

## **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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### **Dandruff Shampoo**

**612**

#### **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, methylchloroisoithiazolinone, methylisothiazolinone, blue 1, yellow 5, citric acid

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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612.001/612AC

### **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 (420 mL)



## CLEAN APPLE

pyrrithione 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
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
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<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: HBR47K3TBD)
<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 (790752542)

### Establishment

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