

HEAD AND SHOULDER MEN OLD SPICE- pyrithione zinc lotion/shampoo
Teresa Cecena DBA Genesis

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.

DRUGS FACTS

ACTIVE INGREDIENTS

Pyrithione zinc 1%

PURPOSE

Anti-dandruff

USES

Help prevent recurrence of flaking and itching associated with dan druff

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 doctor.
- for maximum dandruff control, use every time you shampoo
- shake before use
- wet hair, massage onto scalp, rinse, repeat if desired.

WATER, SODIUM LAURYL SULFATE, SODIUM LAURETH SULFATE, GLYCOL DISTEARATE, ZINC CARBONATE, SODIUM CHLORIDE, SODIUM XYLENESULFONATE, COCAMIDOPROPYL BETAINE, FRAGRANCE, DIMETHICONE, SODIUM BENZOATE, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, MAGNESIUM CARBONATE HYDROXIDE, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, BLUE 1, RED 33

*associated with dandruff

Drug Facts

Active ingredient	Purpose
Pyrithione zinc 1%	Anti-dandruff

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Inactive ingredients Water, sodium lauryl sulfate, sodium laureth sulfate, glycol distearate, zinc carbonate, sodium chloride, sodium xylene sulfonate, cocamidopropyl betaine, fragrance, dimethicone, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, methylchloroisothiazolinone, methylisothiazolinone, blue 1, red 33.

Questions for comments?

with
fresh scent
technology



head & shoulders

pyrithione zinc dandruff shampoo

MEN



Old Spice

an amazing clean powered
by a handsome scent



13.5 FL OZ (400 mL)

96891821

HELP PREVENT RECURRENCE OF FLAKING AND ITCHING ASSOCIATED WITH DANDRUFF

HEAD AND SHOULDER MEN OLD SPICE

pyrithione zinc lotion/shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69772-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	0.01 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69772-102-01	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/16/2015	
2	NDC:69772-102-02	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/16/2015	
3	NDC:69772-102-03	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/16/2015	
4	NDC:69772-102-04	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/16/2015	
5	NDC:69772-102-05	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/16/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/16/2015	

Labeler - Teresa Cecena DBA Genesis (078760958)

Registrant - Teresa Cecena (078760958)

Establishment

Name	Address	ID/FEI	Business Operations
Teresa Cecena DBA Genesis		078760958	relabel(69772-102)

Establishment

Name	Address	ID/FEI	Business Operations
Procter and Gamble Manufacturara SA De CV		812807550	manufacture(69772-102)

Revised: 6/2015

Teresa Cecena DBA Genesis