

## **2 IN 1 DANDRUFF- pyrithione zinc shampoo**

### **Big Lots**

*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, citric acid, methylchloroisothiazolinone, methylisothiazolinone, blue 1, yellow 5

healthy accents

clean apple dandruff shampoo plus conditioner pyrithione zinc

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

DISTRIBUTED BY: DZA BRANDS, LLC  
2110 EXECUTIVE DRIVE, SALISBURY, NC 28147  
1-866-322-2439  
612.001/612AC

**Principal display panel**

SOUND BODY

COMPARE TO HEAD & SHOULDERS 2 IN 1 DANDRUFF SHAMPOO\*

CLEAN APPLE 2 IN 1

Dandruff Shampoo Pyrthione Zinc

Dandruff Shampoo Plus Conditioner

- Battles dandruff with a refreshing & clean scent
- Helps prevent Flakes
- Gentle and pH balanced for everyday use even on permed or color treated hair

23.7 FL OZ (700 mL)



## 2 IN 1 DANDRUFF

pyrithione zinc shampoo

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50594-612
<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
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: 5OCF3O11KX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (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)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50594-612-35	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/18/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	01/18/2016	

**Labeler** - Big Lots (017885351)**Registrant** - Vi-Jon (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(50594-612)

