TOPCARE MEDICATED DANDRUFF- selenium sulfide shampoo
Topco Associates LLC

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 Box - Back Label

ACTIVE INGREDIENT

SELENIUM SULFIDE 1%

PURPOSE

- ANTI DANDRUFF

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 THE EYES. IF CONTACT OCCURS, RINSE EYES THOROUGHLY WITH WATER. FOR USE ON COLOR-TREATED OR PERMED HAIR, RINSE THOROUGHLY.

STOP USE 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

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

USE

FOR RELIEF OF FLAKING AND ITCHING DUE TO DANDRUFF, AND SEBORRHEIC DERMATITIS, AND TO HELP PREVENT THE CHANCE OF RE-OCCURRENCE.

DIRECTIONS

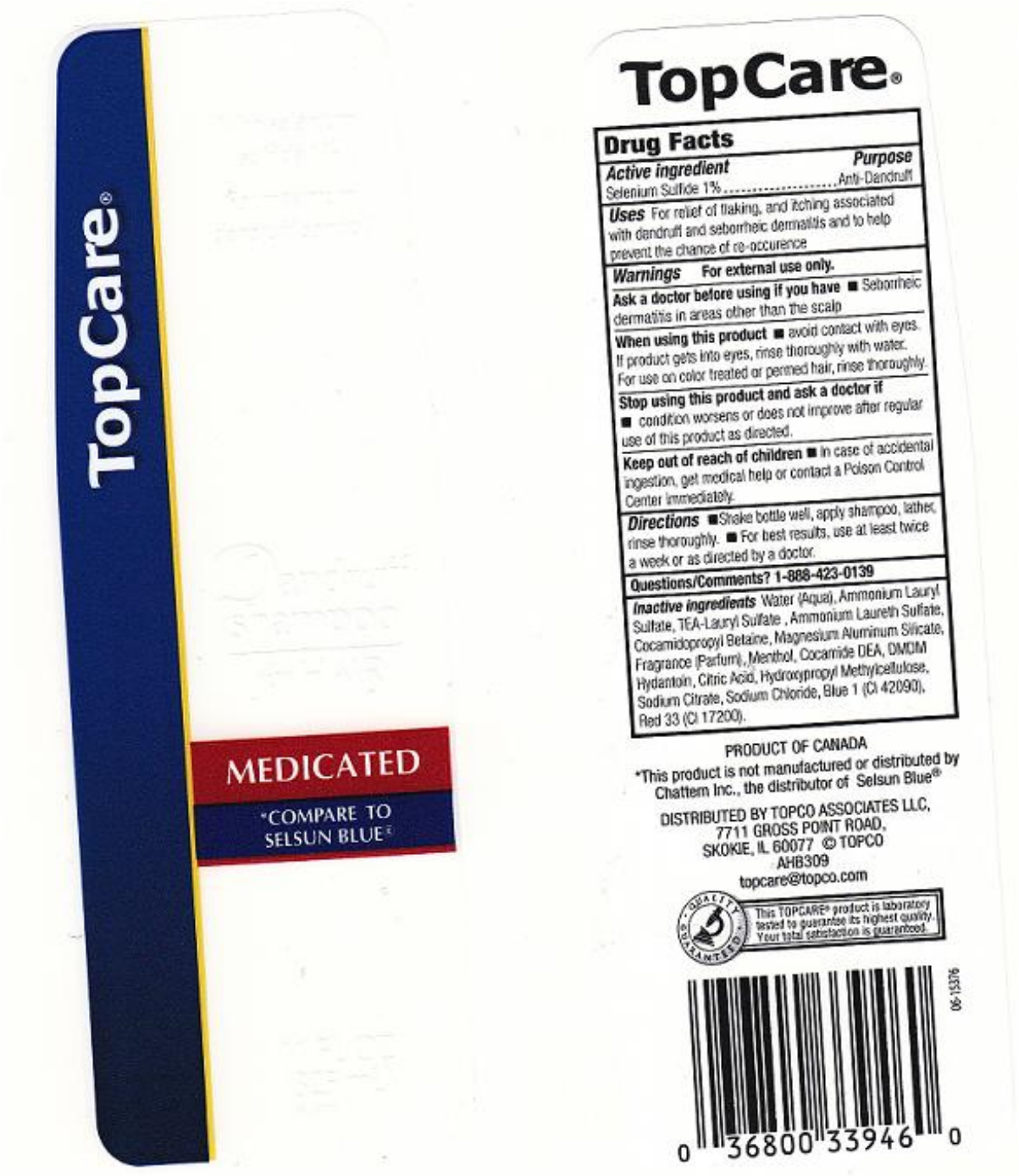
- SHAKE WELL, SHAMPOO, THEN RINSE THROUGHLY.
- FOR BEST RESULTS, USE AT LEAST TWICE A WEEK OR AS DIRECTED BY A DOCTOR.

INACTIVE INGREDIENTS

WATER, AMMONIUM LAURYL SULFATE, TEA-LAURYL SULFATE, AMMONIUM LAURETH SULFATE, COCAMIDOPROPYL BETAINE, MAGNESIUM ALUMINUM SILICATE,

FRAGRANCE, MENTHOL, COCAMIDE DEA, DMDM HYDANTOIN, CITRIC ACID, HYDROXYPROPYL METHYLCELLULOSE, SODIUM CITRATE, SODIUM CHLORIDE, BLUE 1 (CI 42090), RED 33 (CI 17200)

PACKAGE FRONT AND BACK LABELS



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TOPCARE MEDICATED DANDRUFF

selenium sulfide shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-610
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 LAURYL SULFATE (UNII: Q7AO2R1M0B)	
TROLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
AMMONIUM LAURETH-5 SULFATE (UNII: 43ZIH89I48)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
MENTHOL (UNII: L7T10EIP3A)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36800-610-11	325 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	09/29/2010	

Labeler - Topco Associates LLC (006935977)

Revised: 9/2010 Topco Associates LLC