

2 IN 1 DANDRUFF- pyrithione zinc shampoo
DZA Brands

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.

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

Healthy Accents

clean apple dandruff shampoo plus conditioner

pyrithione zinc

2 in 1

battles dandruff with a refreshing & clean scent

compare to Head & Shoulders Green Apple 2 in 1 Dandruff Shampoo*

14.2 FL OZ (420 mL)



healthy accents™
clean apple
dandruff shampoo
plus conditioner
pyrithione zinc

Drug Facts	
<i>Active Ingredient</i>	<i>Purpose</i>
Pyrithione zinc 1%.....	Anti-dandruff
Use helps prevent recurrence of flaking and itching associated with dandruff	
Warnings	
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2110 Executive Drive, Salisbury, NC 28147
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2 IN 1 DANDRUFF

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-011
Route of Administration	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:55316-011-15	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 mono graph final	part358H	03/20/2015	

Labeler - DZA Brands (090322194)**Registrant** - Vi-Jon (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(55316-011)