

HEAD AND SHOULDERS 2 IN 1 SMOOTH AND SILKY- pyrrithionr zinc lotion/sampoo
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.

DRUG FACTS

ACTIVE INGREDIENTE

Pyrrithione Zinc 1%

PURPOSE

Anti-drandruff

USES

Help 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 maximun drandruff contral, use every time you shampoo.
- Wet hair, massage onto scalp, rinse, repeat if desired.
- For best results use at least twice a week or as directed by a doctor.

Water, soium laureth sulfate, sodium lauryl sulfate, dimethicone, cocamide MEA, zinc carbonate, glycoldistearate, sodium xylenesulfonate, fragance, cethyl alcohol, guar hydroxypropyltrimonium chloride, magnesium sulfate, sodium chloride, sodium benzoate, magnesium carbonate hydroxide, benzyl alcohol, methylchloroisothiazolinone, methlylisothiazolinone.

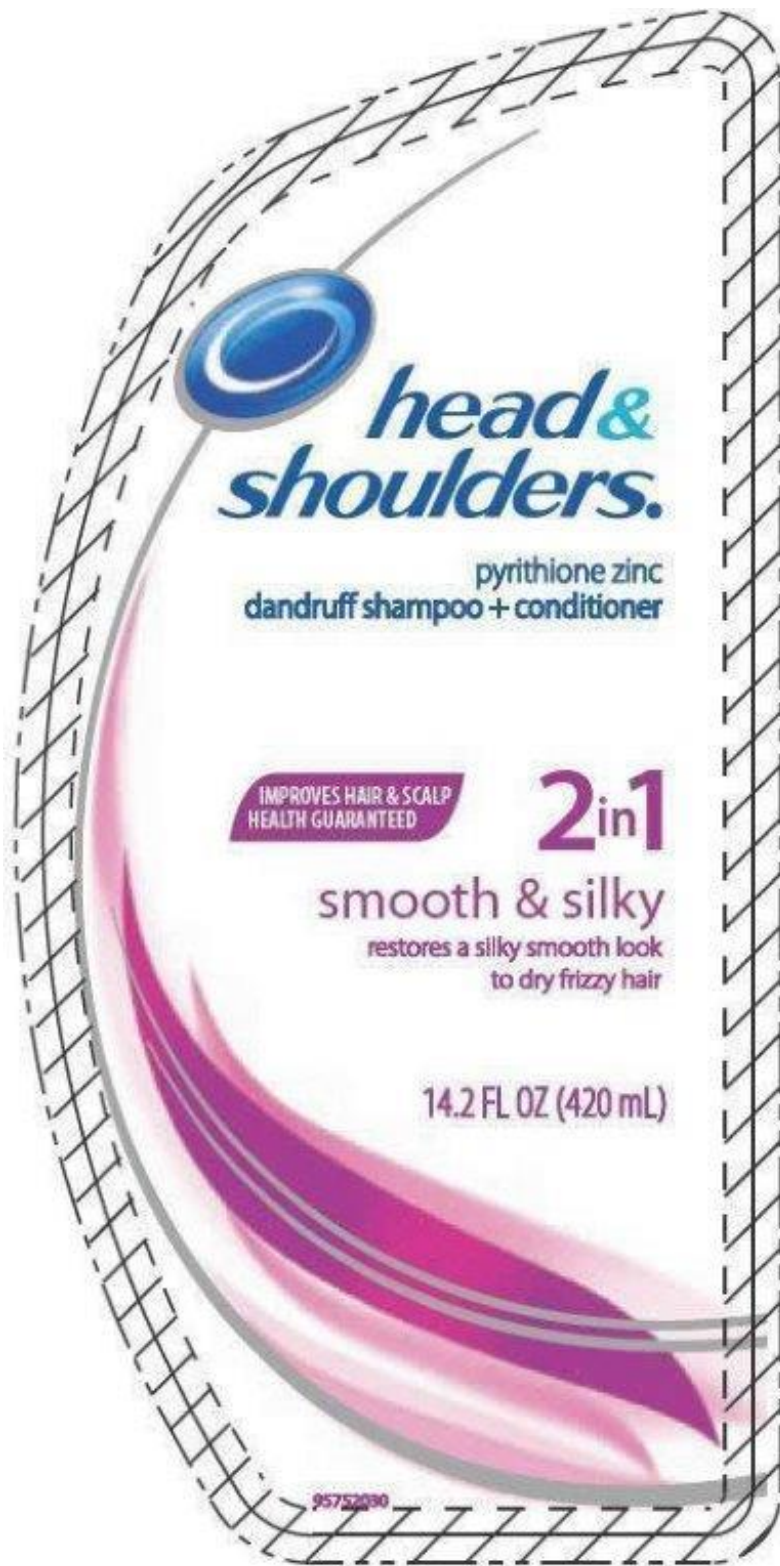
Made in Mexico By:

Procter and Gamble

#69772

FOR EXTERNAL USE ONLY

FOR BEST RESULT USE AT LEAST TWICE A WEEK OR AS DIRECTED BY A DOCTOR



Shoulder

HEAD AND SHOULDERS 2 IN 1 SMOOTH AND SILKY

pyrithionr zinc lotion/shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69772-324
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 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69772-324-68	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2015	
2	NDC:69772-324-14	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2015	
3	NDC:69772-324-23	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2015	
4	NDC:69772-324-33	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	05/13/2015	

Labeler - Teresa Cecena DBA Genesis (078760958)**Registrant** - Teresa Cecena (078760958)**Establishment**

Name	Address	ID/FEI	Business Operations
Teresa Cecena DBA Genesis		078760958	relabel(69772-324)

Establishment

Name	Address	ID/FEI	Business Operations
Procter & Gamble Manufacturera S. De R.L. De C.V.		812807550	manufacture(69772-324)

Establishment

Name	Address	ID/FEI	Business Operations
Roir SA de CV		812825434	relabel(69772-324)

Revised: 4/2017

Teresa Cecena DBA Genesis