HEB DANDRUFF- pyrithione zinc shampoo
HEB

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

HELPS PREVENT RECURRENCE OF FLAKING AND ITCHING ASSOCIATED WITH DANDRUFF

WARNINGS

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 WORSONS OR DOES NOT IMPROVE AFTER REGULAR USE OF THIS PRODUCT AS DIRECTED

KEEP OUT OF REACH OF CHILDREN

IF SWALLOWED GET MEDICAL HELP OR CONTACT POISON CONTROL CENTER IMMEDIATELY

DIRECTIONS

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, COCAMIDE DEA, ZINC CARBONATE, GLYCOL DISTEARATE, FRAGRANCE, DIMETHICONE, CETYL ALCOHOL, POLYQUATERNIUM-10, MAGNESIUM SULFATE, SODIUM BENZOATE, MENTHOL, PEG-7M, MAGNESIUM CARBONATE HYDROXIDE, AMMONIUM LAURETH SULFATE, SEA SALT, FUCUS VESICULOSUS EXTRACT, BENZYL ALCOHOL, SODIUM CHLORIDE,

METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, SODIUM XYLENE SULFONATE, BLUE 1, YELLOW 5

LABEL COPY

HEB DANDRUFF

pyrithione zinc shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37808-424
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL 7000 (UNII: Q0JET65GEL)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
AMMONIUM LAURETH-3 SULFATE (UNII: 896SJ235FN)	
SEA SALT (UNII: 87GE52P74G)	
FUCUS VESICULOSUS (UNII: 535G2ABX9M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:37808-424-14	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	12/23/2011	

Labeler - HEB (007924756)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture

Revised: 12/2011 HEB