HEAD AND SHOULDERS TEA TREE OIL DAILY- 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 ® Tea Tree Oil Shampoo

Men Old Spice ® Pure Sport 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, sodium chloride, fragrance, cocamidopropyl betaine, sodium xylenesulfonate, dimethicone, menthol, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, sodium laureth sulfate, mentha piperita (peppermint) flower/leaf/stemoil, mentha arvensis leaf/stem oil, melaleuca alternifolia (tea tree) leaf oil, yellow5, blue 1

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**

TEA TREE

OIL

DAILY SHAMPOO

HYDRATES AND COOLS

FOR SCALP RELIEF

INFUSED with tea tree oil

FLAKE FREE

UP TO 100%

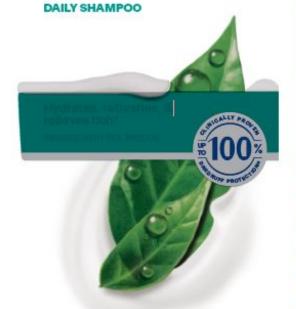
GUARANTEED

12.5 FL OZ (370 mL)





TEA TREE



head& shoulders

tea tree oil pyrithione zinc dandruff shampoo



ignite your senses & feel it working with every wash. Head & Shoulders' unique formula works 7 surface layers deep to help stop dandruff at its source & maintain healthy hair.

DERMATOLOGIST RECOMMENDED BRAND

Drug Facts

Active ingredient Purpose Pyrithione zinc 196. 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.
- wet hair, massage onto scalp, rinse, repeat if desired.

Inactive ingredients Water, sodium lauryl sulfate, glycol distearate, zinc carbonate, sodium chloride, fragrance, coramidopropyl betaine, sodium xylenesulfonate, dimethicone, menthol, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, sodium laureth sulfate, mentha piperita (peppermint) flower/leaf/stemoil, mentha arvensis leaf/stem oil, melaleuca alternifolia (tea tree) leaf oil, yellow 5, blue 1

Questions (or comments)? 1-800-723-9569



MADE IN U.S.A. of U.S. and/or Imported Ingredients

Distr. by PROCTER & GAMBLE, CINCINNATI, OH 45202 www.headandshoulders.com Patents: www.pg.com/patents





visible fakes; with regular use



12.5 FL OZ (370 mL)

HEAD AND SHOULDERS TEA TREE OIL DAILY

pyrithione zinc lotion/shampoo

Product Information

HUMAN OTC DRUG Item Code (Source) Product Type NDC:69423-416

TOPICAL Route of Administration

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	
Ingredient Name	Strength
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
TEA TREE OIL (UNII: VIF565UC2G)	
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69423- 416-40	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/21/2019	01/01/2024	
2	NDC:69423- 416-95	950 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/15/2021	10/01/2023	
3	NDC:69423- 416-01	2 in 1 CELLO PACK	01/15/2021	10/01/2023	
3		950 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product			
4	NDC:69423- 416-37	370 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2022		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	M032	11/21/2019			