HEB DANDRUFF - selenium sulfide shampoo
H E B

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
SELENIUM SULFIDE ONE PERCENT

PURPOSE
ANTI DANDRUFF

USES
For relief of flaking, and itching associated with dandruff and seborrheic dermatitis and to help prevent the chance of reoccurence

WARNINGS

FOR EXTERNAL USE ONLY.

ASK A DOCTOR BEFORE USING IF YOU HAVE
SEBORRHEIC DERMATITIS IN AREAS OTHER THAN THE SCALP.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF PRODUCT GETS INTO EYES, RINSE THOROUGHLY WITH WATER. FOR USE ON COLOR TREATED OR PERMED HAIR, RINSE THOROUGHLY.

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

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

INACTIVE INGREDIENTS

WATER, AMMONIUM LAURETH SULFATE, AMMONIUM LAURYL SULFATE, GLYCOL DISTEARATE, COCAMIDE MEA, ACRYLATES COPOLYMER, AMMONIUM XYLENESULFONATE, FRAGRANCE, DIMETHICONE, CETYL ALCOHOL, SODIUM BENZOATE, CITRIC ACID, SODIUM HYDROXIDE, STEARYL ALCOHOL, DISODIUM EDTA, HYDROXYPROPYL METHYLCELLULOSE, SODIUM CHLORIDE, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, SODIUM CITRATE,

RED 4 (CI 14700).

HEB DANDRUFF

selenium sulfide shampoo

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37808-613
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM - UNII:H6241UJ22B)	SELENIUM SULFIDE	1 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMONIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
CARBOMER 934 (UNII: Z135WT9208)	
3-HYDROXY-4-METHOXYBENZENESULFONIC ACID (UNII: 05L0075KBX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-613-14	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	08/08/2011	

Labeler - H E B (007924756)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care		3019012093	manufacture