CONTROL ANTI-DANDRUFF- pyrithione zinc shampoo
AG Hair Ltd.

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.

Control Anti-Dandruff Shampoo

ACTIVE INGREDIENT:

ZINC PYRIDINETHIONE (PYRITHIONE) 2%

PURPOSE:

Anti-Dandruff

USES:

HELPS PREVENT RECURRENCE OF FLAKING AND ITCHING ASSOCIATED WITH DANDRUFF.

WARNING:

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT:

AVOID CONTACT WITH 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 OF THIS PRODUCT AS DIRECTED.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN

IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS:

- USE TWICE A WEEK, OR AS DIRECTED BY A PHYSICIAN FOR CHRONIC CONDITIONS.
- MASSAGE INTO SCALP FOR 3-5 MINUTES. RINSE THOROUGHLY.

INACTIVE INGREDIENTS

WATER (AQUA, EAU), AMMONIUM LAURETH SULFATE, COCAMIDOPROPYL BETAINE, PEG-4 RAPESEEDAMIDE, ALOE BARBADENSIS EXTRACT, CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, SODIUM HYDROXIDE, PANTHENOL, HYDROLYZED KERATIN, SODIUM PCA, TOCOPHERYL ACETATE, SODIUM HYDROXYMETHYLGLYCINATE, CITRIC ACID, FRAGRANCE (PARFUM), ENTHOL, TETRASODIUM GLUTAMATE DIACETATE, PROPANEDIOL.

QUESTIONS (OR COMMENTS)?

1-866-924-4247

PRODUCT LABELING

CONTROL ANTI-DANDRUFF

pyrithione zinc shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:46324-2421
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	20 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

PEG-4 RAPESEEDAMIDE (UNII: 89575CN928)	
ALOE (UNII: V5VD430YW9)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PANTHENOL (UNII: WV9CM0O67Z)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
SODIUM HYDROXYMETHYLGLYCINATE (UNII: DIG6BWZ9XT)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MENTHOL (UNII: L7T10EIP3A)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
PROPANEDIOL (UNII: 5965N8W85T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46324-2421-8	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2011	06/30/2016
2	NDC:46324-2421-1	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2011	11/30/2015
3	NDC:46324-2421-2	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2011	10/14/2024
4	NDC:46324-2421-3	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2011	10/28/2011

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	10/28/2011	10/31/2024

Labeler - AG Hair Ltd. (203691886)

Revised: 6/2023 AG Hair Ltd.