HEAD AND SHOULDERS SMOOTH AND SILKY- pyrithione zinc lotion/shampoo
ALL NATURAL DYNAMICS

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.

Head & Shoulders smooth and silky

Drug Facts

Active ingredient

Pyrithione zinc 1%

Purpose

Anti-dandruff

Uses

helps prevent recurrence of flaking and itching associated with dandruff.

Warnings

For external use only.

Directions

- for best results use at least twice a week or as directed by a doctor.
- for maximum dandruff control, use every time you shampoo.
- wet hair, massage onto scalp, rinse, repeat if desired.

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.

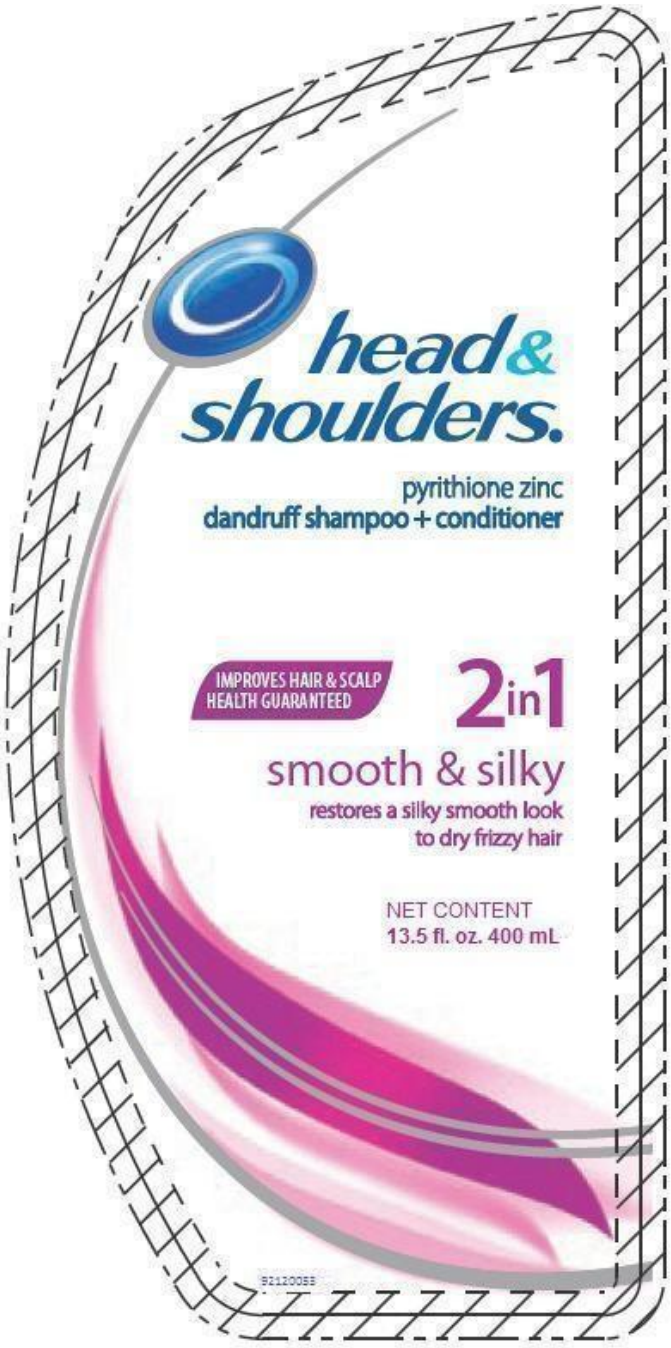
Keep this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Inactive ingredients

Water, sodium lauryl sulfate, sodium laureth sulfate, glycol distearate, zinc carbonate, sodium chloride, fragrance, sodium xylenesulfonate, dimethicone, cocamidopropyl betaine, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, methylchloroisothiazolinone, methylisothiazolinone, pyrithione zinc, blue 1, red 33.

Questions (or comments)?

01-800-717-2413



HEAD AND SHOULDERS SMOOTH AND SILKY

pyrithione zinc lotion/shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51769-901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Pyrithione Zinc (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	Pyrithione Zinc	0.01 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
sodium lauryl sulfate (UNII: 368GB5141J)	
sodium laureth sulfate (UNII: BPV390UAP0)	
glycol distearate (UNII: 13W7MDN21W)	
zinc carbonate (UNII: EQR32Y7H0M)	
sodium chloride (UNII: 451W47IQ8X)	
dimethicone (UNII: 92RU3N3Y1O)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
sodium benzoate (UNII: OJ245FE5EU)	
magnesium carbonate hydroxide (UNII: YQO029V1L4)	
methylchloroisothiazolinone (UNII: DEL7T5QRPN)	
methylisothiazolinone (UNII: 229D0E1QFA)	
POLYQUATERNIUM-10 (400 MPA.S AT 2%) (UNII: HB1401PQFS)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Magnesium Sulfate (UNII: DE08037SAB)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Sodium Xylenesulfonate (UNII: G4LZF950UR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51769-901-40	400 mL in 1 BOTTLE, PLASTIC		
2	NDC:51769-901-70	700 mL in 1 BOTTLE, PLASTIC		
3	NDC:51769-901-11	1000 mL in 1 BOTTLE, PLASTIC		
4	NDC:51769-901-18	1180 mL in 1 BOTTLE, PLASTIC		
5	NDC:51769-901-20	200 mL in 1 BOTTLE, PLASTIC		
6	NDC:51769-901-05	50 mL in 1 BOTTLE, PLASTIC		
7	NDC:51769-901-01	10 mL in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	01/24/2013	

Labeler - ALL NATURAL DYNAMICS (962732892)

Establishment

Name	Address	ID/FEI	Business Operations
Procter & Gamble Manufactura, S. de R.L. de C.V.		810007526	manufacture(51769-901)

Revised: 12/2013 ALL NATURAL DYNAMICS