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	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72133-047
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
POLYQUATERNIUM-10 (1000 MPA.S AT 2%) (UNII: GMR4PEN8PK)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
DMDM HYDANTOIN (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 Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	04/09/2018	

Labeler - Delta Brands & Products LLC (080999173)

Revised: 4/2018 Delta Brands & Products LLC