PERSONAL CARE DRY SCALP- pyrithione zinc shampoo Delta Brands & Products 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

Use

helps to treat flakes, itch, irritation, oilness or dryness caused by dandruff.

Warnings

For external use only

When using this product

■ avoid contact with eyes ■ if contact occurs, rinse eyes with plenty of water.

Stop use and ask a doctor if

■ if condition does not improve or worsen after regular use of this product as directed

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center immediately.

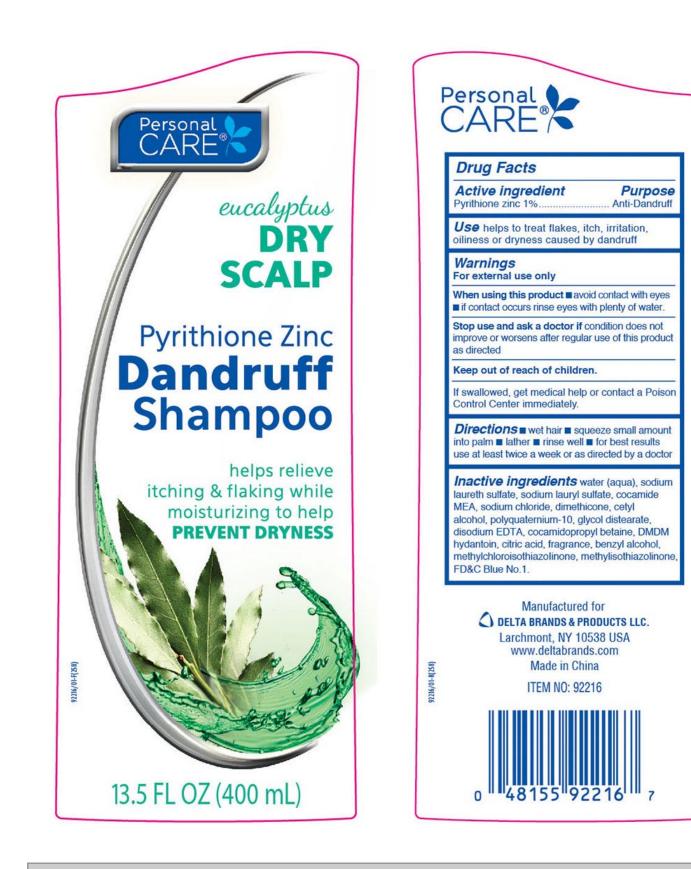
Directions

■ wet hair ■ squeeze small amount into palm ■ lather ■ rinse well ■ for best results use at least twice a week or as directed by a doctor

Inactive ingredients

water (aqua), sodium laureth sulfate sodium lauryl sulfate, cocamide MEA, sodium chloride, dimethicone, cetyl alcohol, polyquaternium-10, glycol distearate, disodium EDTA, cocamidopropyl betaine, DMDM hydantoin, citric acid, fragrance, benzyl alcohol, methylchloroisothiazolinone, methylisothiazolinone,FD&C Blue No. 1

Package Label



PERSONAL CARE DRY SCALP

pyrithione zinc shampoo

Product Information

Product Type

Route of Administration

HUMAN OTC DRUG

Item Code (Source)

NDC:72133-047

TOPICAL

A . A . T . 14			
Active Ingredie	nt/Active Moiety		
	Ingredient Name	Basis of Str	ength Strength
PYRITHIONE ZINC	(UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ	5) PYRITHIONE Z	INC 1 g in 100 mL
Inactive Ingred	ients		
	Ingredient Name		Strength
METHYLCHLORO	SOTHIAZOLINONE (UNII: DEL7T5QRPN)		
METHYLISOTHIA 2	OLINONE (UNII: 229 D0 E1QFA)		
FD&C BLUE NO. 1	(UNII: H3R47K3TBD)		
BENZYL ALCOHO	L (UNII: LKG8494WBH)		
COCAMIDOPROPY	L BETAINE (UNII: 50CF3011KX)		
SODIUM LAURETH	SULFATE (UNII: BPV390UAP0)		
SO DIUM LAURYL	SULFATE (UNII: 368GB5141J)		
COCO MONOETH	NOLAMIDE (UNII: C80684146D)		
DIMETHICO NE (UN	II: 92RU3N3Y1O)		
GLYCOL DISTEAR	ATE (UNII: 13W7MDN21W)		
POLYQUATERNIU	M-10 (1000 MPA.S AT 2%) (UNII: GMR4PEN8PK)		
SODIUM CHLORID	E (UNII: 451W47IQ8X)		
CETYL ALCOHOL	(UNII: 936JST6JCN)		
EDETATE SODIUM	(UNII: MP1J8420LU)		
CITRIC ACID MON	DHYDRATE (UNII: 2968PHW8QP)		
WATER (UNII: 0590	F0KO0R)		
DMDM HYDANTOI	N (UNII: BYR0546TOW)		
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:72133-047- 13	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/09/2018	
Marketing I	formation		
Marketing Categ	ory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph fina	l part358H	04/09/2018	

Labeler - Delta Brands & Products LLC (080999173)

Revised: 4/2018

Delta Brands & Products LLC