HEAD AND SHOULDERS DUAL SACHETS 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 Sachets

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 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 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, menthal 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 $_{\circledR}$ pyrithione zinc dandruff conditioner smooth & silky

24 hour frizz control from root to tip

0.34 FL OZ (10 mL)





pyrithione zinc kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69423-296

Packaging			
#	Itam Cada	Dackage Description	1.

Item Code Package Description Marketing Start Date Marketing End Date
1 NDC:69423-296-01 1 in 1 PACKAGE, COMBINATION 09/01/2018

Quantity of Parts Part # Package Quantity Total Product Quantity Part 1 1 POUCH 10 mL Part 2 1 POUCH 10 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

8	<u> </u>		
	Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC	(UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R9	53O2RHZ5) PYRITHIONE ZINC	1 g in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)				
WATER (UNII: 059QF0KO0R)				
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
COCO MONOETHANOLAMIDE (UNII: C80684146D)				
ZINC CARBO NATE (UNII: EQR32Y7H0 M)				
GLYCOL DISTEARATE (UNII: 13W7MDN21W)				
SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)				
DIMETHICO NE (UNII: 92RU3N3Y1O)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)				

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MAGNESIUM CARBO NATE HYDRO XIDE (UNII: YQO029 V1L4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISO THIAZO LINO NE (UNII: 229 D0 E1QFA)	

l	Packaging						
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
l	1 NDC:37000-094-10	10 mL in 1 POUCH; 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	09/01/2013			

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)	
STEARAMIDO PRO PYL DIMETHYLAMINE (UNII: K7VEI00 UFR)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
GLUTAMIC ACID (UNII: 3KX376GY7L)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	

METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69423-103-10	10 mL in 1 POUCH; 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	11/10/2016			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part358H	09/01/2018			

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 1/2020 The Procter & Gamble Manufacturing Company