RITE AID MEDICATED DANDRUFF- selenium sulfide shampoo Rite Aid Corporation

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

eql11.jpg



MEDICATED DANDRUFF SHAMPOO

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 the chance of re-occurence.

Warnings

- . For external use only.
- Ask a doctor before using if you have Seborrheic dermatitis in areas other than the scalo.
- 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.

Other information Store at room temperature

Inactive Ingredients

AMMONIUM LAURETH SULFATE, AMMONIUM LAURYL SULFATE, CITRIC ACID, COCAMIDE DEA, COCAMIDOPROPYL BETAINE, DMDM HYDANTOIN, D&C RED 33, FD&C BLUE 1, FRAGRANCE, HYDROXYPROPYL METHYL-CELLULOSE, MAGNESIUM ALUMINUM SILICATE, MENTHOL, SODIUM CHLORIDE, TEA-LAURYL SULFATE, WATER

06-13239

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50600700 Product of Canada



Distributed by Rite Aid Corporation Harrisburg, PA 17105

RITE AID MEDICATED DANDRUFF

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-6101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SELENIUM SULFIDE (UNII: Z69 D9 E38 1Q) (SELENIUM - UNII: H6241UJ22B)	SELENIUM SULFIDE	1 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)		
TROLAMINE LAURYL SULFATE (UNII: E8458C1KAA)		
AMMO NIUM LAURETH-5 SULFATE (UNII: 43ZIH89I48)		
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)		
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)		
MENTHOL (UNII: L7T10EIP3A)		
COCO DIETHANOLAMIDE (UNII: 92005F972D)		
DMDM HYDANTO IN (UNII: BYR0546 TOW)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
HYDRO XYPRO PYL CELLULO SE (UNII: RFW2ET671P)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-6101-1	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 - Rite Aid Corporation (014578892)

Revised: 9/2010 Rite Aid Corporation