MEDICATED DANDRUFF MAXIMUM STRENGTH- selenium sulfide shampoo WAL-MART STORES 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

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-OCCURENCE.

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 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

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, RED 33.

QUESTIONS?

CALL: 1-888-287-1915

Front and back labels





MEDICATED DANDRUFF MAXIMUM STRENGTH

selenium sulfide shampoo

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-610	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength	
l	SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM - UNII:H6241UJ22B)	SELENIUM SULFIDE	1.0000 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
TROLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
COCAMIDO PRO PYL BETAINE (UNII: 50CF3011KX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
MENTHOL (UNII: L7T10EIP3A)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
DMDM HYDANTO IN (UNII: BYR0546TOW)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SO DIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
AMMO NIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-610-11	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	08/19/2011		

Labeler - WAL-MART STORES INC (051957769)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

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

Revised: 8/2011 WAL-MART STORES INC