

DG BODY MEDICATED DANDRUFF- selenium sulfide shampoo
DOLGENCORP INC

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

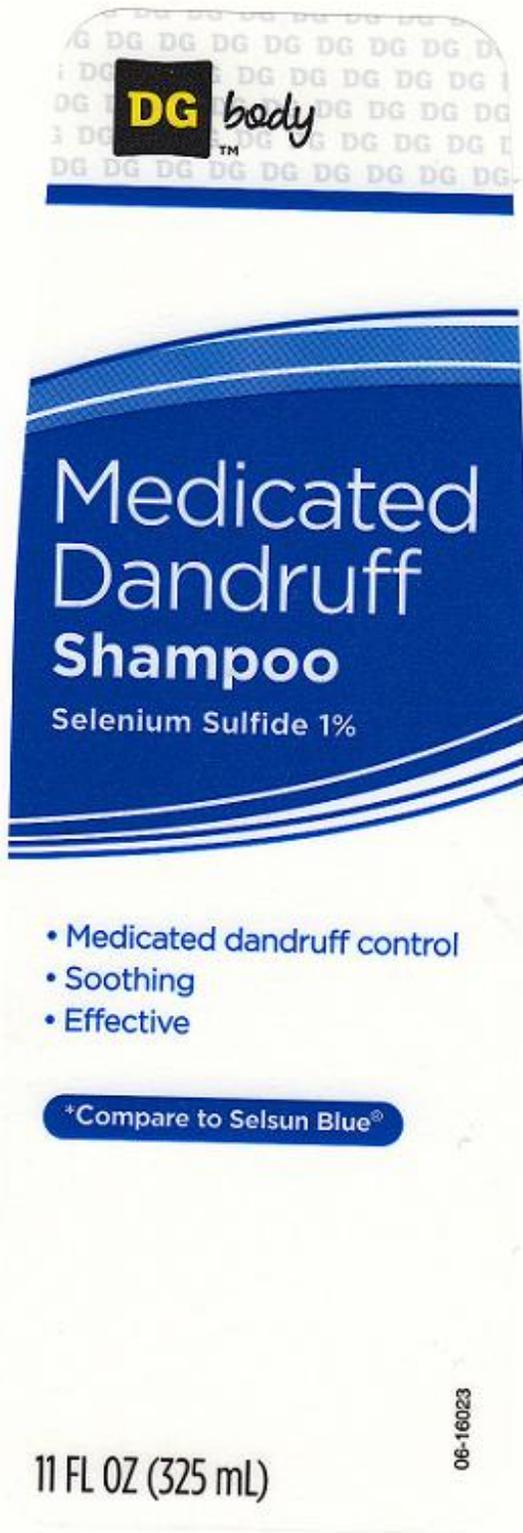
- SHAKE WELL, SHAMPOO, THEN RINSE THOROUGHLY.
- FOR BEST RESULTS, USE AT LEAST TWICE A WEEK OR AS DIRECTED BY A DOCTOR.

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



Medicated Dandruff Shampoo
Selenium Sulfide 1%

Effective dandruff control that leaves hair feeling soft and clean, with refreshing menthol that cools and soothes the scalp. For maximum results, use two times or more, per week.

Drug Facts	
Active ingredient Selenium Sulfide 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-occurrence	
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 shampoo, rinse thoroughly. ■ For best results, use at least twice a week or as directed by a doctor.	
Inactive ingredients Water (Aqua), Ammonium Lauryl Sulfate, TEA-Lauryl Sulfate, Ammonium Laureth Sulfate, Cocamidopropyl Betaine, Magnesium Aluminum Silicate, Fragrance (Parfum), Menthol, Cocamide DEA, DMDM Hydantoin, Citric Acid, Hydroxypropyl Methylcellulose, Sodium Citrate, Sodium Chloride, Blue 1 (CI 42090), Red 33 (CI 17200).	

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 PRODUCT OF CANADA

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 (888) 309-9030



DG BODY MEDICATED DANDRUFF

selenium sulfide shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-610
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: 059QF0K00R)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
TROLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
AMMONIUM LAURETH-5 SULFATE (UNII: 43ZIH89I48)	
COCAMIDO PROPYL BETAINE (UNII: 5OCF3O11KX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
MENTHOL (UNII: L7T10EIP3A)	
CO CO 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:55910-610-11	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 - DOLGENCORP INC (068331990)