

**HEAD AND SHOULDERS BREAKAGE PREVENTION- pyrithione zinc 1% 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.*

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**DRUG FACTS**

**ACTIVE INGREDIENT**

PHYRITHIONE ZINC 1%

**PURPOSE**

Anti-dandruff

**USES**

Helps prevent recurrence of flaking and itching associated with dandruff

Help prevent hair loss

**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 maximum dandruff control, 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, sodium lauryl sulfate, sodium lauryl sulfate. Coco monoethanolamide, zinc carbonate, glycol distearate, dimethicone, guar hydroxypropyltrimonium chloride, magnesium sulfate, sodium benzoate, magnesium carbonate hydroxide, benzyl alcohol, tocopheryl acetate, FD&C yellow No5, methylchloroisothiazolinone, methylisothiazolinone, FD&C blue No 1



KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN

**DIRECTIONS**

- FOR MAXIMUM DANDRUFF CONTROL, USE EVERY TIME YOU SHAMPOO
- WET HAIR, MESSAGE ONTO SCALP, RINSE, REPEAT IF DESIRED
- FOR BEST RESULTS USE AT LEAST TWICE A WEEK OR AS DIRECTED BY A DOCTOR

**HEAD AND SHOULDERS BREAKAGE PREVENTION**

pyrithione zinc 1% lotion/shampoo

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69772-141
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69772-141-50	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2015	
2	NDC:69772-141-40	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2015	
3	NDC:69772-141-20	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2015	
4	NDC:69772-141-11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2015	
5	NDC:69772-141-18	1180 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/12/2015	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part358H	05/12/2015	

**Labeler** - TERESA CECENA DBA GENESIS (078760958)

**Registrant** - Teresa Cecena (078760958)

**Establishment**

Name	Address	ID/FEI	Business Operations
PROCTER AND GAMBLE MANUFACTURA S. DE R.L. DE C.V.		8 12807550	manufacture(69 772-141)

Revised: 5/2015

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