2 IN 1 DANDRUFF- pyrithione zinc shampoo Vi-Jon

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.

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 controll, 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 sulate, 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

Disclaimer

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

Adverse Reactions

Manufactured by: Vi-Jon, Inc.,

St. Louis, MO 63114

Questions or Comments? 1-888-593-0593

Made in the USA

with US and foreign parts.

311.007/311AL

Principal Display Panel

mountain

falls

*Compare to Head

& Shoulders

helps

prevent

flakes

leaves hair

clean and

manageable

+

conditioner

pΗ

balanced

formula

2 in 1

dandruff

shampoo

with pyrithione zinc

smooth spice

23.7 FL OZ (700 mL)





*Compare to Head & Shoulders®



leaves hair clean and manageable

> pH balanced formula

2-in-1 dandruff shampoo

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0016810F4

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mountaın falls™

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pH balanced formula

2-in-1 dandruff shampoo

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0016810F/

23.7 FL OZ (700 mL)

2 IN 1 DANDRUFF

pyrithione zinc shampoo

Product Information

NDC:11344-311 Product Type HUMAN OTC DRUG Item Code (Source)

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PVPITHIONE ZINC (LINII: P953O2PHZ5) (PVPITHIONE ZINC - LINII: P953O2PHZ5)	PVRITHIONE ZINC	10 mg in 1 mI

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 CARBO NATE (UNII: EQR32Y7H0 M)

SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)

AMO DIMETHICO NE (800 CST) (UNII: 363Z2T48P7)

COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11KX)

SODIUM BENZOATE (UNII: OJ245FE5EU)

GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16 G315W7A)

MAGNESIUM CARBO NATE HYDRO XIDE (UNII: YQO029 V1L4)

CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)

METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)

METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

D&C RED NO. 33 (UNII: 9DBA0SBB0L)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-311- 15	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/23/2005	
2	NDC:11344-311- 21	88 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/23/2005	
3	NDC:11344-311- 39	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2005	
4	NDC:11344-311- 35	700 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2005	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	06/23/2005		

Labeler - Vi-Jon (150931459)

Registrant - Vi-Jon (088520668)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon		088520668	manufacture(11344-311)	

Revised: 4/2018 Vi-Jon