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.

Drug Facts

Dandruff Care for Great Looking Hair

This product helps relieve scalp dryness, itch, irritation and helps prevent flakes.

Clean Manageable Hair for Everyday

- Dual Formula cleans and conditions hair in one easy step
- Gentle and pH balanced for everyday use
- -even for permed or colored-treated hair

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, cocamidopropyl betaine, fragrance, amodimethicone, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, methylchloroisothiazolinone, methylisothiazolinone, blue 1, red 33

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Quality guaranteed or your mone back

Principal Display Panel

CAREONE

everyday clean 12 in 1

Dandruff shampll pls conditioner for normal hair pyrithione zinc 14.2 fl 0z (420 mL)



everyday clean 2 in 1 Dandr shampoo plus

> for normal hair pyrithione zinc

14.2 FL OZ (420 mL)

L0002548FD

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DANDRUFF

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41520-311
Route of Administration	TOPICAL	DEA Sche dule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (PYRITHIONE ZINC)	PYRITHIONE ZINC	1 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER	
SO DIUM LAURYL SULFATE	
SO DIUM LAURETH SULFATE	
GLYCOL DISTEARATE	
SO DIUM CHLO RIDE	
ZINC CARBONATE	
SO DIUM XYLENESULFO NATE	
COCAMIDO PRO PYL BETAINE	
AMODIMETHICONE (800 CST)	
SO DIUM BENZO ATE	
GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE)	
MAGNESIUM CARBONATE HYDRO XIDE	
METHYLCHLOROISOTHIAZOLINONE	
METHYLISOTHIAZOLINONE	
FD&C BLUE NO. 1	
D&C RED NO. 33	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41520-311-15	420 mL in 1 BOTTLE, PLASTIC		

Marketing Info	rmation		
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: 2/2013 American Sales Company