HEAD AND SHOULDERS HAIR THICKENING SYSTEM WITH BIOTIN- pyrithione zinc

The Procter & Gamble Manufacturing Company

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 and Shoulders ® Hair Thickening System

Active ingredient

Pyrithione zinc 1%

Hair Thickening

Step 1 2in1

with BIOTIN

Cleans to restore fullness to thinning hair, while helping maintain a healthy scalp.

pyrithione zinc dandruff shampoo + conditioner

Step 1: Use 2in1 to massage into wet hair and scalp. Lather and rinse.

Drug Facts

Purpose

Anti-dandruff

Uses

helps prevent recurrence of flaking and itching associated with dandruff.

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

Inactive ingredients

Water, sodium lauryl sulfate, sodium laureth sulfate, glycol distearate, sodium chloride, zinc carbonate, sodium xylenesulfonate, dimethicone, cocamidopropyl betaine, fragrance, sodium benzoate, menthol, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, biotin, methylchloroisothiazolinone, methylisothiazolinone.

Questions (or comments)?

1-800-723-9569

Hair Thickening

Step 2 Treatment

with BIOTIN

Thickens existing hair, while helping maintain a healthy scalp.

pyrithione zinc dandruff treatment

Step 2: Use treatment out of shower. Apply directly to roots and scalp.

Drug Facts

Active ingredient

Pyrithione zinc 0.1%

Purpose

Anti-dandruff

Uses

helps prevent recurrence of flaking and itching associated with dandruff.

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

- apply to affected areas one to four times daily or as directed by a doctor.
- place package tip close to scalp on damp or dry hair and use 15 sprays to cover the entire scalp. Massage into scalp with fingertips. DO NOT rinse off.

Inactive ingredients

Water, niacinamide, PEG-40 hydrogenated castor oil, phenoxyethanol, caffeine, bis-PEG/PPG-16/16 PEG/PPG-16/16 dimethicone, fragrance, glycerin, benzyl alcohol, menthol, acrylates/C10-30 alkyl acrylate crosspolymer, panthenol, tetrahydroxypropyl ethylenediamine, ethylhexylglycerin, mentha piperita (peppermint) oil, mentha arvensis leaf oil, biotin.

Questions (or comments)?

1-800-723-9569

Dist. by PROCTER & GAMBLE, CINCINNATI, OH 45202

PRINCIPAL DISPLAY PANEL - Kit Package

head & shoulders ®

HAIR THICKENING SYSTEM

WITH BIOTIN

head & shoulders

pyrithione zinc dandruff shampoo + conditioner

2in1 Hair Thickening Step 1

with Biotin

23.7 FL OZ (700 mL)

head & shoulders ®

pyrithione zinc dandruff treatment

Treatment

Hair Thickening Step 2

with Biotin 6.7 FL OZ (200 mL)

Ohead&shoulders, HAIR **THICKENING SYSTEM**

with BOTIN

1 PYRITHIONE ZINC DANDRUFF TREATMENT 6.7 FL OZ (200 mL) 1 PYRITHIONE ZINC DANDRUFF SHAMPOO + CONDITIONER 23.7 FL OZ (700 mL)





HEAD AND SHOULDERS HAIR THICKENING SYSTEM WITH BIOTIN

pyrithione zinc kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69423-593

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	10/01/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	700 mL
Part 2	1 BOTTLE, PLASTIC	200 mL

Part 1 of 2

HEAD AND SHOULDERS 2IN1 HAIR THICKENING STEP 1

pyrithione zinc lotion/shampoo

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength	ı
PYRITHIONE ZINC (LINII: R95302RHZ5) (PYRITHIONE ZINC - LINII: R95302RHZ5)	PYRITHIONE ZINC	1 a in 100 ml	ı

Inactive Ingredients	
Ingredient Name	Strength
MENTHOL (UNII: L7T10EIP3A)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
BIOTIN (UNII: 6SO6U10H04)	

Pa	Packaging						
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
1		700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part358H	10/01/2021			

Part 2 of 2

HEAD AND SHOULDERS TREATMENT HAIR THICKENING STEP 2

pyrithione zinc liquid

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Prod	IUCT	Inform	lation

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.1 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
EDETOL (UNII: Q4R969U9FR)	
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
BIOTIN (UNII: 6SO6U10H04)	
BIS-PEG/PPG-16/16 PEG/PPG-16/16 DIMETHICONE (UNII: 55A74AJ3KB)	
CAFFEINE (UNII: 3G6A5W338E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PANTHENOL (UNII: W/9CM0O67Z)	
NIACINAMIDE (UNII: 25X51I8RD4)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	

Pa	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1		200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part358H	10/01/2021			

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part358H	10/01/2021			