

HEAD AND SHOULDERS RENEWING CLEAN- pyrrithione zinc lotion/shampoo
ALL NATURAL DYNAMICS

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 renewing clean

Drug Facts

Active ingredient

Pyrrithione 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 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.

Inactive ingredients

Water, sodium laureth sulfate, sodium lauryl sulfate, cocamide MEA, zinc carbonate, glycol distearate, dimethicone, fragrance, guar hydroxypropyltrimonium chloride, magnesium sulfate, sodium benzoate, magnesium carbonate hydroxide, ammonium laureth sulfate, sodium chloride, methylchloroisoithiazolinone, methylisoithiazolinone, sodium xylenesulfonate, blue 1, D&C red 33.

Questions (or comments)?

01-800-717-2413

Dist. by

Procter & Gamble Manufactura, S. de R.L. de C.V.

San Andr`s Atoto No. 326, Naucalpan de Juarez,

Estado de Mexico, MX

www.headandshoulders.com



92023427

head & shoulders classic clean

pyrithione zinc dandruff shampoo

Healthy Hair Starts From a Healthy Scalp™

Advanced formula relieves scalp itch, dryness, irritation and helps prevent flakes while improving hair and scalp health.

Basic Cleaning for Normal Hair

- clean manageable hair everyday
- gentle and pH balanced for everyday use even on permed or color treated hair

for best results on hair and scalp use Head & Shoulders conditioners

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|--------------------|---------------|
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MADE IN MEXICO
and/or Imported Ingredients
Dist. by PROCTER & GAMBLE,
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HEAD AND SHOULDERS RENEWING CLEAN

pyrithione zinc lotion/shampoo

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51769-139 |
| 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) | |
| sodium laureth sulfate (UNII: BPV390UAP0) | |
| sodium lauryl sulfate (UNII: 368GB5141J) | |
| Coco Monoethanolamide (UNII: C80684146D) | |
| 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) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| methylchloroisothiazolinone (UNII: DEL7T5QRPN) | |
| methylisothiazolinone (UNII: 229D0E1QFA) | |
| sodium xylenesulfonate (UNII: G4LZF950UR) | |
| FD&C blue no. 1 (UNII: H3R47K3TBD) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------|----------------------|--------------------|
| 1 | NDC:51769-139-40 | 400 mL in 1 BOTTLE, PLASTIC | | |
| 2 | NDC:51769-139-50 | 500 mL in 1 BOTTLE, PLASTIC | | |
| 3 | NDC:51769-139-20 | 200 mL in 1 BOTTLE, PLASTIC | | |
| 4 | NDC:51769-139-70 | 700 mL in 1 BOTTLE, PLASTIC | | |
| 5 | NDC:51769-139-11 | 1000 mL in 1 BOTTLE, PLASTIC | | |
| 6 | NDC:51769-139-18 | 1180 mL in 1 BOTTLE, PLASTIC | | |
| 7 | NDC:51769-139-05 | 50 mL in 1 BOTTLE, PLASTIC | | |
| 8 | NDC:51769-139-01 | 10 mL in 1 POUCH | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part358H | 01/29/2013 | |

Labeler - ALL NATURAL DYNAMICS (962732892)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| Procter & Gamble Manufactura, S. de R.L. de C.V. | | 810007526 | manufacture(51769-139) |

Revised: 1/2013

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