

DANDRUFF- pyrithione zinc shampoo

Publix

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

Option claims

Dandruff Care for Great Looking Hair

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

Dry Scalp Care and Shiny Clean hair

- With moisturizes, it soothes the scalp while cleansing and conditioning the hair
- pH balanced for everyday use-even for permed or color-treated hair

Active ingredient

Pyrithione zinc 1%

Purpose

Anti-dandruff

Use

help 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

- condition worsens or does not improve after regular use as directed

Keep out of reach of children

If swallowed, get medical help or contact 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 laureth sulfate, sodium lauryl sulfate, amodimethicone, cocamide MEA, zinc carbonate, glycol distearate, sodium xylenesulfonate, fragrance, cetyl alcohol, guar hydroxypropyltrimonium chloride, magnesium sulfate, sodium chloride, sodium benzoate, magnesium carbonate hydroxide, benzyl alcohol, prunus amygdalus dulcis (sweet almond) oil, trideceth-12, cetrimonium chloride, sodium hydroxide, methylchloroisothiazolinone, methylisothiazolinone

Disclaimer

This product is not manufactured or distributed by Procter + Gamble, distributor of Head + Shoulders Dry Scalp Care

Adverse reactions

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LAKELAND, FL 33811

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Principal display panel

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PYRITHIONE ZINC

dryscalp

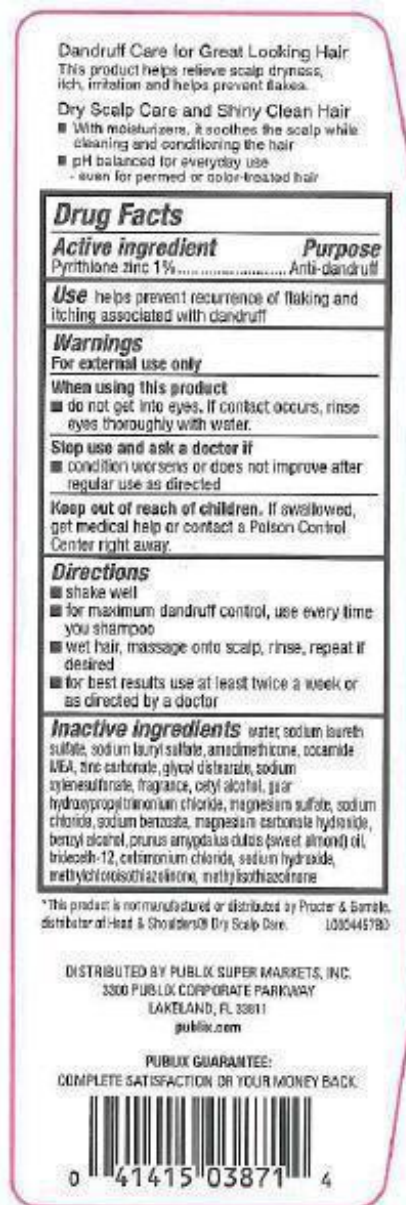
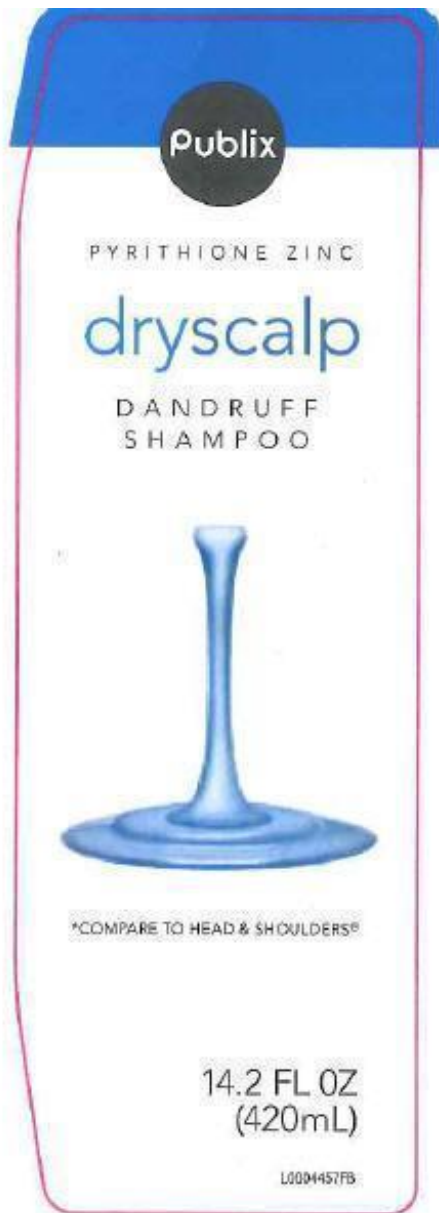
DANDRUFF

SHAMPOO

COMPARE TO HEAD + SHOULDERS

14.2 FL OS

(420 mL)



DANDRUFF
pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-281
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	10.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

SODIUM LAURETH SULFATE (UNII: BPV390UAP0)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
AMODIMETHICONE (800 CST) (UNII: 363Z2T48P7)
COCO MONOETHANOLAMIDE (UNII: C80684146D)
ZINC CARBONATE (UNII: EQR32Y7H0M)
GLYCOL DISTEARATE (UNII: 13W7MDN21W)
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)
CETYL ALCOHOL (UNII: 936JST6JCN)
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)
MAGNESIUM SULFATE (UNII: DE08037SAB)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
SODIUM BENZOATE (UNII: OJ245FE5EU)
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQ0029V1L4)
BENZYL ALCOHOL (UNII: LKG8494WBH)
ALMOND OIL (UNII: 66YXD4DKO9)
TRIDECETH-12 (UNII: YFY3KG5Y7O)
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-281-15	420 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	01/13/2009	

Labeler - Publix (006922009)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(56062-281)