FRUITOPIA - pyrithione zinc liquid CVS PHARMACY

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

ACTIVE INGREDIENT

PYRITHIONE ZINC 1%

PURPOSE

ANTI-DANDRUFF

USES

FOR RELIEF OF FLAKING, AND ITCHING ASSOCIATED WITH DANDRUFF AND SEBORRHEIC DERMATITIS AND TO HELP PREVENT THE CHANCE OF RE-OCCURENCE.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF PRODUCT GETS INTO EYES, RINSE THOROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK A DOCTOR IF

CONDITION WORSENS OR DOES NOT IMPROVE AFTER REGULAR USE OF THIS PRODUCT AS DIRECTED.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

APPLY SHAMPOO ON WET HAIR, RINSE THOROUGHLY. FOR BEST RESULTS, USE AT LEAST TWICE A WEEK OR AS DIRECTED BY A DOCTOR.

QUESTIONS? COMMENTS?

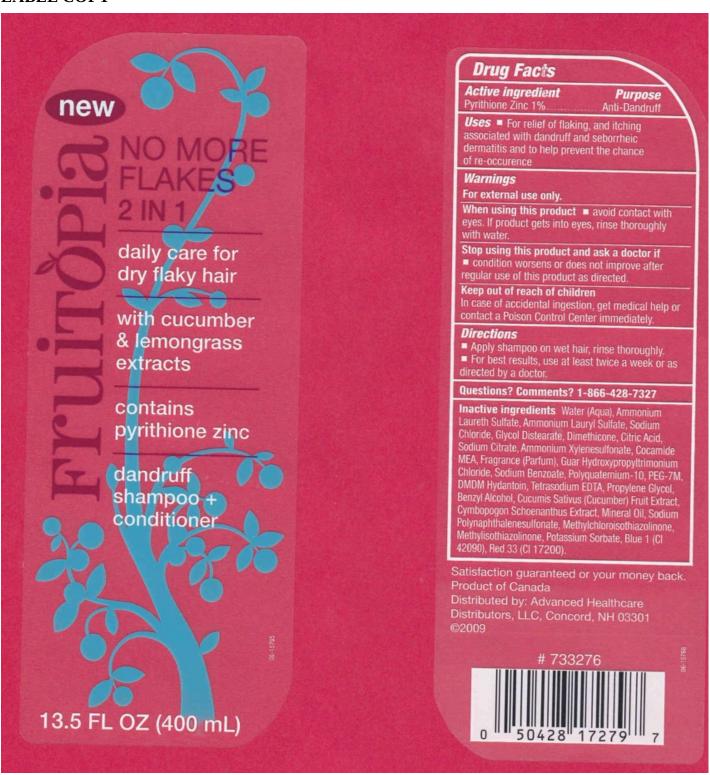
1-866-428-7327

INACTIVE INGREDIENTS

WATER (AQUA), AMMONIUM LAURETH SULFATE, AMMONIUM LAURYL SULFATE,

SODIUM CHLORIDE, GLYCOL DISTEARATE, DIMETHICONE, CITRIC ACID, SODIUM CITRATE, AMMONIUM XYLENESULFONATE, COCAMIDE MEA, FRAGRANCE (PARFUM), GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, SODIUM BENZOATE, POLYQUATERNIUM-10, PEG-7M, DMDM HYDANTOIN, TETRASODIUM EDTA, PROPYLENE GLYCOL, BENZYL ALCOHOL, CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT, CYMBOPOGON SCHOENANTHUS EXTRACT, MINERAL OIL, SODIUM POLYNAPHTHALENESULFONATE, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, POTASSIUM SORBATE, BLUE 1 (CI 42090), RED 33 (CI 17200).

LABEL COPY



FRUITOPIA

pyrithione zinc liquid

D	4	Trafara	
Pro	auct	HILLOR	mation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-421

Route of Administration TOPICAL

Active Ingredient/Active Moiety

retive ingredient/retive windery			
Ingredient Name	Basis of Strength	Strength	
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1.0 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMO NIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)	
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
AMMO NIUM XYLENESULFO NATE (UNII: 4FZY6L6 XCM)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16 G315W7A)	

GOTH ITEMOTICAL CIECKED (I... SEDSTITULATO LEK STOCIETADE) (CITIE DIOGSISWA)

SODIUM BENZOATE (UNII: OJ245FE5EU)

POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)

POLYETHYLENE GLYCOL 7000 (UNII: Q0JET65GEL)

DMDM HYDANTO IN (UNII: BYR0 546 TO W)

EDETATE SO DIUM (UNII: MP1J8420LU)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

BENZYL ALCOHOL (UNII: LKG8494WBH)

CUCUMBER (UNII: YY7C30VXJT)

CYMBOPOGON SCHOENANTHUS LEAF (UNII: XF54B1Z2HF)

MINERAL OIL (UNII: T5L8T28FGP)

SODIUM 2-NAPHTHALENESULFONATE (UNII: R5F0CTD2OJ)

METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)

METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)

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

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

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-421-14	400 mL in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	02/17/2012		

Labeler - CVS PHARMACY (062312574)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment			
Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		20 19 0 12 0 9	manufacture

Revised: 2/2012 CVS PHARMACY