

**CLEAN APPLE- pyrithione zinc shampoo**  
**Meijer Distribution**

*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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**Meijer 612.001/612AC/AE Dandruff Shampoo**

**Active ingredient**

Pyrithione zinc 1%

**Purpose**

Anti-dandruff

**Use**

helps prevent recurrence of flaking and itching associated with dandruff

**Warnings**

**For external use only**

**When using this product**

- do not get into 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 as directed

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- shake well
- 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 lauryl sulfate, sodium laureth sulfate, glycol distearate, sodium chloride,

zinc carbonate sodium xylenesulfonate, amodimethicone, cocamidopropyl betaine, fragrance, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, citric acid methylchloroisothiazolinone, methylisothiazolinone, blue 1, yellow 5,

#### Dandruff Care for Great Looking Hair

This product helps prevent the recurrence of flaking and itching associated with dandruff.

Conditioning Formula

pH balanced formula

leaves hair soft and manageable.

\*This product is not manufactured or distributed by Procter + Gamble, distributor of Head + Shoulders green apple 2 in 1 Dandruff Shampoo + conditioner

DIST. BY MEIJER DISTRIBUTION, INC

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GRAND RAPIDS, MI 49544

[www.meijer.com](http://www.meijer.com)

#### **principal display panel**

meijer

Clean Apple dandruff shampoo

pyrithione zinc dandruff shampoo plus conditioner

Normal or Dry Hair

2 in 1

helps relieve dryness, itching and light flaking

Compare to the active ingredient of Head & Shoulders\*

14.2 FL OZ (420mL)



## CLEAN APPLE

pyrithione zinc shampoo

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:41250-045 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

|  |
|--|
| <b>WATER</b> (UNII: 059QF0KO0R)  |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)  |
| <b>SODIUM LAURETH SULFATE</b> (UNII: BPV390UAP0)   |
| <b>GLYCOL DISTEARATE</b> (UNII: 13W7MDN21W)  |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)  |
| <b>ZINC CARBONATE</b> (UNII: EQR32Y7H0M)   |
| <b>SODIUM XYLENESULFONATE</b> (UNII: G4LZF950UR)   |
| <b>AMODIMETHICONE (800 CST)</b> (UNII: 363Z2T48P7)   |
| <b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)   |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)  |
| <b>GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE)</b> (UNII: B16G315W7A) |
| <b>MAGNESIUM CARBONATE HYDROXIDE</b> (UNII: YQO029V1L4)  |
| <b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)  |
| <b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)  |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)  |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)  |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)  |

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:41250-045-15 | 420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/13/2013           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part358H                                 | 12/13/2013           |                    |

**Labeler** - Meijer Distribution (006959555)

**Registrant** - Vi-Jon, LLC (790752542)

### Establishment

| Name        | Address | ID/FEI    | Business Operations    |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC |         | 790752542 | manufacture(41250-045) |

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| Name        | Address | ID/FEI    | Business Operations    |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC |         | 088520668 | manufacture(41250-045) |