# HEAD AND SHOULDERS BREAKAGE PREVENTION- pyrithione zinc 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.

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### Head and Shoulders breakage prevention

**Drug Facts** 

### **Active ingredient**

Pyrithione zinc 1%

### Purpose

Anti-dandruff

#### Uses

helps prevent recurrence of flaking and itching associated with dandruff.

helps prevent hair loss

#### **Warnings**

For external use only.

### 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.

#### **Directions**

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

### **Inactive ingredients**

Water, Sodium laureth sulfate, Sodium lauryl sulfate, Coco Monoethanolamide, Zinc carbonate, Glycol distearate, Dimethicone, Guar hydroxypropyltrimonium chloride, Magnesium sulfate, Sodium benzoate, Magnesium carbonate hydroxide, Benzyl alcohol, Tocopheryl acetate, FD&C Yellow No. 5, Methylchloroisothiazolinone, Methylisothiazolinone, FD&C Blue no. 1

#### Questions (or comments)?

01-800-717-2413

Dist. by

Procter & Gamble Manufactura, S. de R.L. de C.V. San Andr's Atoto No. 326, Naucalpan de Juarez, Estado de Mexico, MX

www.headandshoulders.com



hair more resistant to breakage



## HEAD AND SHOULDERS BREAKAGE PREVENTION

pyrithione zinc shampoo

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51769-141	
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 laureth sulfate (UNII: BPV390UAP0)			
Sodium lauryl sulfate (UNII: 368GB5141J)			

Coco Monoethanolamide (UNII: C80684146D)	
Zinc carbonate (UNII: EQR32Y7H0M)	
Glycol distearate (UNII: 13W7MDN21W)	
Dimethicone (UNII: 92RU3N3Y1O)	
Guar hydroxypropyltrimonium chloride (1.7 substituents per saccharide) (UNII: B16G315W7A)	
Magnesium sulfate (UNII: DE08037SAB)	
Sodium benzoate (UNII: OJ245FE5EU)	
magnesium carbonate hydroxide (UNII: YQO029V1L4)	
Benzyl alcohol (UNII: LKG8494WBH)	
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)	
FD&C Yellow No. 5 (UNII: I753WB2F1M)	
methylchloroisothiazolinone (UNII: DEL7T5QRPN)	
methylisothiazolinone (UNII: 229 D0 E1QFA)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51769-141-50	500 mL in 1 BOTTLE, PLASTIC		
2	NDC:51769-141-40	400 mL in 1 BOTTLE, PLASTIC		
3	NDC:51769-141-20	200 mL in 1 BOTTLE, PLASTIC		
4	NDC:51769-141-11	1000 mL in 1 BOTTLE, PLASTIC		
5	NDC:51769-141-18	1180 mL in 1 BOTTLE, PLASTIC		
6	NDC:51769-141-05	50 mL in 1 BOTTLE, PLASTIC		
7	NDC:51769-141-01	10 mL in 1 POUCH		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	0 2/0 1/20 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(51769-141)

Revised: 2/2013 ALL NATURAL DYNAMICS