

**DANDRUFF- pyrithione zinc shampoo**  
**DZA BRANDS, llc**

*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 and Conditioner**  
**253**

**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, red 33

healthy accents

smooth spice dandruff shampoo plus conditioner

pyrithione zinc

\*This product is not manufactured or distributed by the Procter & Gamble Company, distributor of Head & Shoulders Dandruff Shampoo & Conditioner Old Spice Men 2 in 1

DISTRIBUTED BY: DZA BRANDS, LLC

2110 Executive Drive, Salisbury, NC 28147

1-866-322-2439

253.001/253AB-AC

### **Principal Display Panel**

healthy accents

smooth spice dandruff shampoo plus conditioner

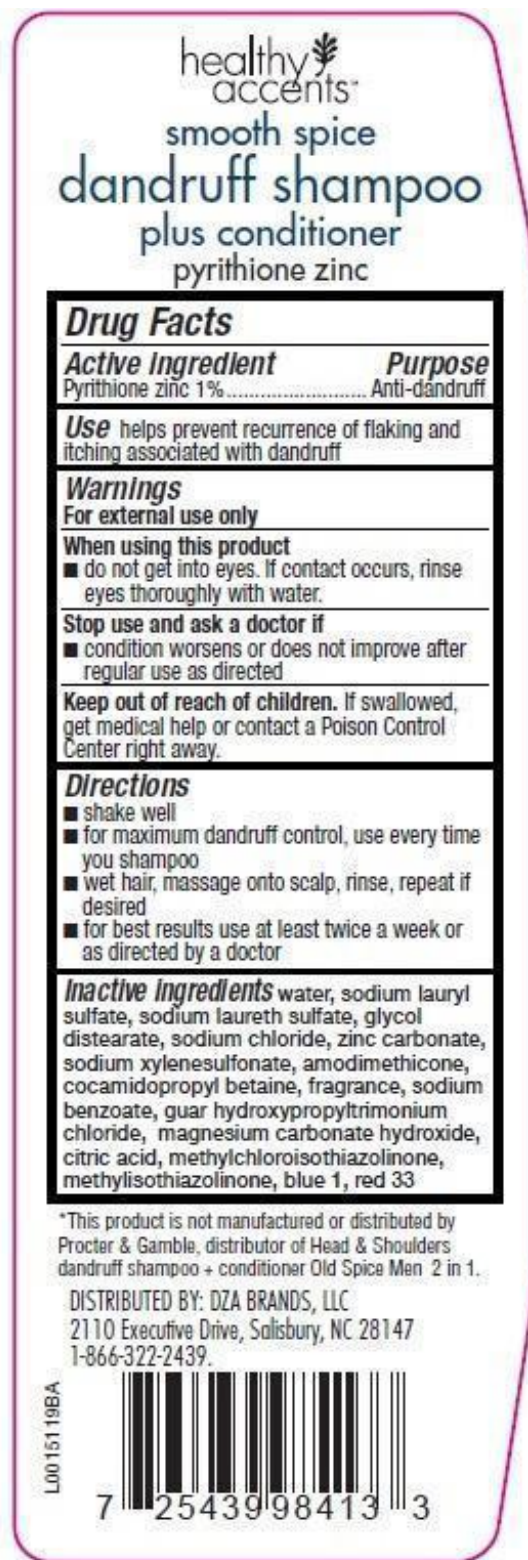
pyrithione zinc

2 in 1 For Men

an energizing clean enhanced with a masculine scent

\*compare to Head & Shoulders Dandruff Shampoo + Conditioner Old Spice Men 2 in 1

14.2 FL OZ (420 mL)



## DANDRUFF

pyrithione zinc shampoo

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-017
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	10 mg 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)	
METHYLCHLOROISO THIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISO THIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-017-15	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/20/2015	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	03/20/2015	

**Labeler** - DZA BRANDS, llc (090322194)**Registrant** - Vi-Jon, Inc (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, Inc		088520668	manufacture(55316-017)

