HEAD AND SHOULDERS DUAL PACK SMOOTH AND SILKY- 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 ® Dual Kit

Smooth and Silky

head & shoulders instant relief pyrithione zinc dandruff shampoo

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.

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 <u>at least</u> 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 laureth sulfate, sodium lauryl sulfate, cocamide MEA, zinc carbonate, glycol distearate, fragrance, sodium xylenesulfonate, dimethicone, cetyl alcohol, guar hydroxypropyltrimonium chloride, magnesium sulfate, sodium chloride, sodium benzoate, magnesium carbonate hydroxide, benzyl alcohol, mentha piperita (peppermint) oil, menthol, mentha arvensis leaf oil, methylchloroisothiazolinone, methylisothiazolinone, yellow 5, blue 1.

Questions (or comments)?

1-800-723-9569

head &
shoulders
instant relief
pyrithione zinc dandruff conditioner
Drug Facts

Active ingredient

Pyrithione zinc 0.5%

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.
- apply to wet hair after shampooing by gently massaging into hair and scalp, rinse well.

Inactive ingredients

Water, stearyl alcohol, cetyl alcohol, stearamidopropyl dimethylamine, fragrance, dimethicone, glutamic acid, phenoxyethanol, benzyl alcohol, citric acid, sodium chloride, mentha piperita (peppermint) oil, menthol, mentha arvensis leaf oil, methylchloroisothiazolinone, methylisothiazolinone, yellow 5, blue 1.

Questions (or comments)?

1-800-723-9569

Dist. by PROCTER & GAMBLE, CINCINNATI, OH 45202

PRINCIPAL DISPLAY PANEL - Kit Package

head & shoulders ®

pyrithione zinc dandruff shampoo

smooth & silky

24 hour frizz control from root to tip

FLAKE FREE.* UP TO 100% COLOR SAFE

0.34 FL OZ (10 mL)

head & shoulders ®

pyrithione zinc dandruff conditioner

smooth & silky

24 hour frizz control from root to tip

0.34 FL OZ (10 mL)





HEAD AND SHOULDERS DUAL PACK SMOOTH AND SILKY

pyrithione zinc kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69423-210

ı	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:69423- 210-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/15/2020			
	NDC:69423- 210-02	1 in 1 CARTON; Type 0: Not a Combination Product	01/15/2020			

Quant	Quantity of Parts				
Part #	Package Quantity	Total Product Quantity			
Part 1	1 BOTTLE, PLASTIC	380 mL			
Part 2	1 TUBE	315 mL			

Part 1 of 2

HEAD AND SHOULDERS SMOOTH AND SILKY

pyrithione zinc lotion/shampoo

Product Information

Item Code (Source) NDC:37000-094

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

mactive migrealenes	
Ingredient Name	Strength
MENTHOL (UNII: L7T10EIP3A)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
POLYQUATERNIUM-10 (30000 MPA.S AT 2%) (UNII: C7RDC8Y4JS)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:37000-	380 mL in 1 BOTTLE, PLASTIC; Type 0: Not a		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	part358H	01/15/2020	

Part 2 of 2

HEAD AND SHOULDERS CONDITIONER SMOOTH AND SILKY

pyrithione zinc lotion

Product Information

Item Code (Source) NDC:69423-103

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.5 g in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
STEARAMIDOPROPYL DIMETHYLAMINE (UNII: K7VEI00UFR)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
GLUTAMIC ACID (UNII: 3KX376GY7L)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69423-103- 31	315 mL in 1 TUBE; 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	01/15/2020		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	M032	01/15/2020			

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 1/2023 The Procter & Gamble Manufacturing Company