HEAD AND SHOULDERS SMOOTH AND SILKY- pyrithione zinc lotion/shampoo 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 ®

Smooth and Silky

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 lauryl sulfate, glycol distearate, zinc carbonate, sodiumchloride,

cocamidopropyl betaine, fragrance, sodium xylenesulfonate, dimethicone, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, sodium laureth sulfate,methylchloroisothiazolinone, methylisothiazolinone

Questions (or comments)?

1-800-723-9569

Dist. by PROCTER & GAMBLE, CINCINNATI, OH 45202

PRINCIPAL DISPLAY PANEL - 370 mL Bottle Label

head &

shoulders ® pyrithione zinc **dandruff shampoo**

ѕмоотн

& SILKY

DAILY SHAMPOO

24 hour frizz control from root to tip

UP TO 100%

COLOR SAFE +

DANDRUFF PROTECTION*

12.5 FL OZ 370 mL



HEAD AND SHOULDERS SMOOTH AND SILKY

pyrithione zinc lotion/shampoo

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Sou	urce)	NDC:37000-094	
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					

		-
Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R95302RHZ5) (PYRITHIONE ZINC - UNII:R95302RHZ5)	PYRITHIONE ZINC	1 g in 100 mL
Inactive Ingredients		
Inactive Ingredients		
Ingredient Name		Strength
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER S B16G315W7A)	SACCHARIDE) (UNII:	
ZINC CARBONATE (UNII: EQR32Y7H0M)		
WATER (UNII: 059QF0KO0R)		
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)		
GLYCOL DISTEARATE (UNII: 13W7MDN21W)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)		
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)		

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000- 094-10	10 mL in 1 POUCH; Type 0: Not a Combination Product	09/01/2013	
2	NDC:37000- 094-70	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2013	12/21/2019
3	NDC:37000- 094-40	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2013	12/21/2019
4	NDC:37000- 094-90	90 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/11/2017	02/28/2023
5	NDC:37000- 094-38	380 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/11/2017	01/01/2025
6	NDC:37000- 094-65	650 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/11/2017	01/01/2025
7	NDC:37000- 094-50	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2020	08/30/2021
8	NDC:37000- 094-37	370 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/15/2022	
9	NDC:37000- 094-61	613 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/15/2022	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	M032	09/01/2013	

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 2/2023

The Procter & Gamble Manufacturing Company