HEAD AND SHOULDERS MENTHOL FRESH- 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 menthol fresh

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 <u>at least</u> 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.

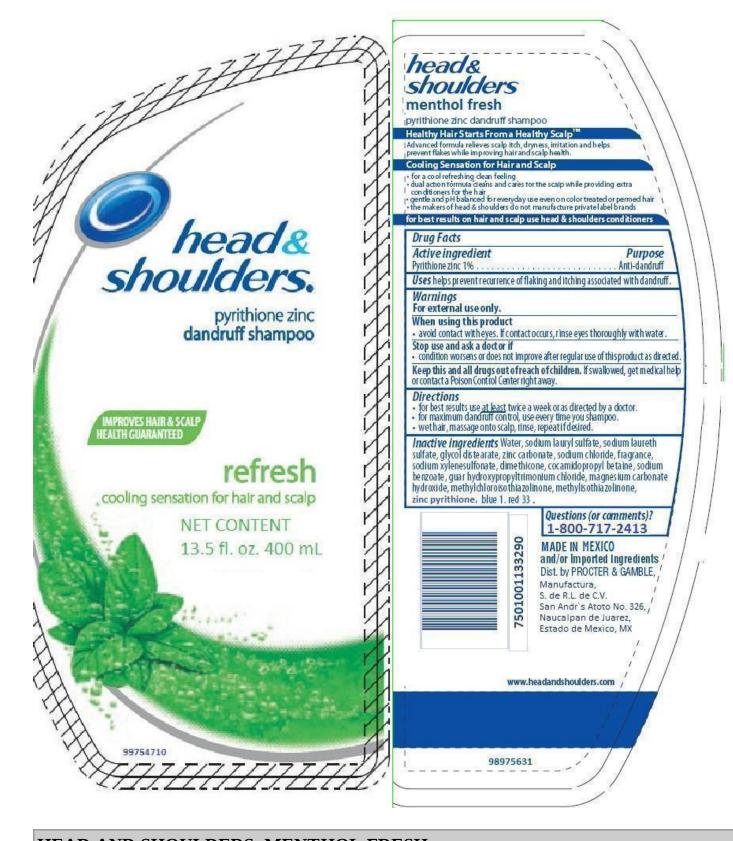
Keep this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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 MENTHOL FRESH

pyrithione zinc lotion/shampoo

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51769-133
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Pyrithione Zinc (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	Pyrithione Zinc	0.01g 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)		
sodium xylenesulfonate (UNII: G4LZF950UR)		
dimethicone (UNII: 92RU3N3Y1O)		
cocamidopropyl betaine (UNII: 5OCF3O11KX)		
sodium benzoate (UNII: OJ245FE5EU)		
magnesium carbonate hydroxide (UNII: YQO029V1L4)		
methylchloroisothiazolinone (UNII: DEL7T5QRPN)		
methylisothiazolinone (UNII: 229 D0 E1QFA)		
pyrithione zinc (UNII: R953O2RHZ5)		
FD&C blue no. 1 (UNII: H3R47K3TBD)		
D&C red no. 33 (UNII: 9DBA0SBB0L)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51769-133-40	400 mL in 1 BOTTLE, PLASTIC		
2 NDC:51769-133-70	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	0 1/24/20 13	

Labeler - ALL NATURAL DYNAMICS (962732892)

Establishment			
Name	Address	ID/FEI	Business Operations
Procter & Gamble Manufactura, S. de R.L. de C.V.		812807550	manufacture(51769-133)

Revised: 1/2013 ALL NATURAL DYNAMICS