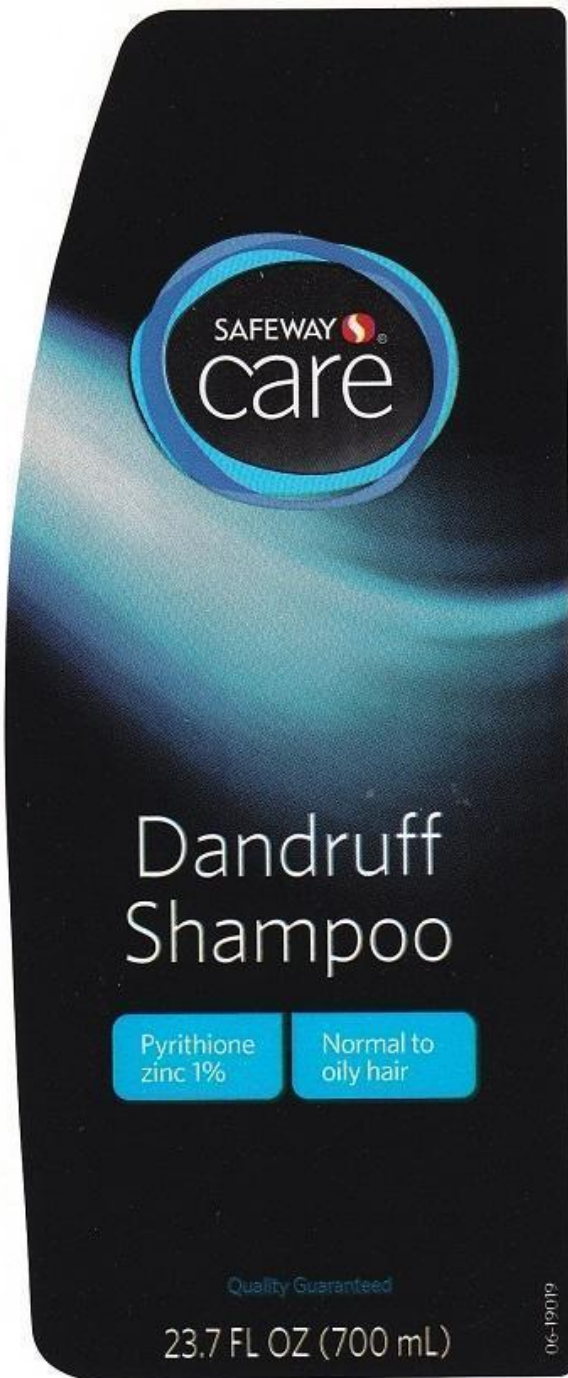
INACTIVE INGREDIENTS

WATER (AQUA), SODIUM LAURETH SULFATE, SODIUM LAURYL SULFATE, COCAMIDE MEA, ZINC CARBONATE, GLYCOL DISTEARATE, DIMETHICONE, FRAGRANCE (PARFUM), CETYL ALCOHOL, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, MAGNESIUM SULFATE, SODIUM BENZOATE, MAGNESIUM CARBONATE HYDROXIDE, AMMONIUM LAURETH SULFATE, BENZYL ALCOHOL, SODIUM CHLORIDE, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, SODIUM XYLENESULFONATE, BLUE 1 (CI 42090), RED 4 (CI 14700), YELLOW 10 (CI 47005).

QUESTIONS OR COMMENTS?

1-888-723-3929

LABEL COPY



SOOTHING • DANDRUFF CONTROL

Drug Facts	
Active ingredient	Purpose
Pyrrithione Zinc 1%	Antidandruff
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 with water.	
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	
■ 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, Cocamide MEA, Zinc Carbonate, Glycol Distearate, Dimethicone, Fragrance (Parfum), Cetyl Alcohol, Guar Hydroxypropyltrimonium Chloride, Magnesium Sulfate, Sodium Benzoate, Magnesium Carbonate Hydroxide, Ammonium Laureth Sulfate, Benzyl Alcohol, Sodium Chloride, Methylchlorisothiazolinone, Methylisothiazolinone, Sodium Xylenesulfonate, Blue 1 (CI 42090), Red 4 (CI 14700), Yellow 10 (CI 47005).	
Questions or comments? 1-888-723-3929	

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 06-19020



SAFEWAY CARE DANDRUFF

pyrrithione zinc liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-427
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)	
CO CO MONOETHANOLAMIDE (UNII: C80684146D)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
AMMONIUM LAURETH-3 SULFATE (UNII: 896SJ235FN)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-427-14	700 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	12/13/2013	

Labeler - SAFEWAY INC (009137209)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(21130-427)

Revised: 12/2013

SAFEWAY INC