

**DANDRUFF- pyrithione zinc lotion/shampoo**  
**American Sales Company**

*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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**Drug Facts**

**claims**

Multiple benefit formula to help:

- Fight dry scalp
- Calm itch
- Relieve irritation
- Soothe and reduce redness
- Reduce oiliness
- Prevent flakes
- Leave hair healthy looking

**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

## **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

## **Disclaimer**

This product is not manufactured or distributed by Procter & Gamble, the distributor of Head & Shoulders Classic clean 2 in 1 Dandruff Shampoo & Conditioner

## **Adverse reactions**

DISTRIBUTED BY FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

1-877-846-9949 2016 S&S Brands, LLC

Quality guaranteed or your money back.

311.007/311AK

## **Principal Display Panel**

CAREONE

everyday clean 2 in 1

Dandruff

shampoo

plus conditioner

for normal hair

pyrithione zinc

helps prevent flakes

Compare to Head & Shoulders

2 in 1 Classic Clean Dandruff

Shampoo + Conditioner

14.2 FL OZ (420 mL)



*everyday clean 2 in 1*

**Dandruff**  
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14.2 FL OZ (420 mL)

L0002548FE

pyrithione zinc lotion/shampoo

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-311
<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	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)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (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:41520-311-15	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/09/2004	
2	NDC:41520-311-35	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/09/2004	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	07/09/2004	

**Labeler** - American Sales Company (809183973)

**Registrant** - Vi-Jon (790752542)

**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(41520-311)

Revised: 6/2017

American Sales Company