# DANDRUFF- pyrithione zinc shampoo Family Dollar Services, Inc.

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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# Clean Apple Dandruff Shampoo and Conditioner 612.001/612AC

## **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 ro contact a Poison Control Center right away.

#### **Directions**

- shake well
- for manimum 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 chloried, zinc carbonate, sodium xylenesulfonate, amodimethicone, cocamidopropyl betaine, fragrance, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, citric acid, methylchloroisothiazolinone, methylisothiazolinone, blue 1, yellow 5

Multiple benefit formula to help:

- Fight dry scalp
- Calm itch
- Relieve irritation
- Soothe and reduce redness
- Reduce oiliness
- Prevent flakes
- Leave hair healthy looking

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

Not 100% satisfied?

Return package and unused product within 30 days to any Family Dollar store for a refund ( with receipt) or exchange.

**DISTRIBUTED BY:** 

FAMILY DOLLAR SERVICES, INC.

10401 MONROE ROAD

MATTHEWS NC 28105

612.001/612AC

## **Principal Display Panel**

FAMILY DOLLAR 100% SATISFACTION GUARANTEED OR YOUR MONEY BACK

Compare to HEAD & SHOULDERS DANDRUFF SHAMPOO\*

pyrithione zinc

dandruff shampoo plus conditioner 2 in 1

clean apple

helps relieve scalp dryness, itcing, and light flaking while keeping hair clean, soft, and healthy looking

14.2 FL OZ (420 mL)





#### **DANDRUFF**

pyrithione zinc shampoo

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-612

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

PYRITHIONE ZINC (UNII: R95302RHZ5) (PYRITHIONE ZINC - UNII:R95302RHZ5) PYRITHIONE ZINC 1 g in 1 mL

#### **Inactive Ingredients**

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)

| SODIUM LAURYL SULFATE (UNII: 368GB5141J)   |  |
|--|--|
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0)  |  |
| GLYCOL DISTEARATE (UNII: 13W7MDN21W)   |  |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)   |  |
| ZINC CARBONATE (UNII: EQR32Y7H0M)  |  |
| SODIUM XYLENESULFONATE (UNII: G4LZF950UR)  |  |
| AMODIMETHICONE (800 CST) (UNII: 363Z2T48P7)  |  |
| COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)  |  |
| SODIUM BENZOATE (UNII: OJ245FE5EU)   |  |
| <b>GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE)</b> (UNII: B16G315W7A) |  |
| MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)   |  |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)   |  |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)   |  |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)   |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)   |  |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)   |  |
|  |  |

| l | Packaging                 |  |                         |                       |
|---|---------------------------|--|-------------------------|-----------------------|
|   | # Item Code               | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
|   | <b>1</b> NDC:55319-612-15 | 420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/18/2012              |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC monograph final   | part358H                                    | 12/18/2012              |                       |
|                       |   |                         |                       |

# Labeler - Family Dollar Services, Inc. (024472631)

# Registrant - Vi-Jon (790752542)

| Establishment |         |           |                        |
|---------------|---------|-----------|------------------------|
| Name          | Address | ID/FEI    | Business Operations    |
| Vi-Jon        |         | 790752542 | manufacture(55319-612) |

| Establishment |         |           |                        |
|---------------|---------|-----------|------------------------|
| Name          | Address | ID/FEI    | Business Operations    |
| Vi-Jon        |         | 088520668 | manufacture(55319-612) |